Datenbank für Nebenwirkungen

https://vaers.hhs.gov/

https://wonder.cdc.gov/vaers.html

Liste der Nebenwirkungen und Todesfälle

https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=34346A7B1989D327C2BC4662DCEF

Centers for Disease Control and Prevention. CDC twenty four seven. Saving Lives, Protecting People

The Vaccine Adverse Event Reporting System (VAERS) Results

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Messages:

- The full results are too long to be displayed, only non-zero rows are available.
- VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
- These results are for 1,243 total events.
- When grouped by VAERS ID, results initially don't show Events Reported, Percent, or totals. Use Quick or More Options to restore them, if you wish.
- Click on a VAERS ID to see a report containing detailed information for the event.

Some measures are hidden, use Quick or More Options above to restore them.

Symptoms	Vaccine	VAERS ID	Adverse Event Description	Adverse Events After Prior Vaccinations
ABDOMINAL DISCOMFORT	**COVID19 (COVID19 (MODERNA)) (1201)**			

Stomach upset, sudden heart failure, death No prior vaccinations for this event.

ABDOMINAL DISCOMFORT **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble

No prior vaccinations for this event.

with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their

car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

ABDOMINAL DISCOMFORT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion; On 21Feb he went to the ER after vomiting and passing out; On 21Feb he went to the ER after vomiting and passing out; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; fever; headache; stomach upset; This is a spontaneous report from a contactable consumer reporting for the father: A 75-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EL3428) at single dose at left arm on 03Feb2021 for Covid-19 immunisation. Medical history included type 2 diabetes mellitus. No known allergies. The patient had not experienced Covid-19 prior vaccination. Concomitant medication in 2 weeks included amitriptyline hydrochloride (manufacturer unknown) 10 mg, atorvastatin (manufacturer unknown) 20 mg, dutasteride (manufacturer unknown) 0.5 mg, linaclotide (LINZESS) 290 mcg, gabapentin (manufacturer unknown) 300 mg, montelukast (manufacturer unknown) 10 mg, ramipril (manufacturer unknown) 5 mg, insulin degludec (TRESIBA) 100 unit/ml, liraglutide (VICTOZA) 18 mg/3ml solution. No other vaccine in 4 weeks. The patient experienced cardiac arrest due to pericardial effusion on 21Feb2021 14:15, fever on 13Feb2021, headache on 13Feb2021, stomach upset on 13Feb2021, on 19feb, he began to feel ill again with a fever, he felt worse on 20feb on 19Feb2021, on 21feb he went to	No prior vaccinations for this event.

the ER after vomiting and passing out on 21Feb2021. Events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of cardiac arrest due to pericardial effusion. Course of events: In Feb2021, 10 days after his 1st injection, the patient developed fever, headache, and stomach upset. He went for a rapid Covid-19 test (nasal swab) and it was negative on 11Feb2021. The doctor told him he might be having a delayed reaction to the vaccination. After a couple of days, he improved. On 19Feb2021, he began to feel ill again with a fever. He felt worse on 20Feb2021. On 21Feb2021 he went to the ER after vomiting and passing out and received treatment: IV fluids, diagnostic testing at ER. Rapid Covid test (nasal swab) at ER came back negative again on 21Feb2021. His heart arrested suddenly and he could not be resuscitated. CT scan results, that came back after death, showed Covid like pneumonia and pericardial effusion. The patient died on 21Feb2021 14:15. Cause of death was cardiac arrest due to pericardial effusion. An autopsy was not performed. The outcome of cardiac arrest due to pericardial effusion was fatal, of fever, headache, stomach upset was recovering, of he began to feel ill again with a fever, he felt worse was not recovered, of he went to the ER after vomiting and passing out was unknown.; Reported Cause(s) of Death: cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion

ABDOMINAL DISTENSION

COVID19 (COVID19 (MODERNA)) (1201)

"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."

No prior vaccinations for this event.

ABDOMINAL DISTENSION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."	No prior vaccinations for this event.
ABDOMINAL INJURY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.	No prior vaccinations for this event.
ABDOMINAL PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**

Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21	No prior vaccinations for this event.
ABDOMINAL PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.	No prior vaccinations for this event.
ABDOMINAL PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
On 2/1/2021, the patients daughter, who claims is a nurse, reported this incident to me. She stated that the evening after the patient received the vaccine, she felt some mild injection site pain. The morning after, the patient reported severe abdominal pain, diarrhea and vomiting. The patients daughter then called her physician to report these symptoms and attributed them as an adverse reaction to the vaccine at that time. These symptoms were intermittent for one week and no other adverse reactions were noted. In the early morning hours of 1/27/2021, the patient was toileting and had expired while doing so. An ambulance was called and cause of death was not found. An autopsy was not performed.	No prior vaccinations for this event.
ABDOMINAL PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Toileting and had expired while doing so; Severe abdominal pain; Diarrhea; Vomiting; Mild injection site pain; A spontaneous report was received from a healthcare professional concerning an 88-year-old , female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced the events, toileting and had expired while doing so (death), mild injection site pain, severe abdominal pain, diarrhea, and vomiting. The patient's medical history was not provided. No relevant concomitant medications were reported. On 20 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 029L20A)	No prior vaccinations for this event.

intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 20 Jan 2021, the patient felt mild pain at the injection site after receiving the vaccine. On 21 Jan 2021, the patient reported severe abdominal pain, diarrhea and vomiting. These symptoms were intermittent for a week and no other adverse events were noted. On 27 Jan 2021, the patient passed away while toileting. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 27 Jan 2021. The cause of death was unknown. An autopsy was not performed.; Reporter's Comments: The gastrointestinal events were consistent with increased risk associate with elderly age of patient. The cause of death was unknown. Autopsy was not performed. Very limited information regarding the events is available at this time. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Reported Cause(s) of Death: unknown cause of death

ABDOMINAL PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.
ABDOMINAL PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
911 called to patients house for trouble breathing and abdominal pain. Patient coded, wife presented DNR paperwork. Patient presented to Hospital DOA at 0958.	No prior vaccinations for this event.
ABDOMINAL PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated	No prior vaccinations for

liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration		this event.
	ABDOMINAL PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
54 y/o M with PMH of HTN, HLD, Alcoholic Cirrhosis, Aortic Valve Stenosis, and angina BIBA as a Medical Alert for cardiac arrest noted PTA. Per EMS, the patient called because he was having constant, diffuse abdominal pain x 1 day that radiated to his chest. On scene, the patient had a witnessed arrest with EMS starting CPR. He was given 3 rounds of epi without ROSC. Pt had no associated shockable rhythm. Of note, pt's wife, had noted pt had received covid vaccine the prior day.		No prior vaccinations for this event.
	ABDOMINAL PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21		No prior vaccinations for this event.
	ABDOMINAL PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient stated he wasn't feeling well on January 25, 2021, wasn't eating and complained of abdominal pain. Patient noted to have indigestion and was constipated. Meds provided and labs ordered. On morning of January 26, 2021, patient became weak, lethargic and hypoxic and was sent to emergency department		No prior vaccinations for this event.

around 0700 hours on January 26, 2021. At approximately 1100 hours, emergency physician notified this writer that patient was not going to overcome his illness and would be placed on comfort care. At approximately 1130 hours, this writer was notified that patient had passed away from multi-organ failure.		
	ABDOMINAL PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient with inoperable pancreatic cancer received second Pfizer vaccine approximately 12:30 pm on 1/27/21. At approximataely 16:30, patient complained of abdominal pain and was given Levsin 0.125mg and morphine 5mg orally. At approximately 19:30 patient was found on the floor covered in a large amount of emesis, unresponsive without a pulse.		No prior vaccinations for this event.
	ABDOMINAL PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Day after receiving the vaccine, the patient complained of abdominal pain which worsened over the day. She went to the ED and was hospitalized. Abdominal pain complaints increased and continued, she decompensated rapidly, was intubated and subsequently died 3 days later. Imaging results showed, progressive ovarian cancer in the bowels. Blood culture revealed that she had E.Coli in her blood. It is thought that this is NOT related to the vaccine.		No prior vaccinations for this event.
	ABDOMINAL PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned		No prior vaccinations

to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.	for this event.
ABDOMINAL PAIN LOWER	**COVID19 (COVID19 (MODERNA)) (1201)**
Cardiac arrest; Pain on her upper right chest; Lot of pain in lower abdomen; Pain underneath arm; Thought it was muscle aches; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed upper right chest pain and underneath the arm, severe abdominal pain, muscle aches and cardiac arrest. The patient's medical history was not provided Concomitant product use was not provided by the reporter. On 14 Jan 2021, approximately five days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the arm for prophylaxis of COVID-19 infection. On 19 Jan 2021, the patient developed upper right chest pain and pain underneath the arm. They thought it was muscle aches. Sometime later, the patient developed a lot of pain in the lower abdomen. The called emergency services and an ambulance arrived but the patient then suffered cardiac arrest. Treatment for the event included tramadol. Action taken with mRNA-1273 in response to the events was not applicable due to the patient was died. The patient died on 19 Jan 2021. The cause of death was reported as cardiac arrest. Autopsy were not provided.; Reporter's Comments: Company Comment: This case concerns a 92-year-old female patient who experienced unexpected serious events of cardiac arrest, upper right chest pain and underneath the arm, severe abdominal pain, muscle aches. The event occurred 5 days after the administration of the first dose of the vaccine mRNA-1273 vaccine (Lot #: unknown, expiration date-unknown). Although a temporal association exist between the events and the administration of the vaccine, in the absence of critical details such as the patient's medical history, any diagnostic test or autopsy result, adequate evaluation and assessment cannot be established. Main field defaults to æpossibly related' for all events.; Reported Cause(s) of Death: Cardiac	No prior vaccinations for this event.

arrest

	ABDOMINAL PAIN UPPER	**COVID19 (COVID19 (MODERNA)) (1201)**
Feb 8 states she had a cold. Feb 9 added stomach ache and nausea. Feb 9 visited urgent care facility for exam and Covid-19 test. Rapid test results were negative. Appeared tired but fine. Told to go home and rest. Feb 10 at 9:00 am found dead on the floor in pool of blood and aspirated. Excessive blood in toilet, pooled on floor and hallway rug.		No prior vaccinations for this event.
	ABDOMINAL PAIN UPPER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.		No prior vaccinations for this event.
	ABDOMINAL PAIN UPPER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
She had the first dose of Pfizer vaccine at the Campus on Friday 1/15 at 4:30 pm. After the vaccine, she		No prior vaccinations for

had no new symptoms or signs of vaccine reaction and MD friend reports that he checked her pulse which was not elevated from baseline. On 1/16, she awakened and continued to feel at her recent baseline. However, in the early afternoon, she complained of headache, nausea/epigastric pain, and chest heaviness. These apparently were not unusual symptoms for her to feel intermittently. Per her niece, who has a home O2 sat device, her 02 sat that morning was 97 with a HR of 87 irregularly irregular. She was afebrile. (continue on page 2)

this event.

ABDOMINAL PAIN UPPER

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at

No prior vaccinations for this event.

time of this report."

	ABDOMINAL PAIN UPPER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
bowel perforation; pain in her upper abdomen; This is a spontaneous report from a contactable consumer. An 86-year-old female patient received the 2nd dose of bnt162b2 (BNT162B2) at single dose on 13Jan2021 for Covid-19 immunisation, administerd at nursing home/senior living facility Medical history included dementia, arthritis. No known allergies. Patient was not pregnant. Patient had not COVID prior vaccination. Concomitant medication in 2 weeks included: memantine (manufacturer unknown) 10 mg BID, diclofenac (manufacturer unknown) BID, carbidopa, levodopa (manufacturer unknown) 25-100 mg TID, quetiapine (manufacturer unknown) 12.5 mg q HS, escitalopram oxalate (LEXAPRO) 10 mg q HS, paracetamol (TYLENOL) 650 mg BID, glucosamine (manufacturer unknown) drink. The patient received the 1st dose of bnt162b2 (BNT162B2) at single dose on 24Dec2020 for Covid-19 immunisation. No other vaccine received in 4 weeks. The patient experienced bowel perforation and pain in her upper abdomen on 18Jan2021 07:30. The events resulted in Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event), and death. On 18Jan2021 07:30 AM, less than a week after the second shot, she had pain in her upper abdomen and was taken to the ER on 18Jan2021. CT showed a bowel perforation in the small bowel. She had never had bowel surgery or diverticulitis. She had been healthy other than her dementia and arthritis. Patient received treatment for the events: hospice and pain management. COVID-19 was not tested post vaccination. The cause of death was bowel perforation. An autopsy was not performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: bowel perforation		No prior vaccinations for this event.
	ABDOMINAL WALL HAEMATOMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Pt with acute resp failure, COVID PNA, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior toa admit, then shortly after progressed with other covid symptoms and was admitted. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. Pt passed soon after(2/2).	No prior vaccinations for this event.
ABDOMINAL WALL HAEMATOMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt passed soon after; shortly after progressed with other covid symptoms and was admitted / acute resp failure, COVID pneumonia; acute resp failure, COVID pneumonia; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; This is a spontaneous report from a non-contactable Pharmacist. A 76-years-old non-pregnant female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE lot number EL3247), intramuscular on 19Jan2021 at single dose for COVID-19 immunisation. The patient medical history included COVID symptoms from 16Jan2021 and ongoing. Concomitant medications were not reported. The patient with acute resp failure, COVID pneumonia, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior to a admit, then shortly after progressed with other covid symptoms and was admitted on 25Jan2021. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. The patient died on 02Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Sender's	No prior vaccinations for this event.

Comments: Based on temporal association, the causal relationship between bnt162b2 and the events death, COVID-19 pneumonia, acute respiratory failure, hypotension, abdominal wall haematoma and abdominal wall haemorrhage cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pt passed soon after

ABDOMINAL WALL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt passed soon after; shortly after progressed with other covid symptoms and was admitted / acute resp failure, COVID pneumonia; acute resp failure, COVID pneumonia; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; This is a spontaneous report from a non-contactable Pharmacist. A 76-years-old non-pregnant female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE lot number EL3247), intramuscular on 19Jan2021 at single dose for COVID-19 immunisation. The patient medical history included COVID symptoms from 16Jan2021 and ongoing. Concomitant medications were not reported. The patient with acute resp failure, COVID pneumonia, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior to a admit, then shortly after progressed with other covid symptoms and was admitted on 25Jan2021. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics	No prior vaccinations for this event.

deteriorated. The patient died on 02Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events death, COVID-19 pneumonia, acute respiratory failure, hypotension, abdominal wall haematoma and abdominal wall haemorrhage cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pt passed soon after

ABDOMINAL WALL OEDEMA

COVID19 (COVID19 (MODERNA)) (1201)

ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.

No prior vaccinations for this event.

ABDOMINAL X-RAY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm No prior vaccinations for this event.

ABNORMAL BEHAVIOUR	**COVID19 (COVID19 (MODERNA)) (1201)**	
"Patient was found ""acting abnormal"" on 1/9/2021 at 1215. VS HR 20-30's. EMS activated. EMS arrived and patient was found pulseless in PEA/ asystole, CPR and ACLS initiated and then transported to the MC. Unsuccessful resuscitation and expired on 1/09/2021 at 1348. Clinical impression Cardiopulmonary arrest."		No prior vaccinations for this event.
ABNORMAL BEHAVIOUR	**COVID19 (COVID19 (MODERNA)) (1201)**	
"Patient was tested positive for Covid-19 on 12/9/20. Patient received Covid Vaccine on 1/21/21. Patient was observing for 15 minutes in treatment room by Nursing staff. Patient denied any signs/symptoms adverse effect: headache, dizziness & weakness, difficulty breathing, muscle pain, chills, nausea and vomiting, and fever . Patient seated on treatment table appeared to be relaxed, respiration even and unlabored. Health teaching provided. Patient educated to report any changes in condition to staff immediately. Patient verbalized understanding and able to verbalize signs and symptoms and adverse effects to be aware of related vaccine. On 1/22/21: patient was seen by medical provider for ""altered behavior"". Per medical provider's documentation: ""Patient was fallen on 1/2/21 and was sent out to outside hospital on 1/4/21. CT head: no intracranial abnormality, age-related changes. Patient had labs (B12, RPR, folate) were within normal limit"". We did MMSE today: 22/30 score ""mild dementia"" On 1/23/20: ""Patient was inside his cell. He was walking towards cell door to obtain his breakfast, when custody witnessed him collapse and activated the alarm. Nursing staff arrived at cell front at 06:34 am and found the patient pulseless and unresponsive, and CPR was immediately initiated. AED was attached at 06:35 am and no shock advised. AMR then arrived and patient did not have ROSC, and was pronounced dead at 06:54 am.""""		No prior vaccinations for this event.
ABNORMAL BEHAVIOUR	**COVID19 (COVID19 (MODERNA)) (1201)**	
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had		No prior vaccinations for

shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.	this event.
ABNORMAL BEHAVIOUR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"The resident received is vaccine around 11:00 am and tolerated it without any difficulty or immediate adverse effects. He was at therapy from 12:36 pm until 1:22 pm when he stated he was too tired and could not do anymore. The therapist took him back to his room at that time and he got into bed himself but stated his legs felt heavy. At 1:50 pm the CNA answered his call light and found he had taken himself to the bathroom. She stated that when he went to get back into the bed it was ""abnormal"" how he was getting into it so she assisted him. At that time he quit breathing and she called a RN into the room immediately. He was found without a pulse, respirations, or blood pressure at 1:54 pm. He was a DNR."	No prior vaccinations for this event.
ABNORMAL BEHAVIOUR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS	No prior vaccinations for this event.

VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.

ABNORMAL BEHAVIOUR		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.		No prior vaccinations for this event.

ABNORMAL BEHAVIOUR		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately.		No prior vaccinations for this event.

when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."

ABNORMAL FAECES

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

He started vomiting 2 days later. we suspect he was having stool issues as well. he vomited blood at some point over the weekend. there was black vomit right before he passed. from 2am-6am he was wheezing and rattling and then he passed at approximately 6am 3/1/2021 at home. EMS did come and try to revive him and were unsuccessful.

No prior vaccinations for this event.

ABSENCE OF IMMEDIATE TREATMENT RESPONSE

COVID19 (COVID19 (MODERNA)) (1201)

CARDIAC ARREST, DEATH Narrative: The patient presents to the emergency department in cardiopulmonary arrest. CPR was continued upon arrival. The Combi tube was removed and an endotracheal tube was placed without complications. ROSC was obtained multiple times but the patient continued to go into PEA. The patient was seen in the emergency department by both critical care and Cardiology. EKG shows ST elevations, but the patient was unstable to go to catheterization. The patient had 1 episode of asystole. Despite best efforts and multiple attempts we were unable to resuscitate the patient. Time of death 1253 on 1/24/21.

No prior vaccinations for this event.

ABSENCE OF IMMEDIATE TREATMENT RESPONSE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient developed hypoxia on 1/4/2021 and did not respond to maximal treatment and passed way on 1/5/2021

No prior vaccinations for this event.

ABSENCE OF IMMEDIATE TREATMENT RESPONSE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

patient declined 12/30/2020 and was transferred to hospital where he did not respond to treatment and passed away 1/4/2020

No prior vaccinations for this event.

ACIDOSIS

COVID19 (COVID19 (MODERNA)) (1201)

Sudden death 2/7/21 @ 0309 Started acute encephalopathy & required intubation Soon after intubation went into cardiac arrest Likely severe acidosis.

No prior vaccinations for this event.

ACIDOSIS

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

ACIDOSIS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P

No prior vaccinations for this event.

67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

ACIDOSIS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

For the two days prior to presentation the patient had been complaining of chest pain, his breathing seemed to be labored Monday. He and the family thought the pain was due to shingles as he carried this diagnosis from a month ago. Patient had also received the COVID vaccine 2 days prior to presentation and assumed he was feeling unwell due to the vaccine. Family wanted to take him to the hospital yesterday and earlier today but he refused. She left him in his home earlier this afternoon prior to presentation and returned to check on him finding him unresponsive and apneic at which time EMS was activated. #cardiac arrest -- suspect primary cardiac given collateral from family at home, consider hypoxemia which was corrected with advanced airway and 100% FiO2, patient clinically euvolemic and with soft brown stool in diaper not suggestive of GI hemorrhage, attempt to address acidosis with CPR and bicarbonate, not hypoglycemia, on

No prior vaccinations for this event.

bedside ultrasound FAST neg and no pericardial effusion suggestive of tamponade and +lung sliding bil not spontaneous pneumothorax Assessment/Diagnosis: -cardiac arrest, cause unspecified

ACIDOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO WITHDRAWL EXTRME MEASURES	No prior vaccinations for this event.
ACTIVATED PARTIAL THROMBOPLASTIN TIME	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
ACTIVATED PARTIAL THROMBOPLASTIN TIME SHORTENED	**COVID19 (COVID19 (UNKNOWN)) (1202)**
5 days after receiving his COVID vaccination the patient had a spontaneous (nontraumatic) subarachnoid hemorrhage which was fatal. The patient had previously been stable on his coumadin dosing with therapeutic INRs for the past several months per his wife. At time of presentation his blood pressure in the ER was elevated to 223/94 and his INR was risen to 3.1	No prior vaccinations for this event.
ACUTE CORONARY SYNDROME	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident passed away unexpectedly on 01/19/21 after developing acute hypoxic respiratory failure on morning of 01/19/21. She was transferred to hospital via EMS where she was intubated, coded, and ultimately expired with uncertain underlying cause, potentially ACS.	No prior vaccinations for this event.
ACUTE HEPATIC FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver failure,	No prior vaccinations for this event.

pneumonia, and DIC>"

ACUTE KIDNEY INJURY	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.	No prior vaccinations for this event.
ACUTE KIDNEY INJURY	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.	No prior vaccinations for this event.
ACUTE KIDNEY INJURY	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient, who was a pharmacist, developed fatigue and shortness of breath hours after receiving vaccine. Two days later, on 01/28/2021, the patient went to local urgent care for worsening shortness of breath and was referred to Hospital for worsening dyspnea and hypoxia. The patient was admitted to the hospital We was found to have bilateral pulmonary infiltrates and treated for pneumonia with Rocephin and azithromycin. He was tested for COVID-19 multiple times, but each of the results were negative. Despite the negative results, there was high clinical suspicion for COVID-19 and the patient was started on Remdesivir and Decadron. The patient's oxygen requirements continued to worsen and the patient was transferred to another	No prior vaccinations for this event.

facility for higher level of care. There his hypoxia worsened and he required mechanical ventilation. Patient then developed hypotension and required vasopressors for blood pressure support. Furthermore, patient developed acute renal failure requiring hemodialysis. Despite mechanical ventilation with FiO2 100%, and for vasopressors, patient clinically deteriorated and family decided to palliatively extubate on 02/05/2021.

ACUTE KIDNEY INJURY	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had Covid-19 in October of 2020. He recovered. He received the vaccination on 12/30/2020 with no complaints. On 01-05-2021 it was noted to he was incontinent of urine and bilateral lower extremity edema. Lab work was completed showed acute kidney injury. He had decreased blood pressure and oxygen saturations on 01-06-2021 He was admitted to the hospital with rapid progression of symptoms and suggested multi-system failure. He had a long cardiac history. On 01-14-2021 he passed away with a diagnosis of Cardiomyopathic CHF, A.Fib contributory.	No prior vaccinations for this event.
ACUTE KIDNEY INJURY	**COVID19 (COVID19 (MODERNA)) (1201)**
Admitted to hospital with sob upon exertion that started prior to vaccine. Hx COPD, HTN, CKD, hyperlipidemia, bladder cancer in remission. Stated he has been taking Eliquis and Xarelto between renal doctor and cardiologist Dr. Anticipating going home 2/5/21 but then turned blue and stopped breathing under a DNR. COVID test negative. Labs show acute on chronic renal failure with an elevated troponin likely from demand ischemia.	No prior vaccinations for this event.
ACUTE KIDNEY INJURY	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presents to ER with increased weakness, hypoxia, history of COPD, but not oxygen dependent., hypotension. Acute Kidney failure noted in labs, not previously diagnosed , new hyperkalemia. BP 73/39, HR	No prior vaccinations

67. dopamine initiated, and switched to Levophed. Oxygen Sat 86%, requiring 10 L O2. Transferred from this critical access hospital to another Hospital. Expires later 2-13-2021	for this event.
ACUTE KIDNEY INJURY	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.	No prior vaccinations for this event.
ACUTE KIDNEY INJURY	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP	No prior vaccinations for this event.

support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.		
	ACUTE KIDNEY INJURY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.		No prior vaccinations for this event.
	ACUTE KIDNEY INJURY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer.		No prior vaccinations for this event.

Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

ACUTE KIDNEY INJURY		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021.	No prior vaccinations for this event.	

ACUTE MYELOID LEUKAEMIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident expired on 1/23/21 . Resident receiving care under hospice ,diagnosis Acute Myeloid Leukemia.	No prior vaccinations for this event.	

ACUTE MYELOID LEUKAEMIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall; fatigued; arm pain; AML; Sepsis secondary to AML; This is a spontaneous report from a contactable consumer. An 88-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19	No prior vaccinations	

VACCINE, lot# EL3249), via an unspecified route of administration on 19Jan2021 17:30 in right arm at single dose for covid-19 immunization. Medical history included hypertension, hyperlipidemia, OA (osteoarthritis), cognitive impairment. No other vaccine in four weeks was administrated. Concomitant medication in two weeks included atorvastatin, aspirin, calcium, gabapentin, losartan and memantine hydrochloride (NAMENDA). The patient previously took lisinopril and tetracycline and both experienced allergies. The patient had no covid prior vaccination. The patient initially had no symptoms but arm pain in Jan2021, no bleeding or bruising from injection. On 31Jan2021 19:00, patient felt fatigued. Patient suffered fall on 01Feb2021. She was admitted to hospital. All cell lines were down in Feb2021. She was diagnosed with AML (acute myeloid leukemia) in 2021. She expired 07Feb2021. Events resulted in emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event) and patient died. The patient received the treatment of blood and platelet transfusions, bone marrow biopsy, cytogenetic testing, antibiotics, intubation for events. The patient died on 07Feb2021 due to sepsis secondary to AML. An autopsy was not performed. Outcome of events were fatal.; Reported Cause(s) of Death: arm pain; fatigued; fall; Sepsis secondary to AML; Sepsis secondary to AML	for this event.

ACUTE MYOCARDIAL INFARCTION	**COVID19 (COVID19 (MODERNA)) (1201)**
pt received vaccine on 2/3. early on 2/4 developed chest pain, dyspnea, and was seen in ED and diagnosed with acute exacerbation of CHF and NSTEMI type 2, and anemia. on 2/5 transfusion was started and pt developed worsening dyspnea and then PEA arrest. Pt achieved ROSC and was transferred to the cardiac intensive care unit where he required vasopressor support. he subsequently declined and died on 2/7	No prior vaccinations for this event.

ACUTE MYOCARDIAL INFARCTION	**COVID19 (COVID19 (MODERNA)) (1201)**
"The decedent experienced severe chest pain and dyspnea approximately nine days following the first series of the vaccine. He reported to family members that he was having a ""severe reaction"" to the	No prior vaccinations for this event.

vaccine and believed it was acute pericarditis due to the same symptoms he experienced prior. He reported that on 2/1/21 around 0300 hours, the symptoms were the most severe and he was going to seek medical attention, but did not. He waited till the convenient store opened and purchased OTC Tylenol for relief of symptoms. He continued to have dyspnea and chest pain up until 2/9/21, when he called 911 complaining of chest pain and was found to have a STEMI; subsequently died at Hospital in the ER."

	ACUTE MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Acute anterior MI with death	No prior vaccinations for this event.	

ACUTE MYOCARDIAL INFARCTION COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident was hospitalized for confusion, and hypotension and increased weakness; resident proceeded to have a NSTEMI and died on 5th day in hospital on 1/31/2021.	No prior vaccinations for this event.

	ACUTE MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021.		No prior vaccinations for this event.

	ACUTE MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.	No prior vaccinations for this event.
ACUTE MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of covid vaccine on 1/22/2021. Patient had no immediate reaction. Patient presented to the Emergency Department on 1/26/2021 c/o shortness of breath and chest pain. ECG showed a ST elevation myocardial infarction. Patient was treated and transferred to a cath lab where he died. Patient had significant coronary artery disease.	No prior vaccinations for this event.
ACUTE MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)	No prior vaccinations for this event.
ACUTE MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Pt he reports he developed chills SOB body aches the same night as receiving the COVID vaccine on 1.26.2021-pt is currently reporting CheSt tightness and SOB Admitted to hosp: ICU with Bilateral Pulmonary Emboli, LLE DVT, NSTEMI, Arrhythmia.	No prior vaccinations for this event.

ACUTE MYOCARDIAL INFARCTION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient hospitalized for NSTEMI (from 2/18/2021 to 2/20/2021) and discharged on hospice/comfort care. Patient died 2/21/2021.		No prior vaccinations for this event.
ACUTE PULMONARY OEDEMA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
within 24 hours after her second injection she developed chills, had a syncopal episode and had, difficulty breathing. this progressed over the next day when she had a second syncopal episode and her dyspnea and confusion worsened EMT was called and she was brought to the hospital. she was in flash pulmonary edema and with her history of severe aortic stenosis she was admitted to the cardiac icu. she had no prior history up to that time of pulmonary edema and was functioning without distress in her home. she had a history of covid in early april, manifesting primarily as severe confusion, from which she recovered.		No prior vaccinations for this event.
ACUTE RESPIRATORY DISTRESS SYNDROME		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the Moderna COVID vaccine 1/28/21. He was tested for COVID 19 on 1/29/31. Results were received 1/30/21, at which time he was evaluated and found to be hypoxic with tachycardia. He was sent to the local ER and returned this same day. On 2/2/21, he was evaluated by the provider, who sent him to the emergency room with acute respiratory distress and poor O2 sats		No prior vaccinations for this event.
ACUTE RESPIRATORY DISTRESS SYNDROME		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was vaccinated on 1/14/2021. On 1/22/2021, patient tested positive for COVID-19 and admitted to the		No prior vaccinations

hospital for acute hypoxemic respiratory failure, COVID-19 pneumonia, and severe ARDS. Patient was intubated on 1/23/2021 and later died on 2/10/2021 after being extubated and placed on comfort measures.	for this event.
ACUTE RESPIRATORY DISTRESS SYNDROME	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.	No prior vaccinations for this event.
ACUTE RESPIRATORY DISTRESS SYNDROME	**COVID19 (COVID19**

	(PFIZER-BIONTECH)) (1200)
Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021.	No prior vaccinations for this event.
ACUTE RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**
51 year old M with h/o O2 dependent COPD, Severe pulmonary fibrosis became increasingly hypoxic around 1800hours 1/7/2021. He was transported to hospital for acute on chronic hypoxia respiratory failure. On 1/12/2021 he decompensated further, and after discussing with family and palliative care, He was changed to comfort care. He expired on 1/12/2021@2325 at medical center.	No prior vaccinations for this event.
ACUTE RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**
Lethargy/altered level of consciousness lead to hospital admission. Multiple interventions during hospitalization. Final hospital diagnoses: Acute respiratory failure with hypercapnia, acute pansinusitis.	No prior vaccinations for this event.
ACUTE RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**
chronic hypoxia respiratory failure; Unresponsive; A spontaneous report was received from Pfizer concerning a 51-year old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had	No prior vaccinations for

developed hypoxia a sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 07 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 07 Jan 2021, around 6:00 pm, the patient became increasingly hypoxic. He was transported to the hospital for acute on chronic hypoxia respiratory failure. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Jan 2021 at 11:25pm. The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death		this event.
	ACUTE RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was vaccinated on 12/31/20. Then on 1/14/21 he tested positive for SARS-CoV-2 on routine surveillance PCR testing. Another resident on the same hall was COVID positive on 1/11/21. Results of the PCR test were obtained on 1/16/21. He appeared asymptomatic at that time. Given his COVID positive status, all aerosol generating procedures had to be stopped. Overnight on 1/16/21 into 1/17/21, he had the onset of acute respiratory failure and was transported to the hospital. Per notes, he was put on BiPAP for several hours, but his CO2 level did not improve. Per prior advance directives completed with the resident and his two brothers, he had DNR/DNI orders. The hospital physician spoke with his brother and the decision was made to move to comfort care. He was discharged to inpatient hospice and died around 4pm on 1/18/21. This outcome does not appear to be vaccine-related, but death from COVID-19 infection is listed as a reportable event following COVID-19 vaccination.		No prior vaccinations for this event.
	ACUTE RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

According to medical report, Pt presented to the ED on 1/14/21 w/ cc of SOB for 1 day. She received her COVID-19 vaccine on 1/9/21. Pt stated that she developed a dry hacking cough 2 days prior to the vaccine on 1/7/21. Over the last few days prior to admission, she developed generalized weakness, SOB, loss of sense of taste and smell w/ associated decreased appetite and nausea ultimately SOB in the24 hours prior to admission. Final Diagnosis- acute hypoxic respiratory failure secondary to COVID-19 pneumonia. Pt died on 2/3/21. See Medical report for more information.	No prior vaccinations for this event.
ACUTE RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt with acute resp failure, COVID PNA, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior toa admit, then shortly after progressed with other covid symptoms and was admitted. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. Pt passed soon after(2/2).	No prior vaccinations for this event.
ACUTE RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt passed soon after; shortly after progressed with other covid symptoms and was admitted / acute resp failure, COVID pneumonia; acute resp failure, COVID pneumonia; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; This is a spontaneous report from a non-contactable Pharmacist. A 76-years-old non-pregnant	No prior vaccinations for this event.

female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE lot number EL3247), intramuscular on 19Jan2021 at single dose for COVID-19 immunisation. The patient medical history included COVID symptoms from 16Jan2021 and ongoing. Concomitant medications were not reported. The patient with acute resp failure, COVID pneumonia, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior to a admit, then shortly after progressed with other covid symptoms and was admitted on 25Jan2021. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. The patient died on 02Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events death, COVID-19 pneumonia, acute respiratory failure, hypotension, abdominal wall haematoma and abdominal wall haemorrhage cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pt passed soon after

ACUTE RESPIRATORY FAILURE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she

No prior vaccinations for this event.

had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

ACUTE RESPIRATORY FAILURE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect

No prior vaccinations for this event.

d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

ADENOVIRUS TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became	No prior vaccinations for this event.

acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.

ADJUSTED CALCIUM

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

No prior vaccinations for this event.

ADULT FAILURE TO THRIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient with failure to thrive symptoms prior to 2nd dose, not eating, not taking medications.

No prior vaccinations for this event.

AGEUSIA

COVID19 (COVID19 (MODERNA)) (1201)

Patient experienced loss of taste and lack of appetite. Passed away on 1/23/21. No prior vaccinations for this event.

AGEUSIA	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
According to medical report, Pt presented to the ED on 1/14/21 w/ cc of SOB for 1 day. She received her COVID-19 vaccine on 1/9/21. Pt stated that she developed a dry hacking cough 2 days prior to the vaccine on 1/7/21. Over the last few days prior to admission, she developed generalized weakness, SOB, loss of sense of taste and smell w/ associated decreased appetite and nausea ultimately SOB in the24 hours prior to admission. Final Diagnosis- acute hypoxic respiratory failure secondary to COVID-19 pneumonia. Pt died on 2/3/21. See Medical report for more information.	No prior vaccinations for this event.

AGITATION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said	No prior vaccinations for this event.

that everything was okay, but he was very agitated; reported as not like this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away

	AGITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated		No prior vaccinations for this event.

hospital bed. Patient committed suicide in home.

	AGITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccinated 2/20. At that time, had symptoms of incarcerated hernia, went to ED for evaluation. Not felt to warrant hospital admission. Returned two days later with agitation, altered mental status, and incarceration. Went to OR, uncomplicated hernia repair. Postoperatively, did not recover mental status. Went into arrythmias POD 4, hypotension ensued, had multiple interventions and evaluations without satisfying answers for clinical course.		No prior vaccinations for this event.
	AGONAL DEATH STRUGGLE	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).		No prior vaccinations for this event.
	AGONAL RHYTHM	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient found down at home with agonal respirations and per EMS asystole, received 2 rounds of epi at her house with return of spontaneous pulses, lost pulse again in route to ER and another round of epi was given,		No prior vaccinations

CPR in progress when arrived at hospital. Prior to this patient's husband states he heard her fall in the bathroom but did not immediately check on her as he states that this has happened before. He checked on her 10 min later and that's when he found her unconscious. Daughter called 911 and she began CPR. No previous complaints of headache, chest pain, back pain, fever or chills. Husband states patient was drinking that evening which is not unusual for her. Patient died at hospital.	for this event.	
AGONAL RHYTHM		**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.	No prior vaccinations for this event.	
AGONAL RHYTHM		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was	No prior vaccinations for this event.	

stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

AIRWAY SECRETION CLEARANCE THERAPY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient has been under Hospice services for almost a year. She began to demonstrate a large amount of oral secretions on 1/10/21 at 2130. She was suctioned and a Rapid COVID-19 test was performed, which was negative. The COVID-19 Rapid test was repeated on 1/11/21 and was positive. Oxygen saturation was noted to be 78% on 1/12/21, and oxygen was initiated at 1133 at 3L per nasal cannula. Oxygen was increased to 4L at 1635 d/t shortness of breath. On 1/15/21 @ 0645 patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.	No prior vaccinations for this event.
AIRWAY SECRETION CLEARANCE THERAPY	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

After being observed for approximately 20 minutes and patient walked to her car without assistance I was called to assess the patient in the parking lot for troubles breathing. EMS was called as I made my way outside. Upon my arrival patient was leaning out of the car and stating that she could not breath. She was able to tell me that she was allergic to penicillin. Oxygen was immediately placed on the patient with minimal relief. Lung sounds were coarse throughout. She then began to vomit about every 20-30 seconds. Epipen was administered in the right leg with no relief. Patient continued to complain of troubles breathing and vomiting. A second epipen was administered in the patients right arm again with no relief. A few minutes later patient was given racemic epinephrine through the oxygen mask. There appeared to be mild improvement in her breathing as she appeared more comfortable, but still complaining of shortness of breath and vomiting. When EMS arrived patient was unable to transport herself to the stretcher. When EMS and clinical staff transferred patient to the stretcher she became unresponsive. She appeared to still be breathing. She did not respond to verbal stimuli. Per ED report large amount of fluid was suctioned from the patients lungs following intubation in the ambulance. When patient arrived to the ED she was extubated and re-intubated without difficulty and further fluid was suctioned. At that time patient was found to be in PEA, shock was delivered. Shortly thereafter no cardiac activity was found and patient pronounced dead.

No prior vaccinations for this event.

ALANINE AMINOTRANSFERASE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.

No prior vaccinations for this event.

ALANINE AMINOTRANSFERASE DECREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"	No prior vaccinations for this event.	
ALANINE AMINOTRANSFERASE INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."	No prior vaccinations for this event.	
ALANINE AMINOTRANSFERASE INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.	No prior vaccinations for this event.	
ALANINE AMINOTRANSFERASE INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**

Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.	No prior vaccinations for this event.
ALANINE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.
ALANINE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR	No prior vaccinations for this event.

resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

ALANINE AMINOTRANSFERASE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

No prior vaccinations for this event.

ALANINE AMINOTRANSFERASE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD

No prior vaccinations for this event.

A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.

ALANINE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	No prior vaccinations for this event.

ALANINE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for	No prior vaccinations for this event.

a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

ALANINE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration	No prior vaccinations for this event.

pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

ALANINE AMINOTRANSFERASE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Death on 1/31/2021 multiple comorbidities No prior vaccinations for this event.

ALANINE AMINOTRANSFERASE INCREASED COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.	No prior vaccinations for this event.

ALANINE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.

ALANINE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Cardiogenic shock occurred on 2/10/2021, approximately 12 hours after patient received her 12th dose of pemetrexed/pembrolizumab and 4 days after COVID vaccine. Coronary angiography was done on 2/10/2021 and no significant coronary narrowing or blockage were noted. Baseline troponin on 2/10/21 was 0.02 and later on 2/10/21, troponins were 9.99 & 25.27. Creatinine increase from 1.2 to 3.4 within 24hours, and AST/ALT increased from 23 & 31 to 4,220 & 4,786 respectively on 2/11. Patient expired on 02/11/2021.	No prior vaccinations for this event.

ALANINE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)	No prior vaccinations for this event.
ALANINE AMINOTRANSFERASE NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.	No prior vaccinations for this event.
ALANINE AMINOTRANSFERASE NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.	No prior vaccinations for this event.
ALANINE AMINOTRANSFERASE NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

ALANINE AMINOTRANSFERASE NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further

No prior vaccinations for this event.

testing.

ALBUMIN GLOBULIN RATIO	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
ALBUMIN GLOBULIN RATIO ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.	No prior vaccinations for this event.
ALTERED STATE OF CONSCIOUSNESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Lethargy/altered level of consciousness lead to hospital admission. Multiple interventions during hospitalization. Final hospital diagnoses: Acute respiratory failure with hypercapnia, acute pansinusitis.	No prior vaccinations for this event.
AMMONIA INCREASED	**COVID19 (COVID19 (PFIZER-**

	BIONTECH)) (1200)
"death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death ""cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its components or a severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed. MDs recommending hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative status. 1/29 Pt passed away."	No prior vaccinations for this event.
ANAEMIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.	No prior vaccinations for this event.
ANAEMIA	**COVID19 (COVID19 (MODERNA)) (1201)**

Fever 101.1, unresponsive episode. Transferred to Hospital on 1/28. Diagnosis there was anemia and CHF, aware that he had vaccine day prior. Transfused with 2 units pRBC's. Transferred back to Nursing Home on 1/30 and passed away 0140 1/31/2021	No prior vaccinations for this event.
ANAEMIA	**COVID19 (COVID19 (MODERNA)) (1201)**
pt received vaccine on 2/3. early on 2/4 developed chest pain, dyspnea, and was seen in ED and diagnosed with acute exacerbation of CHF and NSTEMI type 2, and anemia. on 2/5 transfusion was started and pt developed worsening dyspnea and then PEA arrest. Pt achieved ROSC and was transferred to the cardiac intensive care unit where he required vasopressor support. he subsequently declined and died on 2/7	No prior vaccinations for this event.
ANAEMIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Received Moderna #1 on 1/12/2021. 1/15/2021 developed worsening shortness of breath. Went to hospital and diagnosed with anemia, 4 negative fecal tests, neg EGD and colonoscopy. Discharged and readmitted (circumstances unknown for this episode) then readmitted a third time 1/20/2021 for shortness of breath. Diagnosed covid + at third hospitalization and continued to get worse. He died 1/23/2021.	No prior vaccinations for this event.
ANAEMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report	No prior vaccinations for this event.

she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

	ANAEMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom only had site soreness after her covid vaccine on 1/21 which resolved within a couple days. However, she died in the early morning hours of 1/25, she was fine the day before, no sign of injury. We found her collapsed on the ground and although we tried cpr she was already dead. She had gone to the hospital on 12/28 for shortness of breath, angina and symptomatic anemia, her ekg was unchanged and blood work normal except for anemia. The cardiologist did not think a cardiac cath was needed. Her shortness of breath improved with a blood transfusion and a dose of lasix (no heart failure).		No prior vaccinations for this event.
	ANAEMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.	No prior vaccinations for this event.	
ANAEMIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	No prior vaccinations for this event.	
ANAEMIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.	
ANAEMIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation,	No prior vaccinations for	

elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.

ANAEMIA MACROCYTIC	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg	No prior vaccinations for this event.

of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well.

Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure""""

ANAL INCONTINENCE

COVID19 (COVID19 (MODERNA)) (1201)

The patient passed away today, 1/13/2021. She was a hospice patient. She showed no adverse effects after receiving the vaccine on 1/12/2021. This morning she woke up as normal and during her morning shower she had a bowel movement, went limp and was non-responsive. The patient passed away at 7:45 am.

No prior vaccinations for this event.

ANAL INCONTINENCE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated at 11:30am. By 7pm he started presenting symptoms of fatigue, chest pain. Patient urinated and defecated in himself. Was not feeling well. Patient died at 10:30pm.

No prior vaccinations for this event.

ANAL INCONTINENCE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/23 - Mild injection site discomfort. Appetite loss compared to previous day. Beginning loss of mental acuity compared to previous day. 1/24 - Continued loss of appetite. Near complete loss of ability to move. Continued decline of mental acuity. Very little speaking. 1/25 - Stopped speaking completely. Loss of bowel control in the evening and continued until death. Complete loss of appetite. 1/26 - Near complete loss of

No prior vaccinations for this event.

ability to swallow. Moved to hospice 4:00pm. 1/27 - Died 4:00am

ANALGESIC DRUG LEVEL DECREASED	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.

ANALGESIC DRUG LEVEL THERAPEUTIC	COVID19 (COVID19 (MODERNA)) (1201)
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain	No prior vaccinations

which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.	for this event.
ANAPHYLACTIC REACTION	**COVID19 (COVID19 (MODERNA)) (1201)**
Brain aneurysm; Anaphylactic reaction; Collapsed; BP sky rocketed; Shortness of breath; A spontaneous report was received from a consumer concerning a 69-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced blood pressure skyrocketed, shortness of breath, loss of consciousness, massive anaphylactic reaction, and brain aneurysm. The patient's medical history, as provided by the reporter, included high blood pressure and arthritis. Products known to have been used by the patient, within two weeks prior to the event, included an antihypertensive. On 04 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. Twenty-two minutes later she had a massive anaphylactic reaction. She experienced shortness of breath, blood pressure skyrocketed, and loss of consciousness. She was taken to the emergency room. The patient had a brain aneurysm and never recovered. No treatment information was provided. The patient died on 04 Jan 2021. The cause of death was reported as brain aneurysm. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns a 69-year-old, female patient with a medical history of hypertension, who experienced fatal, serious, unexpected events of Anaphylactic reaction, hypertension, dyspnea, loss of consciousness and brain aneurysm. The events occurred 22 minutes after the first dose of mRNA-1273 was administered. No treatment information was provided. The patient never recovered and died. The cause of death was reported as brain aneurysm. Very limited information regarding this event has been provided at this time. Based on temporal association between the	No prior vaccinations for this event.

use of the product and the start date of the event, a causal relationship cannot be excluded. Additional information has been requested.; Reported Cause(s) of Death: Brain aneurysm

ANAPHYLACTIC SHOCK **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

She started having breathing problems/heart attack appearance. on 1/22/21 and went to the ER. Upon admittance was told it was an anaphylactic shock from the Covid shot. They kept her in ICU and released her 1/23/21. At 12:45 am on 1/24/21 she passed out and we called the ambulance. Hospital admitted her and worked through multiple organ failure issues and thought her numbers were under control. She was released on 1/27/21 and was driving on 1/28/21 around 4:15 pm and appears to have had heart failure and had a wreck. She passed away that day. No prior vaccinations for this event.

ANEURYSM **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm No prior vaccinations for this event.

ANEURYSM RUPTURED **COVID19 (COVID19 (MODERNA)) (1201)**

Patient received her first dose of the Moderna COVID-19 Vaccination on Saturday January 16th 2021 at approximately 12pm. She completed all necessary screening forms and was deemed to be at low risk for serious allergic reactions. She tolerated the vaccination well, and no complications or immediate adverse events occurred. She was observed for a full 15 mins per CDPHE/CDC guidelines and left the Clinic in stable condition after her observation period was complete. On the morning of Tuesday, January 19th, 2021, the patient was found unconscious and unresponsive by her husband. She was transferred by Ambulance to Hospital shortly thereafter. She was diagnosed with a brain bleed that was determined to be No prior vaccinations for this event.

inoperable. She was transferred to other Hospital for higher level care. She was seen by neurosurgery and diagnosed with a ruptured aneurysm. She was treated in the ICU for 24 hours, at which point her team determined that the severity of her brain bleed would not respond to treatment. Supportive cares were withdrawn on Wednesday Jan 20th, and she passed away shortly thereafter.

ANGINA PECTORIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1-12-21 Resident is complaining of heart pain. Resident blood pressure is 228/105. 1-22-21 Dx UTI 1-13-21 His nurse called MD at approximately 0645, reported to him that it was reported to this nurse that resident has not slept in 2 days and night, has an increased blood pressure, reports severe pain in lower back, and appears to be uncomfortable Resident is able to verbalize his pain and where it is at, but is unable to explain the quality of the pain or give a number on the 0/10 pain scale.	No prior vaccinations for this event.
ANGINA PECTORIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom only had site soreness after her covid vaccine on 1/21 which resolved within a couple days. However, she died in the early morning hours of 1/25, she was fine the day before, no sign of injury. We found her collapsed on the ground and although we tried cpr she was already dead. She had gone to the hospital on 12/28 for shortness of breath, angina and symptomatic anemia, her ekg was unchanged and blood work normal except for anemia. The cardiologist did not think a cardiac cath was needed. Her shortness of breath improved with a blood transfusion and a dose of lasix (no heart failure).	No prior vaccinations for this event.
ANGIOCARDIOGRAM	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Cardiogenic shock occurred on 2/10/2021, approximately 12 hours after patient received her 12th dose of pemetrexed/pembrolizumab and 4 days after COVID vaccine. Coronary angiography was done on 2/10/2021 and no significant coronary narrowing or blockage were noted. Baseline troponin on 2/10/21 was 0.02 and later on 2/10/21, troponins were 9.99 & 25.27. Creatinine increase from 1.2 to 3.4 within 24hours, and AST/ALT increased from 23 & 31 to 4,220 & 4,786 respectively on 2/11. Patient expired on 02/11/2021.

No prior vaccinations for this event.

ANGIOGRAM

COVID19 (COVID19 (MODERNA)) (1201)

On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of the MCA territory (TPA not recommended). CTA did show distal L M1/M2 occulsion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.

No prior vaccinations for this event.

ANGIOGRAM CEREBRAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm No prior vaccinations for this event.

ANGIOGRAM CEREBRAL ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of the

No prior vaccinations for this event.

MCA territory (TPA not recommended). CTA did show distal L M1/M2 occulsion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.

ANGIOGRAM PULMONARY ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to the Emergency Department complaining of chest pain, pale, cool diaphoretic, and hypotensive. The patient was discovered to have a large saddle pulmonary embolism, went into cardiac arrest and expired. Of note, the patient received her second Moderna COVID vaccine on 1/23, which would place her first one approximately 12/25 if she received them at the appropriate interval. This information is from the patient's daughter and the ED record, the information is not available in CAIR. Per the daughter, the patient started feeling ill on 1/21, improved on 1/25, and then acutely worsened on 1/27, resulting in the ED visit.

No prior vaccinations for this event.

ANGIOGRAM PULMONARY ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

ANGIOGRAM PULMONARY ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive.

No prior vaccinations for this event.

EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.

ANGIOGRAM PULMONARY ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.

No prior vaccinations for this event.

ANGIOGRAM PULMONARY NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

ANGIOGRAM PULMONARY NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration	No prior vaccinations for this event.	
ANION GAP		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.	No prior vaccinations for this event.	
ANION GAP		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.	
ANION GAP		**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.	
ANION GAP		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

No prior vaccinations for this event.

ANION GAP

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer,

No prior vaccinations for this event.

however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

	ANION GAP	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness,		No prior vaccinations for

altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM		this event.
	ANION GAP	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
	ANION GAP INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause		No prior vaccinations for this event.

for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

ANOSMIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
According to medical report, Pt presented to the ED on 1/14/21 w/ cc of SOB for 1 day. She received her COVID-19 vaccine on 1/9/21. Pt stated that she developed a dry hacking cough 2 days prior to the vaccine on 1/7/21. Over the last few days prior to admission, she developed generalized weakness, SOB, loss of sense of taste and smell w/ associated decreased appetite and nausea ultimately SOB in the24 hours prior to admission. Final Diagnosis- acute hypoxic respiratory failure secondary to COVID-19 pneumonia. Pt died on 2/3/21. See Medical report for more information.		No prior vaccinations for this event.
ANTICONVULSANT DRUG LEVEL DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received vaccine at Public Health Clinic. Patient ended up having a seizure 3 days later and ended up in the hospital. Found to have right lobe pneumonia and low depakote level. Patient noted to have multiple seizures at hospital, issues with stabilizing HR and BP, and passed away on 1/20/21.		No prior vaccinations for this event.
ANURIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Pale, not eating, no urine output After 1st covid vaccine

ANXIETY **COVID19 (COVID19 (MODERNA)) (1201)**

"The patient came to the Emergency Room at approx 3:30 am on 02/03/2021 with pain in right arm (same arm the COVID vaccine had been administered in approx 12 hours earlier) and feeling generally unwell. Patient was concerned about possibility of gout flare or that something was wrong with her arm. Elevated blood pressure was noted; this was attributed to anxiety. She was evaluated, given 500 mg Tylenol, and discharged since the pain was decreasing and blood pressure was stabilized. Patient instructed to follow-up with physician. The next day, on 02/04/2021, the patient arrived at the Emergency Room by ambulance; cardiac arrest was the chief complaint. The patient's daughter stated the patient had been ""feeling generally poor and then suddenly collapsed."" Daughter described ""gurgling respirations"" and being unresponsive. 911 was called, police arrived within 5 minutes and initiated CPR. Epinephrine, atropine, lidocaine and bicarb administered after arrival to Emergency Room. Shockable rhythm never demonstrated. Patient never recovered spontaneous respiration or movement. The death was called at 23:04. Coronary artery disease with cardiac arrest is the cause from the ER records; the coroner is putting COVID-19 vaccination in Part 1 of the death certificate."

No prior vaccinations for this event.

ANXIETY **COVID19 (COVID19 (MODERNA)) (1201)**

Patient described feeling nervous, anxious the next morning (Wednesday) after the vaccine. He later fell in the bathroom after using the restroom, his legs gave out (his words) and consequently was on the ground for 23 hours before being transported to the hospital. That was Thursday afternoon. He was diagnosed with COVID-19 on Saturday night and died the following Friday morning.

No prior vaccinations for this event.

ANXIETY **COVID19 (COVID19 (MODERNA)) (1201)**

Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse	No prior vaccinations for this event.

ANXIETY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Within 24 hours of receiving the vaccine, fever and respiratory distress, and anxiety developed requiring oxygen, morphine and ativan. My Mom passed away on the evening of 12/26/2020.	No prior vaccinations for this event.

ANXIETY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID	No prior vaccinations for this event.

shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.

	ANXIETY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The day following the vaccine, the patient complained of throat issues and anxiety. This was not new... however . That evening he reported difficulty breathing and was placed on oxygen; a COVID test was performed and was negative. On 12/30/2020, patient complained of sternal pressure and was transferred to the hospital. The patient died 12/31/2020 and records obtained from the hospital indicated the patient died from a massive myocardial infarction.		No prior vaccinations for this event.
	ANXIETY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient's wife called this morning stating that her husband has passed away last night. After receiving first dose of Pfizer COVID-19 vaccine at around 0830, patient remained in the Immunizations Department for the 15-minute monitoring period. Per wife, patient's only complaint was pain at the injection site. At 1300, wife states that patient complaint of dizziness which ""dissipated after a few minutes"" followed by a headache which ""dissipated after a few minutes"" as well. Then patient complained of nausea, no vomiting and ""couldn't relax."" Per wife, from around 1400/1500, patient stayed on his recliner while still having a conversation with her--""he didn't get up to eat."" Last conversation they had was around 2000/2100. Per wife, at around 2100/2200, patient was quiet and when she checked on him, ""he wasn't responding		No prior vaccinations for this event.

anymore."" Wife then called 911, ""but they couldn't revive him."""

	ANXIETY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
respiratory distress; fever; anxiety developed requiring oxygen; Passed away; This is a spontaneous report via a Pfizer-sponsored program from a non-contactable consumer. A 63-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot and expiry not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. Medical history included anaphylactic reaction (broad), neuroleptic malignant syndrome (broad), anticholinergic syndrome (broad), acute central respiratory depression (broad), hypersensitivity (broad), respiratory failure (narrow), drug reaction with eosinophilia and systemic symptoms (broad), hypoglycaemia (broad), COVID-19 (broad) and chronic obstructive pulmonary disease (COPD); all from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine sodium and lorazepam (ATIVAN). Within 24 hours of receiving the vaccine, the patient experienced fever, respiratory distress, and anxiety developed requiring oxygen, morphine and lorazepam (ATIVAN). The patient passed away on the evening of 26Dec2020. The patient underwent lab tests and procedures which included SARS-COV-2 antibody test: negative on an unspecified date. The outcome of the event death was fatal, while of the other events was unknown. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Passed a		No prior vaccinations for this event.

	ANXIETY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of		No prior vaccinations for this event.

chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

ANXIETY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness.	No prior vaccinations for this event.

He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is

elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

AORTIC ANEURYSM	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive MI, PE or ruptured AAA"". Death certificate notes indicate ""signficant conditions contributing to death after cardiac arrest; ASCVD""."	No prior vaccinations for this event.
AORTIC ANEURYSM RUPTURE	**COVID19 (COVID19 (MODERNA)) (1201)**
This resident of the assisted living facility received his Covid-19 Moderna (1st) vaccination and he has a leaking Aortic Aneurysm which resulted in hospitalization and he entered into Hospice care on 1.30.2021 and passed away on 1.30.2021.	No prior vaccinations for this event.
AORTIC ANEURYSM RUPTURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated approx 9a. Later that evening, patient was having trouble breathing so they called son who lives down the road to come, 20 mins after the call the patient has passed. Per medical examiner, pt	No prior vaccinations for this event.

died due to possible PE, MI, or his aortic aneurysm ruptured.

AORTIC DISSECTION	**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation	No prior vaccinations for this event.
AORTIC STENOSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.	No prior vaccinations for this event.
AORTIC STENOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
within 24 hours after her second injection she developed chills, had a syncopal episode and had, difficulty	No prior vaccinations

breathing. this progressed over the next day when she had a second syncopal episode and her dyspnea and confusion worsened EMT was called and she was brought to the hospital. she was in flash pulmonary edema and with her history of severe aortic stenosis she was admitted to the cardiac icu. she had no prior history up to that time of pulmonary edema and was functioning without distress in her home. she had a history of covid in early april, manifesting primarily as severe confusion, from which she recovered.		for this event.
	AORTITIS	**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation		No prior vaccinations for this event.
	APHASIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient vaccinated on 12/28. Approximately one day later, develops cough and on azithromycin x 1 week. On 1/3, patient develops left-sided weakness and aphasia. Taken to the hospital, tested COVID+, required intubation -- acute hypoxic respiratory failure secondary to COVID - on H&P. Patient died on 1/4/21 at 7:20am.		No prior vaccinations for this event.
	APHASIA	**COVID19 (COVID19 (MODERNA)) (1201)**
On the evening of 10JAN2021, patient experienced a low grade fever, decreased oxygen saturation of 38%,		No prior vaccinations

heart rate of 124, confusion. Patient received oxygen via face mask, morphine and ativan. By 11JAN2021, patient was no longer verbal, able to eat or communicate and was kept on comfort measure only. On the morning of 17JAN2021, the patient passed away.		for this event.
	APHASIA	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of the MCA territory (TPA not recommended). CTA did show distal L M1/M2 occulsion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.		No prior vaccinations for this event.
	APHASIA	**COVID19 (COVID19 (MODERNA)) (1201)**
"86yo female alert, stable with ankle abrasion eating 100% prior to vaccine in assisted living facility. On 2/1/2021, received Moderna vaccine. Starting thereafter, eating 50% on 2/2/21. Temperature was 98 tympanic. On 2/3, the leg abrasion started having moderate bleeding. On 2/4, the caregiver noted patient ""not looking good, unable to talk, arms moving aimlessly, grasping"". BP 95/41, temperature 98, oxygen on room air 92-93%. POA did not want hospital transfer. 2/5 Hospice started, oxygen given, morphine given. 2/5-2/8 comfort care given, patient responsive to tactile stimuli, resting, not taking oral medications or food. 2/8/2021 patient expired."		No prior vaccinations for this event.
	APHASIA	**COVID19 (COVID19 (MODERNA)) (1201)**
death; hemiparesis; respiratory failure; Aphasia; SARS-COV-2 test positive; cough; A spontaneous report was		No prior vaccinations

received from other health care professional concerning a 32- year -female patient who received Modena's COVID-19 vaccine (mRNA-1273) and experienced aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive. The patient's medical history was not provided. No relevant concomitant medications were reported. On 28-Dec-2020, the patient received their first of two planned doses of mRNA-1273 (lot/batch 039k20A) intramuscularly on left arm for prophylaxis of COVID-19 infection. Approximately, one day later, patient developed cough and on treatment with azithromycin for one week. On 03-jan-2021, she experienced left sided weakness and aphasia and was shifted to hospital. Patient was confirmed COVID-19 positive which required intubation for acute hypoxic respiratory failure secondary to COVID-19. No laboratory data was provided. Action taken with mRNA-1273 in response to the events aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive not applicable. On an unknown date, the outcome of the events aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive was fatal. On 04 Jan 2021, the patient passed away due to the unknown cause. Autopsy results were unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the event of COVID-19 is assessed as unlikely related. The cause of death was not reported. Autopsy results were unknown.; Reported Cause(s) of Death: Unknown cause of death	for this event.
APHASIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine was administered at Nursing Facility. Patient is an 89-year-old female with prior medical history of CVA with dysphagia, history of possible dementia, GERD, hyperlipidemia, and a pacemaker. She is a resident from town. She was sent for hypotension with a blood pressure of 90/52, tachypnea respirations of 54, possible aspiration pneumonia. Status post Covid vaccine earlier today. History is limited as patient is nonverbal on my exam. Death within 24 hours of vaccination	No prior vaccinations for this event.
APHASIA	**COVID19 (COVID19**

	(MODERNA)) (1201)
Vaccine administered 02/08/2021 , by Thursday 02/11/2021 patient almost nonverbal, by Monday 02/15/2021 patient went to the hospital with bruising, sores on her stomach and clots reported as thrombocytopenia, deceased by Friday 02/19/2021.	No prior vaccinations for this event.
APHASIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Within 15 minutes of the injection, the individual became aphasia and stroke like symptoms. She was taken to the ER where she was later diagnosed with a cerebral hemorrhage and passed away.	No prior vaccinations for this event.
APHASIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Jan 3 vaccine administered, jan 4 started headaches, vomiting, pain in the back of the neck, Headaches, chills, loss of speech,	No prior vaccinations for this event.
APHASIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
she was injected, sh stopped eating and talking, the doctor watched her for 2 days. had her transported to the hospital. i was told she had tested positive for COVID 2 times once at the home and once at the hospital. with in 2 DAYS at the hospital she wa on a ventilator 2 days later she died. i talked with the rehab center and confirmed she tested negative for COVID on Dec 27th 2020 and was given the Vaccine on the 29th Dec 202 was in the hospital 4 day later, was on a ventilator 4 days after that then died a few day later as her heart stopped beating. all the while i had POA and was not contacted by Hospital staff until after	No prior vaccinations for this event.

they had made the next step.

	APHASIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom received the Covid 19 vaccine on Jan 5, 2021 and became very about a week later. I was informed that she tested positive for Covid 19 on January 14th. One January 17th she became very tired and weak and would not eat. Hospice called me and told me that she was in a decline state. I saw her on January 25 and 26 and she was just sleeping and could not open her eyes. Her vitals were good and she seemed to understand when I talked to her - she would squeeze my hand and moan but she could not talk or open her eyes. My mom passed away on January 27, 2021 just 22 days after receiving the Covid 19 vaccine. She was very think to begin with and being to weak and tired to eat resulted in her losing even more weight. Some of the other residents were given fluids to help and they recovered. My mom was not given fluids. I believe there were 20 deaths in her care home for the month of January when they vaccinated. This was an alarming number of deaths for the home. The facility had very few Covid deaths in 2019 and 2020. I asked every week if they had any Covid and or Covid deaths and this amount was shocking to me and the workers there.		No prior vaccinations for this event.

	APHASIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/23 - Mild injection site discomfort. Appetite loss compared to previous day. Beginning loss of mental acuity compared to previous day. 1/24 - Continued loss of appetite. Near complete loss of ability to move. Continued decline of mental acuity. Very little speaking. 1/25 - Stopped speaking completely. Loss of bowel control in the evening and continued until death. Complete loss of appetite. 1/26 - Near complete loss of ability to swallow. Moved to hospice 4:00pm. 1/27 - Died 4:00am		No prior vaccinations for this event.

	APHASIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.		No prior vaccinations for this event.
	APNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
All residents had been in isolation due to multiple cases of COVID in the facility. Resident voiced no health related complaints. He continued to visit with staff and required moderate assist with toileting. Resident had fall 0130 on 1-15-2021, which resulted in laceration with surgical repair. Resident was noted to change in mental status and respirations on morning of 1-16-2021 during morning blood sugar check. Resident had O2 @1.5l/m via n/c and respirations of 10 with periods of apnea and unresponsive to verbal stimuli. Blood sugar was 583. Resident deceased upon re-check after calling PCP to report status change.		No prior vaccinations for this event.
	APNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client tested positive for COVID-19 by rapid test on 1/8/21. On 1/9/21 at 1405 his oxygen saturation dropped to 86% and oxygen was initiated at 2L per nasal cannula. A non-productive cough was noted on		No prior vaccinations for

1/10/21 and oxygen was increased to 3L. On 1/12/21 Client became non-responsive with 30 second periods of apnea. Dexamethasone was initiated on 1/13/21. Lung sounds were noted with crackles on 1/15/21 at 1158 and at 2120 Client was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.	this event.
APNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
For the two days prior to presentation the patient had been complaining of chest pain, his breathing seemed to be labored Monday. He and the family thought the pain was due to shingles as he carried this diagnosis from a month ago. Patient had also received the COVID vaccine 2 days prior to presentation and assumed he was feeling unwell due to the vaccine. Family wanted to take him to the hospital yesterday and earlier today but he refused. She left him in his home earlier this afternoon prior to presentation and returned to check on him finding him unresponsive and apneic at which time EMS was activated. #cardiac arrest -- suspect primary cardiac given collateral from family at home, consider hypoxemia which was corrected with advanced airway and 100% FiO2, patient clinically euvolemic and with soft brown stool in diaper not suggestive of GI hemorrhage, attempt to address acidosis with CPR and bicarbonate, not hypoglycemia, on bedside ultrasound FAST neg and no pericardial effusion suggestive of tamponade and +lung sliding bil not spontaneous pneumothorax Assessment/Diagnosis: -cardiac arrest, cause unspecified	No prior vaccinations for this event.
APNOEIC ATTACK	**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration	No prior vaccinations for this event.

APNOEIC ATTACK	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/17/2021 at 4:35 am resident found apneic and pulseless, at 4:40am death confirmed	No prior vaccinations for this event.
APPARENT LIFE THREATENING EVENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
bowel perforation; pain in her upper abdomen; This is a spontaneous report from a contactable consumer. An 86-year-old female patient received the 2nd dose of bnt162b2 (BNT162B2) at single dose on 13Jan2021 for Covid-19 immunisation, administerd at nursing home/senior living facility Medical history included dementia, arthritis. No known allergies. Patient was not pregnant. Patient had not COVID prior vaccination. Concomitant medication in 2 weeks included: memantine (manufacturer unknown) 10 mg BID, diclofenac (manufacturer unknown) BID, carbidopa, levodopa (manufacturer unknown) 25-100 mg TID, quetiapine (manufacturer unknown) 12.5 mg q HS, escitalopram oxalate (LEXAPRO) 10 mg q HS, paracetamol (TYLENOL) 650 mg BID, glucosamine (manufacturer unknown) drink. The patient received the 1st dose of bnt162b2 (BNT162B2) at single dose on 24Dec2020 for Covid-19 immunisation. No other vaccine received in 4 weeks. The patient experienced bowel perforation and pain in her upper abdomen on 18Jan2021 07:30. The events resulted in Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event), and death. On 18Jan2021 07:30 AM, less than a week after the second shot, she had pain in her upper abdomen and was taken to the ER on 18Jan2021. CT showed a bowel perforation in the small bowel. She had never had bowel surgery or diverticulitis. She had been healthy other than her dementia and arthritis. Patient received treatment for the events: hospice and pain management. COVID-19 was not tested post vaccination. The cause of death was bowel perforation. An autopsy was not performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: bowel perforation	No prior vaccinations for this event.

APPETITE DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient stated he had a migraine after the vaccine. We were advised of a change in appetite on Thursday February 4th. Patient died on February 6th.	No prior vaccinations for this event.
AREFLEXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care	No prior vaccinations for this event.

with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

ARRHYTHMIA

COVID19 (COVID19 (MODERNA)) (1201)

Clients wife reported on 1/18/2021, that her husband died unexpectedly the day after receiving the COVID 19 vaccine. I called and spoke with her. She stated that the client had started experienced some tightness in his chest the evening of 1/11/2021. She stated that it was normal for him to have the tightness in his chest if he got stressed. She stated that she found him on the garage floor on 1/12/2021 at 2120. He was taken by ambulance to the hospital. She stated that the hospital told her that his COPD had caused him to go into arrythmia.

No prior vaccinations for this event.

ARRHYTHMIA

COVID19 (COVID19 (MODERNA)) (1201)

Shortness of Breath, decreased oxygen saturation, irregular heart rhythm, hypertension, Positive for COVID, bilateral pneumonia

No prior vaccinations for this event.

ARRHYTHMIA

COVID19 (COVID19 (MODERNA)) (1201)

The patient fell the day after receiving the Moderna COVID-19 vaccine. She broke her hip in this fall. During surgery to correct the broken hip, she went in to sudden and unexpected cardiac arrest. The anesthetist did not notice any ST changes or A fib; dysrhythmia was very unexpected. The patient had a DNR. She died at 13:00 on 02/07/2021. Causes of death are listed as 1. Cardiac Arrest 2. Recent hip fracture with hip placement 3. History of Breast Cancer 4. Hypothyroid and 5. Dementia

No prior vaccinations for this event.

ARRHYTHMIA

COVID19 (COVID19

(MODERNA)) (1201)

Pt was hospitalized Jan 18, 2021 after he had fallen outside overnight and lay there approximately 12 hours until he was found. Hypothermic & rhabdomyolis diagnosis. Gradually improved w/ strength & mental status - was in swing bed @ hospital. He got his first Covid 19 shot on 2-8-21. Was fine @ 0300 on 2-9-21 and @ 0430 he was found unresponsive. Dx: probable arrythmia & pronounced dead @ 0454. Noted on pain scale @ 2/8/21 @ 21:11, clients pain was a 7/10 They offered pain med & he refused They repositioned & distracted him @ 2047 on 2/8/21 Pain had decreased to 3/10 and nothing given. Then @ 0300 check he was sleeping and @ 0430 unresponsive.

No prior vaccinations for this event.

ARRHYTHMIA

COVID19 (COVID19 (MODERNA)) (1201)

Cardiac arrhythmia, EMS on site within minutes, outcome of death. No prior vaccinations for this event.

ARRHYTHMIA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient noted to have irregular breathing in bed and unable to arouse. Provided life saving measures in the field x 30 minutes and transferred to hospital. Noted to have heart arrhythmia which suspected to cause cardiac arrest.

No prior vaccinations for this event.

ARRHYTHMIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Developed heart arrhythmia and was unable to be revived. No prior vaccinations for this event.

ARRHYTHMIA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"He collapsed due to a cardiac arrest on Friday 15Jan and passed away on 19Jan; He collapsed due to a cardiac arrest on Friday 15Jan and passed away on 19Jan; his cardiac arrest was caused by an arrhythmia; This is a spontaneous report from contactable pharmacist via Pfizer Sales Representative. A 45-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not reported), via an unspecified route of administration on 11Jan2021 at single dose for covid-19 immunisation. Patient had a long history of congenital heart issues. He had been stable and closely monitored for the past 20 years. He had no history of arrhythmia. The patient's concomitant medications were not reported. Patient collapsed due to a cardiac arrest on Friday 15Jan2021 and passed away on 19Jan2021. The doctors feel that his cardiac arrest was caused by an arrhythmia. Reporter reported this through the v safe app. And received a message stating reporter would be contacted by the cdc. After patient passed away reporter replied stop to v safe. But still had not been contacted by anyone. This may or may not be related. Reporter have no way of knowing. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported ""collapsed due to a cardiac arrest"", ""cardiac arrest was caused by an arrhythmia"" and the administration of COVID-19 vaccine, BNT162B2, based on the reasonable temporal association. The patient's pre-existing long history of congenital heart issues might have provided alternative explanations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: He collapsed due to a cardiac arrest on Friday 15Jan and passed away on 19Jan; his cardiac arrest was caused by an arrhythmia; He collapsed due to a cardiac arrest on Friday 15Jan and passed away on 19Jan"

No prior vaccinations for this event.

ARRHYTHMIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

DEATH Narrative: Pt he reports he developed chills SOB body aches the same night as receiving the COVID vaccine on 1.26.2021-pt is currently reporting CheSt tightness and SOB Admitted to hosp: ICU with Bilateral Pulmonary Emboli, LLE DVT, NSTEMI, Arrhythmia.	No prior vaccinations for this event.
ARRHYTHMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccinated 2/20. At that time, had symptoms of incarcerated hernia, went to ED for evaluation. Not felt to warrant hospital admission. Returned two days later with agitation, altered mental status, and incarceration. Went to OR, uncomplicated hernia repair. Postoperatively, did not recover mental status. Went into arrythmias POD 4, hypotension ensued, had multiple interventions and evaluations without satisfying answers for clinical course.	No prior vaccinations for this event.
ARTERIAL DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.	No prior vaccinations for this event.
ARTERIOGRAM CAROTID	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm No prior vaccinations for this event.

ARTERIOGRAM CAROTID NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Cardiogenic shock occurred on 2/10/2021, approximately 12 hours after patient received her 12th dose of pemetrexed/pembrolizumab and 4 days after COVID vaccine. Coronary angiography was done on 2/10/2021 and no significant coronary narrowing or blockage were noted. Baseline troponin on 2/10/21 was 0.02 and later on 2/10/21, troponins were 9.99 & 25.27. Creatinine increase from 1.2 to 3.4 within 24hours, and AST/ALT increased from 23 & 31 to 4,220 & 4,786 respectively on 2/11. Patient expired on 02/11/2021.		No prior vaccinations for this event.
ARTERIOSCLEROSIS		**COVID19 (COVID19 (MODERNA)) (1201)**
No reported adverse reactions from 1st or 2nd vaccine doses Patient died on 2/6/2021 at Correctional facility- autopsy was performed at medical examiner's office. The COD was artherosclerotic cardiovascular disease		No prior vaccinations for this event.
ARTERIOSCLEROSIS		**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive MI, PE or ruptured AAA"". Death certificate notes indicate ""signficant conditions contributing to death after cardiac arrest; ASCVD""."		No prior vaccinations for this event.

ARTERIOSCLEROSIS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
As per patient daughter - patient had some minor chills on the day of the vaccination - Friday 1/15/21; felt well next day -Saturday, than she was found slumped and lifeless on the couch on Sunday 1/17. Cause of death on death certificate was reportedly put as COPD, Lung Ca and ASHD.		No prior vaccinations for this event.
ARTERIOSCLEROSIS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.		No prior vaccinations for this event.
ARTERIOSCLEROSIS CORONARY ARTERY		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
As per patient daughter - patient had some minor chills on the day of the vaccination - Friday 1/15/21; felt well next day -Saturday, than she was found slumped and lifeless on the couch on Sunday 1/17. Cause of death on death certificate was reportedly put as COPD, Lung Ca and ASHD.		No prior vaccinations for this event.
ARTERIOVENOUS FISTULA ANEURYSM		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Admitted to hospital after vaccination with Acute hypoxemic respiratory failure, Septic shock;		No prior vaccinations for this

Aneurysm of arteriovenous dialysis fistula; expired 1/16/2021		event.
	ARTERITIS CORONARY	**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation		No prior vaccinations for this event.
	ARTHRALGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to our Emergency Department via EMS in full code status; asystole. Patient expired. Per nursing, husband stated patient awoke this AM and reported pain in back between shoulders and in bilateral shoulders. Patient then went unresponsive and husband called EMS.		No prior vaccinations for this event.
	ARTHRALGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021and felt poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife		No prior vaccinations for this event.

encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM CHLORIDE 1000 MG ONCE

ARTHRALGIA

COVID19 (COVID19 (MODERNA)) (1201)

"Client came to nursing station about 2pm to report she ""was not feeling well"". Nurses took vital signs, then referred her to the vaccination clinic that was onsite. She was observed by vaccination team for a period of time. She reported shoulder pain radiating into shoulder blade in arm vaccine was received. Vaccination team offered ice pack to her, observed for a period of time, and released back to work. About 10pm that evening, she sent a text to another coworker that her pain was ""off the charts"" and that she had pain covering her whole left side of her body. She did not come to work in the morning and did not contact work. Well being check was performed at approximately 9am on 2/2/2021 and she was found dead in her home. 911 was immediately called and authorities took over the scene."

No prior vaccinations for this event.

ARTHRALGIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Same day as vaccination given, developed pain went from arm up to shoulder, to back, to neck to head - right side of body; chills/body aches

No prior vaccinations for this event.

ASCITES

COVID19 (COVID19 (MODERNA)) (1201)

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after

No prior vaccinations for this event.

receiving the vaccine.

ASCITES	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.
ASCITES	**COVID19 (COVID19 (MODERNA)) (1201)**
Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.	No prior vaccinations for this event.
ASCITES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was hospitalized 15 days after receiving vaccine. Admission was not due to vaccine and was admitted for acute ascites and patient had reported fever and hypoxia. Patients admission resulted in death 7 days after being admitted to hospital.	No prior vaccinations for this event.
ASPARTATE AMINOTRANSFERASE	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
ASPARTATE AMINOTRANSFERASE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"	No prior vaccinations for this event.
ASPARTATE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."	No prior vaccinations for this event.
ASPARTATE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by	No prior vaccinations

ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		for this event.
	ASPARTATE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.		No prior vaccinations for this event.
	ASPARTATE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.		No prior vaccinations for this event.
	ASPARTATE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of		No prior vaccinations for

abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.		this event.
ASPARTATE AMINOTRANSFERASE INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506		No prior vaccinations for this event.
ASPARTATE AMINOTRANSFERASE INCREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in		No prior vaccinations for this event.

refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

ASPARTATE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.	No prior vaccinations for this event.

ASPARTATE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an	No prior vaccinations for this event.

Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

ASPARTATE AMINOTRANSFERASE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

No prior vaccinations for this event.

ASPARTATE AMINOTRANSFERASE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"	No prior vaccinations for this event.
ASPARTATE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into	No prior vaccinations for this event.

full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of

pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

ASPARTATE AMINOTRANSFERASE INCREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death on 1/31/2021 multiple comorbidities No prior vaccinations for this event.

ASPARTATE AMINOTRANSFERASE INCREASED COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.

No prior vaccinations for this event.

ASPARTATE AMINOTRANSFERASE INCREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Cardiogenic shock occurred on 2/10/2021, approximately 12 hours after patient received her 12th dose of pemetrexed/pembrolizumab and 4 days after COVID vaccine. Coronary angiography was done on 2/10/2021 and no significant coronary narrowing or blockage were noted. Baseline troponin on 2/10/21 was 0.02 and later on 2/10/21, troponins were 9.99 & 25.27. Creatinine increase from 1.2 to 3.4 within 24hours, and AST/ALT increased from 23 & 31 to 4,220 & 4,786 respectively on 2/11. Patient expired on 02/11/2021.

No prior vaccinations for this event.

ASPARTATE AMINOTRANSFERASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)	No prior vaccinations for this event.
ASPARTATE AMINOTRANSFERASE NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.	No prior vaccinations for this event.
ASPIRATION	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.	No prior vaccinations for this event.
ASPIRATION	**COVID19 (COVID19 (MODERNA)) (1201)**

Feb 8 states she had a cold. Feb 9 added stomach ache and nausea. Feb 9 visited urgent care facility for exam and Covid-19 test. Rapid test results were negative. Appeared tired but fine. Told to go home and rest. Feb 10 at 9:00 am found dead on the floor in pool of blood and aspirated. Excessive blood in toilet, pooled on floor and hallway rug.	No prior vaccinations for this event.	
ASPIRATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna COVID-19 vaccination administered in left arm at her assisted living facility by Pharmacist at 1153 on 2/19/2021. Pt was monitored for vaccine reaction with no known adverse reaction. Approximately 18 hours post-vaccine, she was found deceased in her sleep at 0540 on 2/20/21. Per circumstances/pt history, it is presumed that the patient aspirated while sleeping, perhaps secondary to a seizure. Coroner was notified and declined as coroner's case. VAERS notification being made due to pt death within 24 hours of receiving a vaccine.	No prior vaccinations for this event.	
ASPIRATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Massive ischemic stroke with aspiration, unable to arouse on the morning of 1/21/2021 and placed on Hospice with death 1/24/2021	No prior vaccinations for this event.	
ASPIRATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death occurred 3 days after vaccine receipt; attributed to complications of her chronic advanced dementia with aspiration at age 87. No evidence of acute vaccine reaction.	No prior vaccinations for this event.	
ASPIRATION		**COVID19 (COVID19 (PFIZER-**

	BIONTECH)) (1200)
My father was in weak condition to begin with. He didn't get out of bed for the next few days after receiving the vaccine. The little amount that he ate was consumed in bed. He began aspirating his food which lead to pneumonia. He wasn't strong enough to fight off the pneumonia even with antibiotics. He died on 1/23/21. While he might have passed soon in any case, I believe that the vaccine may possibly have increased his weakness/exhaustion thereby hastening his demise.	No prior vaccinations for this event.
ASPIRATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Was contacted by the person's daughter on 2/5/21. Patient started vomiting 2 days after vaccination. She aspirated and passed away 1/16/21. Patient had history of stroke and swallowing problems.	No prior vaccinations for this event.
ASPIRATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.	No prior vaccinations for this event.

ASPIRATION	**COVID19 (COVID19 (UNKNOWN)) (1202)**
Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2 diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated) then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and was intubated. Transported to hospital. SARS CoV-2 and influenza negative.	No prior vaccinations for this event.
ASPIRATION PLEURAL CAVITY	**COVID19 (COVID19 (MODERNA)) (1201)**
1/31/2021 12:50 Nursing Note Note Text: Res had low BP, low O2 sats, 30 breaths per minute, eyes open wide, making confused utterances. Started supplemental oxygen via NC, 2L, then 3L. Sats went up to 93% for a while, Sprvsr called. Unable to auscultate Left lung sounds. Called to update Res daughter. Called to page NP, writer went back to assess Res and O2 sats were 88%, turned O2 to 4LPM, called 911 for transport to Hospital ED. Left around 1030. NP called back afterwards, was updated. Family updated that Res was sent to Hospital ED. Note Text: Received phone call from daughter as well as information from hospital. Resident has pneumonia with septic shock. She is on abx and had thoracentesis performed for large pleural effusion. [linked]	No prior vaccinations for this event.
ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Weakness, Low O2, death. Positive for COVID on 1/12/21, dies on 1/16/21	No prior vaccinations for this event.

ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**	
Presented to Urgent Care for weakness and confusion, transferred to ED, patient had a cardiac arrest and was unable to be resuscitated	No prior vaccinations for this event.	
ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**	
Resident was noted to have increase weakness on 1/15/2021. Resident was warm to touch with low grade fever of 99.3 F. Resident was up propelling self in w/c on 1/16/2021 he was pleasant, accepted medications and ate lunch. He was found slumped over in his w/c not responding and vital signs absent.	No prior vaccinations for this event.	
ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**	
Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.	No prior vaccinations for this event.	
ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**	
Pt developed COVID-19 infection, symptoms starting 7 days after first dose was given. Patient was admitted to hospital on 1/21 after falling (secondary to weakness) and striking head on toilet. Patient expired due to respiratory complications of COVID on 1/25.	No prior vaccinations for this event.	
ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**	
"Pt. woke up the next morning after vaccination and ""didn't feel well"", described by wife as fatigue, no	No prior vaccinations	

energy. At approximately 2 PM, he vomited. His wife checked on him at 4:20 PM and he wasn't breathing sitting in his chair. EMS squad was called but when they arrived he was asystole and mottling present. Did not start CPR since he was already gone too long. Pronounced by coroner on scene." for this event.

ASTHENIA **COVID19 (COVID19 (MODERNA)) (1201)**

Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot. No prior vaccinations for this event.

ASTHENIA **COVID19 (COVID19 (MODERNA)) (1201)**

Resident expired on january 21, 2021 No prior vaccinations for this event.

ASTHENIA **COVID19 (COVID19 (MODERNA)) (1201)**

weakness and fallsNarrative: 95 yo male w/ a PMH significant for Afib, legal blindness, Hx of CVA, cognitive impairment, GERD, HTN, pseudogout, BPH, chronic knee infection, and DJD who received his first dose of the Moderna COVID-19 vaccine on 01/08/21. The pt's COVID-19 screening questionnaire prior to receiving the vaccine was negative. The pt presented to the ED on 01/13/21 for weakness and m PCR test on ultiple recent falls (since receiving his first dose of the COVID-19 vaccine). The pt's COVID-19 01/13/20 was positive and he was admitted. He was started on treatment with remdesivir + dexamethasone on 1/14. The pt initially required supplemental oxygen via low-flow NC, however his oxygen requirements increased to 100% NRB. On 01/16/21 his MPOA elected for hospice care. The pt passed on 01/17/21. Unclear if the COVID-19 vaccine attributed to the patient's hospitalization and eventual death, or whether these events occurred from No prior vaccinations for this event.

COVID-19 itself, however this case is being reported the FDA since this vaccine is under an emergency use authorization (EUA).

	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.		No prior vaccinations for this event.

	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.

	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Congestion, Hypoxia, SOB, Tachycardia, Weakness. Started on O2 @ 3L, HOB elevated, Tylenol supp		No prior vaccinations for this event.

	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Per granddaughter's report, pt became very weak within hours of receiving the first dose of the Moderna COVID-19 vaccine and could not get out of bed the next morning without assistance, reported difficulty seeing, and did not recognize some family members. By Sunday, 1/31, pt was unable to be awakened, would not eat, and had low urinary output. Granddaughter reports that the morning of 2/1 he was awake and ate a small amount and seemed to be improving although still weak and unable to get out of bed. Granddaughter reported he died 2/1 around 10am in the morning.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living		No prior vaccinations for this event.

facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident received the vaccine on 1-22-21 and she was diagnosed with COVID-19 during routine testing on 1-28-21. She didn't have any symptoms except feeling weak and she had a decrease in her appetite. She already had a poor appetite prior. She died on 2-2-21.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Within a few days, my mother started reporting profound fatigue and shortness of breath while conducting routine household activities. She no longer had to energy for her daily exercise walks and became increasingly lethargic. She died in her sleep while taking an afternoon nap on Thursday, February 4th. I am highly concerned this could be a vaccine related.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
1-2 days after vaccine, pt developed weakness, fatigue, body aches, nausea, headache and poor appetite. Pt was admitted to the hospital on 2/5/21 and death occured on 2/6/21		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
DIED WITHIN 5 DAYS OF RECEIEVING THE 2ND DOSE, EXPERIENCED GENERALIZED WEAKNESS.		No prior vaccinations for this event.

	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
patient tested positive for covid on 1/29/21. was hospitalized on 2/8/21 for shortness of breath, generalized weakness, nausea.		No prior vaccinations for this event.

	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Nausea, vomiting and generalized weakness. No prior vaccinations for this event.		

ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**	
I video chatted with her Thursday after receiving the vaccine. My mom was in poor health but she was talking in complete sentences and responded appropriately. She was upright in bed and made eye contact. She smiled and denied pain. By Sunday, she was extremely weak and unable to sip water with a straw. Her health had changed dramatically and rapidly. She moaned in pain and was very fatigued. Her condition continued to deteriorate over the week and she stopped talking and was constantly sleeping. They started antibiotics for the oozing cancer lesion and then morphine for pain and end of life care. She passed away on January 22nd which was 15 days post vaccination.		No prior vaccinations for this event.

	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presents to ER with increased weakness, hypoxia, history of COPD, but not oxygen dependent., hypotension. Acute Kidney failure noted in labs, not previously diagnosed , new hyperkalemia. BP 73/39, HR 67. dopamine initiated, and switched to Levophed. Oxygen Sat 86%, requiring 10 L O2. Transferred from this critical access hospital to another Hospital. Expires later 2-13-2021		No prior vaccinations for this event.

ASTHENIA	COVID19 (COVID19 (MODERNA)) (1201)
On monitoring for declining in condition, loss of appetite and generalized body weakness on2/1/2021. Was confirmed COVID-19 positive 4/23/2020.	No prior vaccinations for this event.

ASTHENIA	COVID19 (COVID19 (MODERNA)) (1201)
"Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive MI, PE or ruptured AAA"". Death certificate notes indicate ""signficant conditions contributing to death after cardiac arrest; ASCVD""."	No prior vaccinations for this event.

ASTHENIA	COVID19 (COVID19 (MODERNA)) (1201)
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also	No prior vaccinations for this event.

question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

ASTHENIA

COVID19 (COVID19 (MODERNA)) (1201)

On January 1, 2021, patient was admitted to Medical Center with COVID. Tested positive on January 2, 2021. Spent 10 days in hospital. Once recovered from pneumonia and fever gone, on January 10, 2021, she was transferred to Rehabilitation Center for continued treatment. She spent 16 days there. She developed UTI and CDIF infections and was on/off oxygen. She started physical therapy. She was scheduled to be released to go home on January 27, 2021. On January 26, 2021, the day before going home, Rehabilitation Center gave her the Moderna vaccine. On January 27, the day she went home, she started feeling very weak and couldn't walk. My dad tried lifting her and they both fell to the ground. My dad called 911 and she was taken to Medical Center, with high fever and possible stroke symptoms (which later was negative). Two days later, she had difficulty breathing and was put on a ventilator. She was on a ventilator for about three days. They took it off and she slowly started recovering. The doctors did all kinds of tests (blood clot in lung, heart, etc.) and all was negative. The only thing they could trace it to was an adverse reaction to the vaccine. After spending 11 days at hospital and treating her for various infections, her heart stopped and she passed away suddenly.

No prior vaccinations for this event.

	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Day after second dose decedent had fever and tremors, subsided on day three (less than 72 hours) after dose with exterem wekness followed by death less than 72 hours after second dose		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
2-24-21 patient with development of cough, fatigue, increasing on chronic disability worsening debility and falls. scheduled for office visit 2-25.21 0900 call from spouse 0210 am patient was not breathing and lvad alarming low flow alarm on arrival of ems confirm asystolic not breathing and dead		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
92 yo female who received her first dose of Moderna vaccine on 1/11/2021 with no known adverse effects. Admitted to the hospital on 1/17/21 with a spine compression fracture. Discharged and readmitted on 1/19 /21 with nausea and vomiting. Found to have new atrial flutter and elevated troponin attributed to NSTEMI. Discharge on Aspirin and Plavix. No cath. Second dose of Moderna vaccine 2/25/21. No immediate reaction. One hour later began to feel progressively weak. EMS called shortly after getting home. Intubated in the field. Died at 0658 on 2/26/21 s/p PEA arrest without ROSC.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Beginning in the evening 2/19/21, fever/chills/fatigue; worsening of symptoms 2/20/21 with lethargy/lack of appetite/weakness; unable to arouse on 2/21/21 then breathing stopped, patient's spouse called 911 performed CPR, EMS continued for 15 min then while in ambulance to hospital where he was pronounced		No prior vaccinations for this event.

dead. Official time of death 2:20pm

ASTHENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.	No prior vaccinations for this event.
ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.	Influenza Virus Vaccines - Unknown date/type or brand
ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse	No prior vaccinations for this event.

oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021		
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Admitted 1/14/21: Patient is an elderly 93-year-old female with multiple medical problems including chronic combined CHF, P 80, diabetes mellitus, HTN, hyperlipidemia, CKD stage 3, has been complaining of generalized weakness, fatigue, decreased appetite for the past few days. She had an outpatient COVID-19 vaccine earlier today. Within 2 hr of admitting the patient to the hospital, condition clinically deteriorated. Patient elected to be DNR/DNI while in the ED. Patient was pronounced dead at 10:30 p.m. earlier today. Preliminary cause of death: Hypoglycemia induced lactic acidosis.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia		No prior vaccinations for this event.

likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient stated he wasn't feeling well on January 25, 2021, wasn't eating and complained of abdominal pain. Patient noted to have indigestion and was constipated. Meds provided and labs ordered. On morning of January 26, 2021, patient became weak, lethargic and hypoxic and was sent to emergency department around 0700 hours on January 26, 2021. At approximately 1100 hours, emergency physician notified this writer that patient was not going to overcome his illness and would be placed on comfort care. At approximately 1130 hours, this writer was notified that patient had passed away from multi-organ failure.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/9/21-Diaphoresis, O2 90%, respirations 22, increased weakness, wheezing bilaterally. Send to ER for evaluation and treatment. She was sent to ER, where she was admitted for 2 days, then expired there on 1/11/21		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Heart stopped; Could not swallow; This is a spontaneous report from a contactable nurse (patient's wife). An 85-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 21Jan2021 at a single dose for COVID-19		No prior vaccinations for this event.

immunization. Medical history included blood pressure abnormal (verbatim: blood pressure) from an unknown date and unknown if ongoing, neuropathy from an unknown date and unknown if ongoing, weight issue from an unknown date and unknown if ongoing, diabetes from an unknown date and unknown if ongoing, walker user from an unknown date and unknown if ongoing. Concomitant medications included insulin aspart (NOVOLOG) taken for diabetes from an unspecified date to an unspecified date; and he was taking a long acting one as well. The patient previously received the influenza vaccine (MANUFACTURER UNKNOWN) for immunization on unknown dates (""had flu shots before with no reactions and everything, nothing before""). On 24Jan2021, the patient's heart stopped (death, medically significant), and could not swallow (medically significant). The clinical course was reported as follows: The patient's wife stated the patient was taking insulin aspart (NOVOLOG) and he was taking a long acting one as well. The reporter, the patient's wife and a retired registered nurse (RN) stated, her husband (patient) just died and she thought he died from the COVID vaccine (later clarified the reason of death was-heart stopped). The patient had the vaccine on 21Jan2021, which was on a Thursday, and he was fine. On the following Sunday around 1:30 (on 24Jan2021), the patient was feeling a little weak, however, the patient's wife thought maybe his blood sugar was low. The patient's wife checked, and the patient's blood sugar was 91. The patient's wife went to get some yogurt to feed him in order to get his blood sugar up a little; ""which was a normal thing for him, it was not that low for him."" Then, suddenly, the patient fell, and the patient's wife could not get a pulse or anything. The patient's wife called an unspecified number and she started compressions; however, he was dead. The patient's wife stated the patient just had his heart test, a three hour long one, and it was ""perfect three weeks ago."" The patient had just gone to the doctor the other day and his blood pressure was ""fine and everything."" The patient's wife stated that other than his diabetes, ""which he had for (sentence incomplete)."" Regarding lab tests, the patient's wife stated, ""No, he had it before but not in the last two weeks. He was going for one because we just went to the doctor last week and he was going to call yesterday to make the appointment request to get his blood work done. Blood work has been good except his A1C was always high, but other than that everything was good"" (as reported). Regarding causality, the patient's wife stated, ""I do, because he was fine until about half an hour before he died. He said to me, I feel a little weak today and then I was talking to him that your upper body strength is really good and then I said, we just have to work on your weight a little more because he did have neuropathy. And then, I went

out of the room and all of a sudden I just heard him fall and that is when I just went in to check his blood sugar and it was 91 and I got him yogurt and he started eating that and then that was it, he started spitting it out and he said, I could not swallow and that was it, he just died."" The patient's wife further added, ""I just wanted other people to know that things like this happen and I am sure it was from that because he was healthy as could be. He was walking with his walker, the day before outside and he felt fine."" The clinical outcome of the event, heart stopped, was fatal. The clinical outcome of the event, could not swallow, was unknown. The patient died on 24Jan2021 due to ""heart stopped."" An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: Heart stopped"

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was hospitalized for confusion, and hypotension and increased weakness; resident proceeded to have a NSTEMI and died on 5th day in hospital on 1/31/2021.		No prior vaccinations for this event.

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient received vaccine on Jan 23, 2021. developed weakness on Jan 25, 2021. Sent to ED on Jan 27, 2021 with hypoxia requiring 6 L O2, low Bp, declining mental status. Per family request transitioned to hospice and passed away on Jan 30, 2021		No prior vaccinations for this event.

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
According to medical report, Pt presented to the ED on 1/14/21 w/ cc of SOB for 1 day. She received her		No prior vaccinations for

COVID-19 vaccine on 1/9/21. Pt stated that she developed a dry hacking cough 2 days prior to the vaccine on 1/7/21. Over the last few days prior to admission, she developed generalized weakness, SOB, loss of sense of taste and smell w/ associated decreased appetite and nausea ultimately SOB in the24 hours prior to admission. Final Diagnosis- acute hypoxic respiratory failure secondary to COVID-19 pneumonia. Pt died on 2/3/21. See Medical report for more information.		this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My father was in weak condition to begin with. He didn't get out of bed for the next few days after receiving the vaccine. The little amount that he ate was consumed in bed. He began aspirating his food which lead to pneumonia. He wasn't strong enough to fight off the pneumonia even with antibiotics. He died on 1/23/21. While he might have passed soon in any case, I believe that the vaccine may possibly have increased his weakness/exhaustion thereby hastening his demise.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21		No prior vaccinations for this event.

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom received the Covid 19 vaccine on Jan 5, 2021 and became very about a week later. I was informed that she tested positive for Covid 19 on January 14th. One January 17th she became very tired and weak and would not eat. Hospice called me and told me that she was in a decline state. I saw her on January 25 and 26 and she was just sleeping and could not open her eyes. Her vitals were good and she seemed to understand when I talked to her - she would squeeze my hand and moan but she could not talk or open her eyes. My mom passed away on January 27, 2021 just 22 days after receiving the Covid 19 vaccine. She was very think to begin with and being to weak and tired to eat resulted in her losing even more weight. Some of the other residents were given fluids to help and they recovered. My mom was not given fluids. I believe there were 20 deaths in her care home for the month of January when they vaccinated. This was an alarming number of deaths for the home. The facility had very few Covid deaths in 2019 and 2020. I asked every week if they had any Covid and or Covid deaths and this amount was shocking to me and the workers there.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was weak, fatigued and had a fever of 101. F the following morning after receiving the 2nd dose of vaccine. Later in the day she was feeling better and vital signs were WNL. The next morning, she was found unresponsive and pronounced dead by paramedics.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient got the injection and quickly developed a fever and felt weak. Family was contacted and he was sent to Hospital.	No prior vaccinations for this event.	
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver failure, pneumonia, and DIC>"	No prior vaccinations for this event.	
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids	No prior vaccinations for this event.	

were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

ASTHENIA	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information	No prior vaccinations for this event.

and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
24 hours after shot had high fever 101, chills, weakness, became listless, family called 911, client became unresponsive and died in the Emergency room.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer Covid Vaccine in the AM on 2/9/21. Arrived to emergency department later the same		No prior vaccinations for this

day complaining of nausea, weakness, fatigue, Vomiting, Diarrhea. Post operative diagnosis, Ischemic colon/toxic megacolon. event.

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/7/21 resident complainted of not feeling well, nausea, vomiting and weakness sent to ER passed away.	No prior vaccinations for this event.	

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The individual received the vaccine around 12:00pm on 02/11/21. Around 9pm the individual went to lay down on the couch at home and started to have difficulty breathing. Within 30 minutes the individual became week and unresponsive. She was transported to the hospital where she was pronounced deceased at 11:44 pm on 02/11/21.	No prior vaccinations for this event.	

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Adverse reaction to the vaccine started with variable weakness beginning 1/29/2021. On 1/30/21 around 8:30pm, he needed assistance in the bathroom related to weakness and had what was later identified as a stroke with left side weakness and slurred speech. In accordance with his wishes, he had care at home. Due to his advanced age and frailty, a CT scan was not pursued. The 325 mg of aspirin that he was previously taking daily was discontinued. After the stroke, he needed total care. Hospice was established at home. Nursing assistant care was delivered by daughter. Death followed 9 days later (2/9/2021).	No prior vaccinations for this event.	

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had no energy in the first 24 hours and then began a steady decline that started with vomiting after 48 hours, then an inability to swallow and ultimately the patients death on 2/5/21.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident had slight/slow decline in health prior to vaccine but continued to be able to walk around with walker at community. The day of the vaccine she had a fever. 2 days after vaccine resident did not get out of bed all day and refused to eat. She had small amounts of orange juice as her blood sugar level was low due to not eating. Resident was diagnosed with a UTI and began an oral antibiotic. 3 days after and on day 5 after vaccine resident began feeling weak and had a fall on each day. The following day again resident spent the day in bed. The next day she was quite restless, was on the edge of her bed attempting to self transfer often throughout the day. Resident continued to be restless on the 10th of Feb, had further decline on the 11th of Feb. Resident passed away early the AM of Feb. 12th.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"The day after the 2nd shot, patient developed blisters on his lips and mouth. The care facility said that he had a nut allergy -- but he had never been allergic to nuts. He stopped eating and drinking and his BP had dropped to 60/40. By Jan 16th they called to say he was dying and he passed away on 1/18/21. Patient had COVID19 from Oct 29th - early November. By Nov 21st he had lost 40 lbs. He was 6'3"" and had gone from 189lbs to 149 lbs with COVID. By Nov 21st when we could visit, he had recovered from COVID, but was very thin and weak. He could not bathroom alone and kept falling. He		Shingles - Glaxo 8/22/2020, resulted in hospitalization and LTC.

didn't seem to have a bad reaction to the 1st COVID shot, But he immediately reacted to the 2nd shot and passed away within 6 days."

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.		No prior vaccinations for this event.

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
(02/15/2021): vaccine (02/16/2021) : severe body aches and weakness, increased congestion and mucous production. (02/16-17/2021) : death possibly during the night		No prior vaccinations for this event.

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an		No prior vaccinations for this event.

unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in

the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second

COVID-19 Vaccine.; Reported Cause(s) of Death: Death

	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
02/07/21 through 2/13/21 slightly fatiqued, took all his prescribed medications, ate breakfast, lunch and dinner was drinking eight 10 oz bottles of water. On 02/14/21 was very tired had a difficult time breathing		No prior vaccinations for

after taking the normal meds. He took a breathing treatment with his prescribed Ipratropium Bromide and Albuterol Sulfate via home nebulizer. This did not improve his breathing. He was very weak and breathing was labored. 911 was called by wife. 911EMTchecked pulse and breathing. Informed him they would give him a breathing treatment.He started to go limp. EMT's got him to Ambulance and to Medical Center to the ER. Heroics done. He died. Pulmonary and Cardiac Arrest		this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient felt achy, tired starting the day after the vaccine. Per his wife, he was very tired and ""losing stamina"". On 2/13/21, he woke up feeling dizzy and weak. His wife asked him if he wanted to go to the doctor and he declined. He ate breakfast and went to rest in his easy chair. He passed away an hour later."		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.		No prior vaccinations for this event.
	ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)	No prior vaccinations for this event.
ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per Patients Wife - Same day - Flu like symptoms, Nausea, Headache. Restless that night. Next day - Weak, shortness of breath. Wife called squad to get him out of his wheelchair but patient refused hospital as it gets him agitated. Patient passed away around 11 AM the day after vaccination.	No prior vaccinations for this event.
ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1. Fatigue ? day 1 - Tuesday 2. Loss of appetite ? day 1 Tuesday 3. Fever 102.0 ? day 2 - Wednesday 4. Chills ? day 2 - - Wednesday 5. Weak ? day 2 - - Wednesday 6. Non-ambulatory (unusual) ? day 2 - - Wednesday 7. Two emergency service ambulance assessment ? day 2 - - Wednesday 8. Symptoms improved ? day 3 - Thursday 9. Ambulatory - day 3 - Thursday 10. Symptoms worsened ? day 4 - Friday 11. Chills ? day 4 - Friday 12. Non-ambulatory again ? day 4 - Friday 13. Fever 102.0 ? day 4 - Friday 14. Left side flank pain ? day 4 - Friday 15. CPR and declared decease at home by paramedics - day 5 - Saturday morning @ 1:32am	No prior vaccinations for this event.
ASTHENIA	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.

Influenza Vaccine

ASYMPTOMATIC COVID-19

COVID19 (COVID19 (MODERNA)) (1201)

mi Narrative: patient with asymptomatic covid 19, covid positive 12/10/2020. No prior vaccinations for this event.

ASYMPTOMATIC COVID-19 **COVID19 (COVID19 (MODERNA)) (1201)**

Resident is asymptomatic No prior vaccinations for this event.

ATELECTASIS **COVID19 (COVID19 (MODERNA)) (1201)**

Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of

No prior vaccinations for this event.

severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.

	ATELECTASIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29		No prior vaccinations for this event.

	ATELECTASIS	**COVID19 (COVID19 (MODERNA)) (1201)**
2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.		No prior vaccinations for this event.

	ATELECTASIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.		No prior vaccinations for this event.

	ATELECTASIS	**COVID19 (COVID19 (MODERNA)) (1201)**

Several days after vaccination his left arm turned red. He was taken to the hospital where he was evaluated and admitted with a diagnosis of left axillary vein thrombosis. A chest X-ray was taken and he presented bibasilar atelectasis and pneumonia with pleural effusions.

No prior vaccinations for this event.

ATELECTASIS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

emesis bright yellow in color, liquid BM, increased respirations No prior vaccinations for this event.

ATRIAL FIBRILLATION

COVID19 (COVID19 (MODERNA)) (1201)

Moderna Vaccine Lot 029K20A Patient received second dose of vaccine on 2/2/21. Within 30 minutes patient had a near syncopal episode. She felt lightheaded and shortly after had episode of nonbloody vomiting. Hypotensive 81/69 and started on levophed. Alert and orientated. Lungs clear, abdomen benign on admission. Patient had no reaction when received first dose of the vaccine. Patient developed worsening shortness of breath, tachypnea, Afib with RVR, hypotension and required intubation and multiple pressors.

No prior vaccinations for this event.

ATRIAL FIBRILLATION

COVID19 (COVID19 (MODERNA)) (1201)

Patient had Covid-19 in October of 2020. He recovered. He received the vaccination on 12/30/2020 with no complaints. On 01-05-2021 it was noted to he was incontinent of urine and bilateral lower extremity edema. Lab work was completed showed acute kidney injury. He had decreased blood pressure and oxygen saturations on 01-06-2021 He was admitted to the hospital with rapid progression of symptoms and suggested multi-system failure. He had a long cardiac history. On 01-14-2021 he passed away with a diagnosis of Cardiomyopathic CHF, A.Fib contributory.

No prior vaccinations for this event.

ATRIAL FIBRILLATION		**COVID19 (COVID19 (MODERNA)) (1201)**
covid shot 2/2; feel bad 2/5; covid positive diagnosis - 2/8 s/s cough, fever, shortness of breath , hypertension, afib (in er) - admitted went into DIC per intensivist 2/11 patient died		No prior vaccinations for this event.
ATRIAL FIBRILLATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient went into new-onset atrial fibrillation, resulting in a catastrophic stroke. Patient passed away on 2/11 as a result of the stroke.		No prior vaccinations for this event.
ATRIAL FIBRILLATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21		No prior vaccinations for this event.
ATRIAL FIBRILLATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized		No prior vaccinations for this event.

for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/

slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

ATRIAL FIBRILLATION

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"

No prior vaccinations for this event.

ATRIAL FIBRILLATION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

No prior vaccinations for this event.

ATRIAL FIBRILLATION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information	No prior vaccinations for this event.

and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

ATRIAL FIBRILLATION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received the vaccine at an outside healthcare facility on 2/11/21. At approximately 1 pm she screamed out and fell out of her chair. EMS was called and patient was found to be in Vfib. ACLS was performed for approximately 42 minutes prior to arrival at ED. At that time the patient had been pulseless for 25 minutes. Patient received 450 mg of amiodarone, epinephrine x7, sodium bicarbonate x2, and 7 AED shocks. In the ED 3 more doses of epinephrine were given, one more dose of sodium bicarbonate, and 5 additional shocks. ROSC was not achieved and time of death was called at 1416.

No prior vaccinations for this event.

ATRIAL FIBRILLATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Had a stroke 3 days after round one of Covid vaccine and subsequently died the next week due to complications of stroke. Upon admission to hospital, was in afib.	No prior vaccinations for this event.
ATRIAL FIBRILLATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	No prior vaccinations for this event.
ATRIAL FLUTTER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	No prior vaccinations for this event.
ATRIOVENTRICULAR BLOCK COMPLETE	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN	No prior vaccinations for this event.

of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.

ATROPHY	COVID19 (COVID19 (MODERNA)) (1201)
"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."	No prior vaccinations for this event.

ATYPICAL MYCOBACTERIAL INFECTION	COVID19 (COVID19 (MODERNA)) (1201)
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of	No prior vaccinations for

abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving. this event.

AUTOPSY **COVID19 (COVID19 (MODERNA)) (1201)**

syncopal episode - arrested - CPR - death No prior vaccinations for this event.

AUTOPSY **COVID19 (COVID19 (MODERNA)) (1201)**

Patient received COVID-19 (Moderna) vaccine from the Health Department on afternoon of January 8, 2021 and went to sleep approximately 2300 that night. Was found unresponsive in bed the following morning and pronounced dead at 1336 on January 9, 2021 No prior vaccinations for this event.

AUTOPSY **COVID19 (COVID19 (MODERNA)) (1201)**

Pt collapsed at home approx 5:30 pm and died No prior vaccinations for this event.

AUTOPSY **COVID19 (COVID19 (MODERNA)) (1201)**

Death Hypersensitivity/ anaphylaxis to standard flu vaccine (egg containing) ~ 20 years ago. Of note, did tolerate FluBlok this past

AUTOPSY **COVID19 (COVID19 (MODERNA)) (1201)**

"Pt. woke up the next morning after vaccination and ""didn't feel well"", described by wife as fatigue, no energy. At approximately 2 PM, he vomited. His wife checked on him at 4:20 PM and he wasn't breathing sitting in his chair. EMS squad was called but when they arrived he was asystole and mottling present. Did No prior vaccinations for this event.

not start CPR since he was already gone too long. Pronounced by coroner on scene."

	AUTOPSY	**COVID19 (COVID19 (MODERNA)) (1201)**
UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless and breathless and was pronounced. Autopsy currently pending.		No prior vaccinations for this event.

	AUTOPSY	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient went home around 11 am on 1-31-21 after her vaccine and 15 minute observation period. She was eating breakfast after at home and complained to a neighbor that her teeth hurt and she was nauseated after eating. In the afternoon, she felt dizzy and had diarrhea accompanied with blood. Close to 9 PM, her son went to check on her. The patient was found on the floor--she was unresponsive and had purple lips. Her son called an ambulance and started chest compressions. The patient passed away at the hospital. The doctor has ordered an autopsy, and the results are pending.		No prior vaccinations for this event.

	AUTOPSY	**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away yesterday, found deceased in her apartment; This spontaneous report was received from a consumer which refers to a 91-year-old female patient who received the Moderna COVID-19 vaccine (mRNA-		No prior vaccinations

1273) and next day the patient passed away. The patient's medical history was not provided. Concomitant medications were not reported. On 19 Jan 2021, the patient received her first of two planned doses of mRNA-1273 intramuscularly (Lot number: not provided) for prophylaxis of COVID-19 infection. On 20 Jan 2021, the patient passed away and she was found deceased in her apartment. No treatment medication was provided. Action taken with mRNA-1273 in response to the events was not applicable as the patient passed away. On 20 Jan 2021, the patient died, cause of death was unknown. Autopsy result was unknown. The reporter assessed the causality as related between the event and Moderna COVID-19 vaccine.; Reporter's Comments: This case concerns a 91-year old female patient. The medical history and concomitant medication is not provided. The patient experienced Death. The event occurred approximately one day after receiving their first of two planned doses of mRNA-1273 (Lot unknown). Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the onset of the event, a causal relationship cannot be excluded and the event is considered possibly related to the vaccine.; Reported Cause(s) of Death: Unknown Cause of Death	for this event.
AUTOPSY	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene when EMS arrived. Autopsy showed a left temporal subdural hematoma.	No prior vaccinations for this event.
AUTOPSY	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient's son came to the vaccine clinic today 2/8/2021, stated that his father 2/24/1948 passed away the same day as the vaccine.	No prior vaccinations for this event.

AUTOPSY

COVID19 (COVID19 (MODERNA)) (1201)

No reported adverse reactions from 1st or 2nd vaccine doses Patient died on 2/6/2021 at Correctional facility- autopsy was performed at medical examiner's office. The COD was artherosclerotic cardiovascular disease

No prior vaccinations for this event.

AUTOPSY

COVID19 (COVID19 (MODERNA)) (1201)

Patient felt fine on Friday afternoon and evening after shot. Felt fine on Saturday until the afternoon when she started feeling fatigued and chilled. Decided to take a warm bath at about 6pm. Was found dead in bathtub at approximately 7pm with blisters on arms, legs, and face.

No prior vaccinations for this event.

AUTOPSY

COVID19 (COVID19 (MODERNA)) (1201)

Hepatorenal syndrome- Death No prior vaccinations for this event.

AUTOPSY **COVID19 (COVID19 (MODERNA)) (1201)**

"Agency contacted 2/19 In evening by employer representative- client Died Suddenly after work"""

No prior vaccinations for this event.

AUTOPSY

COVID19 (COVID19 (MODERNA)) (1201)

"""Feeling Hot"" without fever and nausea 10 hours post vaccine and resolved within 1 hour. Seizure, Hypotension, Unresponsive followed shortly by cardiac arrest and pulseless electrical activity 21 hours post

No prior vaccinations for

vaccine. Pronounced dead 22 hours post vaccine"		this event.
	AUTOPSY	**COVID19 (COVID19 (MODERNA)) (1201)**
Spontaneous intracerebral hemorrhage and death on 2/20/2021 No prior vaccinations for this event.		
	AUTOPSY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
LTCF Pfizer Vaccine clinic conducted 12/29/2020 Vaccine lead received a call indicating that a staff member deceased somewhere between 1/3/2021 and 1/4/2021. Cause of death is unknown, and an autopsy is being performed.		No prior vaccinations for this event.
	AUTOPSY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Cardiac Arrest; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; This is a spontaneous report from a contactable other healthcare professional (HCP). A 66-year-old female patient (pregnant at the time of vaccination: no) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284) via intramuscular at left arm on 11Jan2021 12:15 PM at single dose for COVID-19 immunization. Medical history included diastolic CHF, spinal stenosis, morbid obesity, epilepsy, pulmonary hypertension and COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19). The patient received medication within 2 weeks of vaccination included amiodarone, melatonin, venlafaxine hydrochloride (EFFEXOR), ibuprofen, aripiprazole (ABILIFY), lisinopril, cranberry capsules, diltiazem, paracetamol (TYLENOL), famotidine, furosemide (LASIX [FUROSEMIDE]), ipratropium bromide, salbutamol sulfate (IPRATROPIUM/ALBUTEROL), buspirone, senna alexandrina leaf (SENNA [SENNA ALEXANDRINA LEAF]), polyethylene glycol 3350 and morphine. The patient did not receive any		No prior vaccinations for this event.

other vaccines within 4 weeks prior to the COVID vaccine. Patient used took Penicillin, propranolol, quetiapine, topiramate, Lamictal and had allergy to them. Patient used took the first dose of BNT162B2 (lot number: EJ1685) via intramuscular at right arm on 21Dec2020 12:00 PM at single dose for COVID-19 immunization. Since the vaccination, the patient been tested for COVID-19 (Sars-cov-2 PCR) via nasal swab on 06Jan2021, covid test result was negative. Patient was found pulseless and breathless 20 minutes following the vaccine administration (11Jan2021 12:30 AM). MD found no signs of anaphylaxis. Patient died on 11Jan2021 12:30 AM because of cardiac arrest. No treatment received for the events. Outcome of pulseless and breathless was unknown. the autopsy was performed, and autopsy remarks was unknown. Autopsy-determined cause of death was unknown. It was reported as non-serious, not results in death, Life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.; Sender's Comments: Based on the available information this patient had multiple underlying medical conditions including morbid obesity, diastolic CHF, epilepsy, pulmonary hypertension and COVID-19 diagnosed prior to vaccination. All these conditions more likely contributed to patients cardiac arrest resulting in death. However, based on a close temporal association (""Patient was found pulseless and breathless 20 minutes following the second dose of BNT162B2 vaccine administration, contributory role of BNT162B2 vaccine to the onset of reported events cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Cardiac arrest; Autopsy-determined Cause(s) of Death: autopsy remarks was unknown. Autopsy-determined cause of death was unknown"

AUTOPSY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Sudden death 18 hours post vaccine . No prior vaccinations for this event.

AUTOPSY **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient became sick 3 hours after the vaccine and was found deceased 1 day after his vaccination. He passed away in his sleep.

No prior vaccinations for this event.

AUTOPSY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have

No prior vaccinations for this event.

decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

AUTOPSY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

death Narrative: Pt attended arthritis clinic appt 0900; labs shortly after; rec'd vaccine in clinic ~ 1113; seen on surveillance camera walking to parking garage ~ 1145; medical center rec'd call from wife ~ 1900 that pt never returned home; police found vehicle running in parking garage, code called, pt obviously deceased by that time 1930, body sent to medical examiner for autopsy.

No prior vaccinations for this event.

AUTOPSY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Sudden cardiac death. Autopsy report: right coronary artery thrombosis. No prior vaccinations for this event.

AUTOPSY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient stated he had a migraine after the vaccine. We were advised of a change in appetite on Thursday February 4th. Patient died on February 6th.

No prior vaccinations for this event.

AUTOPSY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"Patient and her husband are elderly, but healthy and live independently. Patient took blood pressure medicine 'off and on' according to family. She was 5'2"", 120 pounds and slim and healthy and active, so was her husband, though he had pulmonary fibrosis so they had been staying home and not attending

No prior vaccinations for this event.

church etc, and masking when they did go out to protect against covid disease. They were both vaccinated with covid Pfizer vaccine (dose #1) on Thursday Feb 11. (02/11/2021) Thursday night as they went to bed they checked in with each other on how they each felt. Patient said she felt totally fine, and her husband said his arm was a bit sore. Patient woke before her husband on Friday Feb 12, went downstairs and, from what the family can tell, fixed herself a snack, then sat on the sofa. Patient's husband found her deceased on the sofa. He called 911 and they asked him to do CPR until the paramedics arrived. Because of proximity to covid vaccine, the ME wanted to examine the body in the home and also ordered an autopsy. Autopsy was completed on the same day as death, Feb 12, 2021"

AUTOPSY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death on February 12, 2021 acute cardiac tamponade No prior vaccinations for this event.

AUTOPSY

COVID19 (COVID19 (UNKNOWN)) (1202)

Patient died several days after receiving the second dose of the vaccine. See additional information sent. An autopsy has been performed and results are pending.

No prior vaccinations for this event.

AXILLARY PAIN

COVID19 (COVID19 (MODERNA)) (1201)

Cardiac arrest; Pain on her upper right chest; Lot of pain in lower abdomen; Pain underneath arm; Thought it was muscle aches; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed upper right chest pain and underneath the arm, severe abdominal pain, muscle aches and cardiac arrest. The patient's medical history was not provided Concomitant product use was not provided by the reporter. On 14 Jan 2021, approximately five days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273

No prior vaccinations for this event.

intramuscularly in the arm for prophylaxis of COVID-19 infection. On 19 Jan 2021, the patient developed upper right chest pain and pain underneath the arm. They thought it was muscle aches. Sometime later, the patient developed a lot of pain in the lower abdomen. The called emergency services and an ambulance arrived but the patient then suffered cardiac arrest. Treatment for the event included tramadol. Action taken with mRNA-1273 in response to the events was not applicable due to the patient was died. The patient died on 19 Jan 2021. The cause of death was reported as cardiac arrest. Autopsy were not provided.; Reporter's Comments: Company Comment: This case concerns a 92-year-old female patient who experienced unexpected serious events of cardiac arrest, upper right chest pain and underneath the arm, severe abdominal pain, muscle aches. The event occurred 5 days after the administration of the first dose of the vaccine mRNA-1273 vaccine (Lot #: unknown, expiration date-unknown). Although a temporal association exist between the events and the administration of the vaccine, in the absence of critical details such as the patient's medical history, any diagnostic test or autopsy result, adequate evaluation and assessment cannot be established. Main field defaults to æpossibly related' for all events.; Reported Cause(s) of Death: Cardiac arrest

AXILLARY PAIN

COVID19 (COVID19 (MODERNA)) (1201)

Pt received the vaccine on 1/30/21 Pt reported symptoms of left armpit pain to wife on 2/7/21, went to work 4 am 2/8/21 and found face down, dead at work later that morning. Pt worked at a pet store, per wife he did complete his tasks and generally comes home by 7:30 am. Wife called when pt did not come back home and he was found dead.

No prior vaccinations for this event.

AXILLARY VEIN THROMBOSIS

COVID19 (COVID19 (MODERNA)) (1201)

Several days after vaccination his left arm turned red. He was taken to the hospital where he was evaluated and admitted with a diagnosis of left axillary vein thrombosis. A chest X-ray was taken and he

No prior vaccinations for this event.

presented bibasilar atelectasis and pneumonia with pleural effusions.

AXONAL AND DEMYELINATING POLYNEUROPATHY		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.	Influenza Vaccine	

AZOTAEMIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21	No prior vaccinations for this event.	

AZOTAEMIA		**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
On 2/5/2021 resident noted to be azotemic. Creatinine up to 3.8 and BUN in 80's. He was started on NS hydration. On 2/7/2021 he was noted without VS, per MD notes, possible VF arrest, renal failure; death unclear exact cause.	No prior vaccinations for this event.
BACK PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
"1-2-2021 10:30 PM Complained Right arm/back hurt - took Tylenol 1-3-2021 Complained Right arm hurt, dizzy 1-4-2021 Felt better - did laundry, daughter found her deceased at 3:30 pm. Dr. at hospital said it was ""cardiac event"" according to death certificate."	No prior vaccinations for this event.
BACK PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to our Emergency Department via EMS in full code status; asystole. Patient expired. Per nursing, husband stated patient awoke this AM and reported pain in back between shoulders and in bilateral shoulders. Patient then went unresponsive and husband called EMS.	No prior vaccinations for this event.
BACK PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain	No prior vaccinations for this event.

bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.

BACK PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**

Low Grade Temp, Persistent low back pain, Projectile Vomiting. No prior vaccinations for this event.

BACK PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
EARLY SUNDAY MORNING THE PATIENT BEGAN VOMITTING AND SHORT OF BREATH AND CHEST AND BACK PAIN. SHE CODED WHEN SHE GOT IN THE ER AND LATER PASSED AWAY THE MONDAY. DIAGNOSIS WAS PNEUMONIA AND HEART FAILURE PER STEP DAUGHTER.	No prior vaccinations for this event.

BACK PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient became nauseated about 10 minutes after vaccine administered, this subsided but returned several hours after the vaccine was given. She continued with intractable nausea and vomiting for about 24 hours. This patient was enrolled in hospice and she continued to decline and refused to eat or drink. She was taking Ibuprofen due to intractable back pain. Her emesis was coffee ground color. After this her condition continued to decline until her death	No prior vaccinations for this event.

BACK PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was	No prior vaccinations for this event.

holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

BACK PAIN **COVID19 (COVID19 (MODERNA)) (1201)**

2/12/2021 woke up with sore arm and back. 2/13/2021 woke up with headache around 1am. Headache and nausea all morning. Mid-late afternoon started having seizures. Admitted to Hospital 2/15/2021 expired. Reported per wife on 2/25/2021.

No prior vaccinations for this event.

BACK PAIN **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

muscle aches-increased pain to lower back No prior vaccinations for this event.

BACK PAIN **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1-12-21 Resident is complaining of heart pain. Resident blood pressure is 228/105. 1-22-21 Dx UTI 1-13-21 His nurse called MD at approximately 0645, reported to him that it was reported to this nurse that resident has not slept in 2 days and night, has an increased blood pressure, reports severe pain in lower back, and appears to be uncomfortable Resident is able to verbalize his pain and where it is at, but is unable to explain the quality of the pain or give a number on the 0/10 pain scale.

No prior vaccinations for this event.

BACK PAIN **COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Same day as vaccination given, developed pain went from arm up to shoulder, to back, to neck to head - right side of body; chills/body aches

No prior vaccinations for this event.

BACK PAIN

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt received dose #1 of COVID-19 vaccine (Pfizer-BioNTech) on 12/18/20 and dose #2 (Pfizer-BioNTech) on 1/8/21. On 1/30, patient was evaluated at urgent care due to back pain. No bloodwork done; metronidazole prescribed for 7 days. On 2/8, patient was admitted to outside hospital due to ongoing symptom progression. At time of admission, hgb 5 g/dL and plt 9k. Per Dr. (hematology/oncology), pt with schistocytes, LDH 1500, and elevated reticulocyte count consistent with thrombotic thrombocytopenic purpura (TTP). SCr >2 mg/dL. Patient immediately treated with plasma exchange and steroids, however continued to decline. Patient expired on 2/14/21.

No prior vaccinations for this event.

BACK PAIN

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident complained about back pain in the middle of the night and when they went to do a blood pressure examination, she passed away at 2:40 am.

No prior vaccinations for this event.

BACTERAEMIA

COVID19 (COVID19 (MODERNA)) (1201)

Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran

No prior vaccinations for this event.

negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.		
	BACTERAEMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver failure, pneumonia, and DIC>"		No prior vaccinations for this event.
	BACTERIAL TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd		No prior vaccinations for this event.

admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."

BACTERIAL TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing

No prior vaccinations for this event.

CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

BACTERIAL TEST POSITIVE

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.

No prior vaccinations for this event.

BACTERIAL TEST POSITIVE

COVID19 (COVID19 (MODERNA)) (1201)

"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."

No prior vaccinations for this event.

BACTERIAL TEST POSITIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT

No prior vaccinations for this event.

cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21

BACTERIAL TEST POSITIVE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested	No prior vaccinations for this event.

DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

BACTERIAL TEST POSITIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation

No prior vaccinations for this event.

and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BALANCE DISORDER

COVID19 (COVID19 (MODERNA)) (1201)

on 1/13/2021 at 3:40am Cliff called for assistance. He lost his balance and had fallen. Cliff refused vitals, refused emergency department, denied hitting his head. As the day progressed patient developed a headache, diarrhea, and vomiting. He again declined the offer for the emergency room. At supper time wife and staff found Cliff unresponsive, 911 was called and he was taken to the emergency department. The ER did a CT scan and found an acute subdural hematoma. Patient was placed on comfort cares and expired at 3pm on 01/14/2021. Cliff did not have a history of falls.

Influenza vaccine 10/06/2020, age 88, fever, chills, vomiting, malaise

BAND NEUTROPHIL PERCENTAGE

COVID19 (COVID19

	(PFIZER-BIONTECH)) (1200)
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
BAND NEUTROPHIL PERCENTAGE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
BANDAEMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine	No prior vaccinations for this event.

w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. ""

1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

BASAL GANGLIA STROKE

COVID19 (COVID19 (MODERNA)) (1201)

Hemorrhagic Stroke, Right Basal Ganglion No prior vaccinations for this event.

BASE EXCESS **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status:

No prior vaccinations for this event.

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BASOPHIL COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
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BASOPHIL COUNT INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs	No prior vaccinations for this event.

(see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a

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BASOPHIL COUNT NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
BASOPHIL COUNT NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	No prior vaccinations for this event.
BASOPHIL COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

No prior vaccinations for this event.

BASOPHIL PERCENTAGE

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BASOPHIL PERCENTAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
BASOPHIL PERCENTAGE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff,	No prior vaccinations for this event.

gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

BEDRIDDEN		**COVID19 (COVID19 (MODERNA)) (1201)**
Got vaccine on 1/15/21. He was tired right away, bedridden the next 3 days. He couldn't breathe so he was taken by ambulance on 1/18/21. He was in hospital for several days. put on remdesivir cocktail for 10 days. Slowly getting worse and died in hospital on 1/30/21.		No prior vaccinations for this event.
BEDRIDDEN		**COVID19 (COVID19 (MODERNA)) (1201)**
He developed a fever on 1/8, become unable to swallow and bedbound. He was already end of life and Hospice care at the time of the vaccine.		No prior vaccinations for this event.
BILEVEL POSITIVE AIRWAY PRESSURE		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER		No prior vaccinations

2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from for this event. ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

BILEVEL POSITIVE AIRWAY PRESSURE

COVID19 (COVID19 (MODERNA)) (1201)

Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse

No prior vaccinations for this event.

30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127

BILEVEL POSITIVE AIRWAY PRESSURE

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the

No prior vaccinations for this event.

decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

	BILEVEL POSITIVE AIRWAY PRESSURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away		No prior vaccinations for this event.
	BILEVEL POSITIVE AIRWAY PRESSURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21		No prior vaccinations for this event.
	BILEVEL POSITIVE AIRWAY PRESSURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even		No prior vaccinations for

on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (	this event.
BILEVEL POSITIVE AIRWAY PRESSURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was vaccinated on 12/31/20. Then on 1/14/21 he tested positive for SARS-CoV-2 on routine surveillance PCR testing. Another resident on the same hall was COVID positive on 1/11/21. Results of the PCR test were obtained on 1/16/21. He appeared asymptomatic at that time. Given his COVID positive status, all aerosol generating procedures had to be stopped. Overnight on 1/16/21 into 1/17/21, he had the onset of acute respiratory failure and was transported to the hospital. Per notes, he was put on BiPAP for several hours, but his CO2 level did not improve. Per prior advance directives completed with the resident and his two brothers, he had DNR/DNI orders. The hospital physician spoke with his brother and the decision was made to move to comfort care. He was discharged to inpatient hospice and died around 4pm on 1/18/21. This outcome does not appear to be vaccine-related, but death from COVID-19 infection is listed as a reportable event following COVID-19 vaccination.	No prior vaccinations for this event.
BILEVEL POSITIVE AIRWAY PRESSURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.	No prior vaccinations for this event.	
BILEVEL POSITIVE AIRWAY PRESSURE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.	No prior vaccinations for this event.	
BILIRUBIN CONJUGATED		**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.	
BILIRUBIN CONJUGATED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia	No prior vaccinations for this event.	

(80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

BILIRUBIN CONJUGATED INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell

No prior vaccinations for this event.

count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

BILIRUBIN CONJUGATED INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"

No prior vaccinations for this event.

BILIRUBIN URINE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her

No prior vaccinations for this event.

stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

BILIRUBIN URINE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was	No prior vaccinations for this event.

added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BIOPSY BONE MARROW

COVID19 (COVID19

	(MODERNA)) (1201)
High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death	No prior vaccinations for this event.

BIOPSY SKIN ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Presented from clinic with 3-4 days of extensive rash. There were multiple areas of skin sloughing on bilateral upper extremities and abdominal wall.	No prior vaccinations for this event.

BLADDER CANCER STAGE IV

Patient died at home in hospice care from complications of stage 4 bladder cancer

COVID19 (COVID19 (MODERNA)) (1201)

No prior vaccinations for this event.

BLADDER CATHETERISATION

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this,

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

No prior vaccinations for this event.

her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

BLISTER	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient felt fine on Friday afternoon and evening after shot. Felt fine on Saturday until the afternoon when she started feeling fatigued and chilled. Decided to take a warm bath at about 6pm. Was found dead in bathtub at approximately 7pm with blisters on arms, legs, and face.	No prior vaccinations for this event.
BLISTER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient (now deceased) received 1st dose of Pfizer-BioNTech vaccine around December 21, 2020 and was noticed to be scratching, fatigued, and unresponsive by a family member on December 24, 2020. He received the second dose of the same vaccine around January 22, 2021. Pockmarks and bleeding scratch marks were noted by a family member on the patient's face prior to this second dose. On January 28, 2021 a family member was alerted that the patient was suffering from severe bullous pemphigoid- a skin condition that has never been experienced by the patient, has been reported to be related to COVID-19 viral infection, and to T-cell responses promoted by vaccines. A corticosteroid was given, but did not work. Blisters developed to the point hands had to be dressed.	No prior vaccinations for this event.

BLISTER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Presented from clinic with 3-4 days of extensive rash. There were multiple areas of skin sloughing on bilateral upper extremities and abdominal wall.	No prior vaccinations for this event.
BLOOD ALBUMIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.
BLOOD ALBUMIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was	No prior vaccinations for this event.

completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

BLOOD ALBUMIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.

BLOOD ALBUMIN DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.	No prior vaccinations for this event.

BLOOD ALBUMIN DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.

No prior vaccinations for this event.

BLOOD ALBUMIN DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.

No prior vaccinations for this event.

BLOOD ALBUMIN DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed

No prior vaccinations for this event.

respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

	BLOOD ALBUMIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.		No prior vaccinations for this event.
	BLOOD ALBUMIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.		
	BLOOD ALBUMIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities,		No prior vaccinations for

c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper this event.

lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD ALBUMIN DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death on 1/31/2021 multiple comorbidities No prior vaccinations for this event.

BLOOD ALBUMIN DECREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.

No prior vaccinations for this event.

BLOOD ALBUMIN DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at

No prior vaccinations for this event.

5:54AM

BLOOD ALBUMIN DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

No prior vaccinations for this event.

BLOOD ALBUMIN NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
BLOOD ALBUMIN NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
BLOOD ALKALINE PHOSPHATASE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
BLOOD ALKALINE PHOSPHATASE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at	No prior vaccinations

home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.	for this event.	
BLOOD ALKALINE PHOSPHATASE INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.	No prior vaccinations for this event.	
BLOOD ALKALINE PHOSPHATASE INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.	No prior vaccinations for this event.	
BLOOD ALKALINE PHOSPHATASE INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.	
BLOOD ALKALINE PHOSPHATASE INCREASED		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

No prior vaccinations for this event.

BLOOD ALKALINE PHOSPHATASE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was

No prior vaccinations for this event.

made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

BLOOD ALKALINE PHOSPHATASE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency

No prior vaccinations for this event.

department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD ALKALINE PHOSPHATASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.	No prior vaccinations for this event.
BLOOD ALKALINE PHOSPHATASE INCREASED	**COVID19 (COVID19 (PFIZER-**

BIONTECH)) (1200)

Death on 1/31/2021 multiple comorbidities No prior vaccinations for this event.

BLOOD ALKALINE PHOSPHATASE INCREASED COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.

No prior vaccinations for this event.

BLOOD ALKALINE PHOSPHATASE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM

No prior vaccinations for this event.

BLOOD ALKALINE PHOSPHATASE NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

BLOOD ALKALINE PHOSPHATASE NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was

No prior vaccinations for

unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

this event.

BLOOD ALKALINE PHOSPHATASE NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"

No prior vaccinations for this event.

BLOOD BETA-D-GLUCAN POSITIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac

No prior vaccinations for this event.

artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5%

bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

BLOOD BICARBONATE DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by

No prior vaccinations

ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		for this event.
BLOOD BICARBONATE DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.		No prior vaccinations for this event.
BLOOD BICARBONATE DECREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was		No prior vaccinations for this event.

thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

BLOOD BICARBONATE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

BLOOD BICARBONATE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up.

No prior vaccinations for this event.

CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD BILIRUBIN

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.
BLOOD BILIRUBIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"	No prior vaccinations for this event.

BLOOD BILIRUBIN	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.

BLOOD BILIRUBIN INCREASED	COVID19 (COVID19 (MODERNA)) (1201)
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR	No prior vaccinations for this event.

resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

BLOOD BILIRUBIN INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

No prior vaccinations for this event.

BLOOD BILIRUBIN INCREASED

COVID19 (COVID19

	(PFIZER-BIONTECH)) (1200)
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21	No prior vaccinations for this event.
BLOOD BILIRUBIN INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"	No prior vaccinations for this event.
BLOOD BILIRUBIN INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.	No prior vaccinations for this event.

BLOOD BILIRUBIN INCREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM		No prior vaccinations for this event.
BLOOD BILIRUBIN NORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.		No prior vaccinations for this event.
BLOOD BILIRUBIN NORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.
BLOOD BILIRUBIN NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by		No prior vaccinations for

EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	this event.
BLOOD BILIRUBIN NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	No prior vaccinations for this event.
BLOOD BILIRUBIN NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central	No prior vaccinations for this event.

line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral

central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

	BLOOD CALCIUM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
	BLOOD CALCIUM DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.		No prior vaccinations for this event.
	BLOOD CALCIUM DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021

No prior vaccinations for this event.

BLOOD CALCIUM DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status:

No prior vaccinations for this event.

SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD CALCIUM DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome

No prior vaccinations for this event.

presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he

started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

BLOOD CALCIUM INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

No prior vaccinations for this event.

BLOOD CALCIUM NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.	No prior vaccinations for this event.
BLOOD CALCIUM NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
BLOOD CALCIUM NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
BLOOD CALCIUM NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90%	No prior vaccinations for this

O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.		event.
	BLOOD CALCIUM NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.		No prior vaccinations for this event.
	BLOOD CHLORIDE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
	BLOOD CHLORIDE DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.		No prior vaccinations for this event.
	BLOOD CHLORIDE DECREASED	**COVID19 (COVID19**

	(MODERNA)) (1201)
Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.	No prior vaccinations for this event.
BLOOD CHLORIDE DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.	No prior vaccinations for this event.
BLOOD CHLORIDE DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).	No prior vaccinations for this event.
BLOOD CHLORIDE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in	No prior vaccinations for

refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.		this event.
	BLOOD CHLORIDE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.		No prior vaccinations for this event.
	BLOOD CHLORIDE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-		No prior vaccinations for this event.

ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2

through

	BLOOD CHLORIDE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.		No prior vaccinations for this event.
	BLOOD CHLORIDE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.
	BLOOD CHLORIDE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.		No prior vaccinations for this event.
	BLOOD CHLORIDE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute		No prior vaccinations for this

MD visit-basilar crackles right and coughing. Increased confusion.

event.

BLOOD CHLORIDE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death within thirty days of vaccine. Multiple co-morbidities and placed on hospice 12/28/20.

No prior vaccinations for this event.

BLOOD CHLORIDE NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

BLOOD CHLORIDE NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push

No prior vaccinations for this event.

1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

BLOOD CHLORIDE NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	No prior vaccinations for this event.
BLOOD CHLORIDE NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have	No prior vaccinations for this event.

intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

BLOOD CHOLESTEROL INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
While at counseling appointment on February 17 patient had witnessed sudden cardiac arrest and was not able to be resuscitated. She was pronounced dead at 12:09. At the time of death her glucose was about 500.		No prior vaccinations for this event.
BLOOD CREATINE		**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration		No prior vaccinations for this event.
BLOOD CREATINE ABNORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"		No prior vaccinations for this event.
BLOOD CREATINE PHOSPHOKINASE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.	No prior vaccinations for this event.
BLOOD CREATINE PHOSPHOKINASE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration	No prior vaccinations for this event.
BLOOD CREATINE PHOSPHOKINASE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check.	No prior vaccinations for this event.

No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

BLOOD CREATINE PHOSPHOKINASE MB

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

No prior vaccinations for this event.

BLOOD CREATINE PHOSPHOKINASE MB

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.

No prior vaccinations for this event.

BLOOD CREATINE PHOSPHOKINASE MB DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

No prior vaccinations for this event.

BLOOD CREATINE PHOSPHOKINASE MB DECREASED

COVID19 (COVID19

(PFIZER-BIONTECH))
(1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200

No prior vaccinations for this event.

IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD CREATINE PHOSPHOKINASE NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and

No prior vaccinations for this event.

pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib

fractures on the right at ribs 2 through

BLOOD CREATININE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
BLOOD CREATININE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff.	No prior vaccinations for this event.

Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics

BLOOD CREATININE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.

No prior vaccinations for this event.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.

No prior vaccinations for this event.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out

No prior vaccinations for this event.

bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.

BLOOD CREATININE INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.
BLOOD CREATININE INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face, increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative		No prior vaccinations for this event.

influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

BLOOD CREATININE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.

No prior vaccinations for this event.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29

No prior vaccinations for this event.

BLOOD CREATININE INCREASED

COVID19 (COVID19

	(MODERNA)) (1201)
Pt presents to ER with increased weakness, hypoxia, history of COPD, but not oxygen dependent., hypotension. Acute Kidney failure noted in labs, not previously diagnosed , new hyperkalemia. BP 73/39, HR 67. dopamine initiated, and switched to Levophed. Oxygen Sat 86%, requiring 10 L O2. Transferred from this critical access hospital to another Hospital. Expires later 2-13-2021	No prior vaccinations for this event.
BLOOD CREATININE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
BLOOD CREATININE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.	No prior vaccinations for this event.
BLOOD CREATININE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower.	No prior vaccinations

caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.	for this event.
BLOOD CREATININE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she	No prior vaccinations for this event.

developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

No prior vaccinations for this event.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC

No prior vaccinations for this event.

FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have

No prior vaccinations for this event.

decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

BLOOD CREATININE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	No prior vaccinations for this event.
BLOOD CREATININE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an	No prior vaccinations for this event.

actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21

BLOOD CREATININE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"	No prior vaccinations for this event.
BLOOD CREATININE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/5/2021 resident noted to be azotemic. Creatinine up to 3.8 and BUN in 80's. He was started on NS hydration. On 2/7/2021 he was noted without VS, per MD notes, possible VF arrest, renal failure; death unclear exact cause.	No prior vaccinations for this event.
BLOOD CREATININE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.	
BLOOD CREATININE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019).	No prior vaccinations for this event.

Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

BLOOD CREATININE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
BLOOD CREATININE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal	No prior vaccinations for this event.

labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent

aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD CREATININE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145.

No prior vaccinations for this event.

At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

BLOOD CREATININE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Pt received dose #1 of COVID-19 vaccine (Pfizer-BioNTech) on 12/18/20 and dose #2 (Pfizer-BioNTech) on 1/8/21. On 1/30, patient was evaluated at urgent care due to back pain. No bloodwork done; metronidazole prescribed for 7 days. On 2/8, patient was admitted to outside hospital due to ongoing symptom progression. At time of admission, hgb 5 g/dL and plt 9k. Per Dr. (hematology/oncology), pt with schistocytes, LDH 1500, and elevated reticulocyte count consistent with thrombotic thrombocytopenic purpura (TTP). SCr >2 mg/dL. Patient immediately treated with plasma exchange and steroids, however continued to decline. Patient expired on 2/14/21.

No prior vaccinations for this event.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.

No prior vaccinations for this event.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death on 1/31/2021 multiple comorbidities No prior vaccinations for this event.

BLOOD CREATININE INCREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and

No prior vaccinations for this event.

creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.

No prior vaccinations for this event.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death on same day as vaccination

No prior vaccinations for this event.

BLOOD CREATININE INCREASED COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death within thirty days of vaccine. Multiple co-morbidities and placed on hospice 12/28/20.	No prior vaccinations for this event.

BLOOD CREATININE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.

BLOOD CREATININE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.	No prior vaccinations for this event.

BLOOD CREATININE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Cardiogenic shock occurred on 2/10/2021, approximately 12 hours after patient received her 12th dose of pemetrexed/pembrolizumab and 4 days after COVID vaccine. Coronary angiography was done on 2/10/2021 and no significant coronary narrowing or blockage were noted. Baseline troponin on 2/10/21 was 0.02 and later on 2/10/21, troponins were 9.99 & 25.27. Creatinine increase from 1.2 to 3.4 within 24hours, and AST/ALT increased from 23 & 31 to 4,220 & 4,786 respectively on 2/11. Patient expired on 02/11/2021.

No prior vaccinations for this event.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient

No prior vaccinations for this event.

was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

BLOOD CREATININE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Three days after second COVID-19 vaccine, patient became lethargic. Due to advance directive that instructed that no life saving interventions to take place, patient continued to decline and expired on 29 January 2021.

No prior vaccinations for this event.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)

No prior vaccinations for this event.

BLOOD CREATININE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
BLOOD CREATININE NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
While at counseling appointment on February 17 patient had witnessed sudden cardiac arrest and was not able to be resuscitated. She was pronounced dead at 12:09. At the time of death her glucose was about 500.	No prior vaccinations for this event.
BLOOD CREATININE NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
BLOOD CREATININE NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	No prior vaccinations for this event.
BLOOD CREATININE NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.

No prior vaccinations for this event.

BLOOD CREATININE NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

No prior vaccinations for this event.

BLOOD CULTURE

COVID19 (COVID19 (MODERNA)) (1201)

2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.

No prior vaccinations for this event.

BLOOD CULTURE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Fever, Malaise

No prior vaccinations for this event.

BLOOD CULTURE COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no

No prior vaccinations for this event.

peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

BLOOD CULTURE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.		No prior vaccinations for this event.
BLOOD CULTURE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice, memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown		No prior vaccinations for this event.

date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200 mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation: tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed, metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required

intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral patchy opacities

BLOOD CULTURE NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29

No prior vaccinations for this event.

BLOOD CULTURE NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse	No prior vaccinations for this event.
BLOOD CULTURE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.	No prior vaccinations for this event.
BLOOD CULTURE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	No prior vaccinations for this event.
BLOOD CULTURE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at	No prior vaccinations for this event.

time of this report."

	BLOOD CULTURE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Symptoms of fever (Tmax 102.9), diarrhea, and altered mental status started ~ 24 hours after vaccination. No evidence of septicemia with negative blood cultures Minimal improvement over 3 days, transferred to tertiary care center for MRI brain after which LP was recommended. However family declined as intubation would have been required and was not consistent with patient's goals of care.		No prior vaccinations for this event.

	BLOOD CULTURE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was		No prior vaccinations for this event.

continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

BLOOD CULTURE NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support.

No prior vaccinations for this event.

Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

BLOOD CULTURE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.	No prior vaccinations for this event.

BLOOD CULTURE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.

BLOOD CULTURE POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after	No prior vaccinations for this event.

becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.

BLOOD CULTURE POSITIVE

COVID19 (COVID19 (MODERNA)) (1201)

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.

No prior vaccinations for this event.

BLOOD CULTURE POSITIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Day after receiving the vaccine, the patient complained of abdominal pain which worsened over the day. She went to the ED and was hospitalized. Abdominal pain complaints increased and continued, she decompensated rapidly, was intubated and subsequently died 3 days later. Imaging results showed, progressive ovarian cancer in the bowels. Blood culture revealed that she had E.Coli in her blood. It is thought that this is NOT related to the vaccine.

No prior vaccinations for this event.

BLOOD CULTURE POSITIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM

No prior vaccinations for this event.

	BLOOD FIBRINOGEN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM		No prior vaccinations for this event.
	BLOOD GASES	**COVID19 (COVID19 (MODERNA)) (1201)**
Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127		No prior vaccinations for this event.
	BLOOD GASES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they		No prior vaccinations for this event.

started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

BLOOD GASES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.	No prior vaccinations for this event.

BLOOD GASES ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.

BLOOD GASES ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found

No prior vaccinations for this event.

to have chronic R sided PE, no acute PE.

BLOOD GASES ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia	No prior vaccinations for this event.
BLOOD GLUCOSE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
BLOOD GLUCOSE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1. Fatigue ? day 1 - Tuesday 2. Loss of appetite ? day 1 Tuesday 3. Fever 102.0 ? day 2 - Wednesday 4. Chills ? day 2 - - Wednesday 5. Weak ? day 2 - - Wednesday 6. Non-ambulatory (unusual) ? day 2 - -	No prior vaccinations

Wednesday 7. Two emergency service ambulance assessment ? day 2 - - Wednesday 8. Symptoms improved ? day 3 - Thursday 9. Ambulatory - day 3 - Thursday 10. Symptoms worsened ? day 4 - Friday 11. Chills ? day 4 - Friday 12. Non-ambulatory again ? day 4 - Friday 13. Fever 102.0 ? day 4 - Friday 14. Left side flank pain ? day 4 - Friday 15. CPR and declared decease at home by paramedics - day 5 - Saturday morning @ 1:32am		for this event.
BLOOD GLUCOSE DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.		No prior vaccinations for this event.
BLOOD GLUCOSE DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the		No prior vaccinations for this event.

hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

BLOOD GLUCOSE DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

BLOOD GLUCOSE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to

No prior vaccinations for this event.

be deceased on 1/18 at 11:18 pm.

	BLOOD GLUCOSE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident c/o nausea evening of 1/29 (nausea common for her post dialysis), had a large emesis at approx 2220, 0030 (unusual for resident to vomit)- received Zofran per order. Skin cool and damp, Blood sugar 147 (checked due to h/o diabetes and poor intake). At approx 230am Blood pressured checked and noted to be 52/29. Resident transferred to ER, intubated and transferred to higher level of care where she passed away on 1/30 at 736pm. Resident's medical notes indicated likely shock, cardiogenic in nature, sepsis (source unknown) along with a multitude of other co-morbidities that resident has.		No prior vaccinations for this event.
	BLOOD GLUCOSE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
extreme fatigue. could not awaken for more than few seconds. When briefly awake she was coherent and not confused. slept deeply from 4pm and could not wake to eat or drink. No fever, bp normal, blood oxygen ok. Blood sugar at 11pm was 230. Gave her 15u lantus at 11pm (normally 25u). Was sleeping at 2:30am but had died at next check at 3:30am.		No prior vaccinations for this event.
	BLOOD GLUCOSE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.
	BLOOD GLUCOSE INCREASED	**COVID19 (COVID19**

	(MODERNA)) (1201)
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).	No prior vaccinations for this event.
BLOOD GLUCOSE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
While at counseling appointment on February 17 patient had witnessed sudden cardiac arrest and was not able to be resuscitated. She was pronounced dead at 12:09. At the time of death her glucose was about 500.	No prior vaccinations for this event.
BLOOD GLUCOSE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed	No prior vaccinations for this event.

respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

BLOOD GLUCOSE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

No prior vaccinations for this event.

BLOOD GLUCOSE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

All residents had been in isolation due to multiple cases of COVID in the facility. Resident voiced no health related complaints. He continued to visit with staff and required moderate assist with toileting. Resident had fall 0130 on 1-15-2021, which resulted in laceration with surgical repair. Resident was noted to change in mental status and respirations on morning of 1-16-2021 during morning blood sugar check. Resident had

No prior vaccinations for this event.

O2 @1.5l/m via n/c and respirations of 10 with periods of apnea and unresponsive to verbal stimuli. Blood sugar was 583. Resident deceased upon re-check after calling PCP to report status change.

BLOOD GLUCOSE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.

BLOOD GLUCOSE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis	No prior vaccinations for this event.

involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD GLUCOSE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death within thirty days of vaccine. Multiple co-morbidities and placed on hospice 12/28/20.

No prior vaccinations for this event.

BLOOD GLUCOSE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21- N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

No prior vaccinations for this event.

BLOOD GLUCOSE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19)

No prior vaccinations for this event.

pneumonia á Disposition: Deceased

BLOOD GLUCOSE INCREASED	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"Pt received 2nd Pfizer BioNTech Covid 19 EUA vaccine @1:50 pm; Pt released from Observation @2:09 pm. Approximately 2:18 pm RN called to parking lot and observed pt having difficulties. Called for EMS & crash cart. Vitals taken 2:20 BP 83/55, no respirations noted, pt unresponsive. AED attached. EMS arrived 2:22 and took over care of pt. and transported @2:40 pm to Hospital. Per wife, pt has history of PE in Oct. 2020, HTN, diabetes with insulin pump, obesity, gastroparesis, home oxygen and uses motorized scooter. Wife also said pt had allergy to iodine not previously reported, and MD had stopped Zarelto subsequent to 1st Pfizer vaccine 2/8/21 ""due to breathing difficulty"". Patient was unable to be resuscitated. Time of death 14:59."	No prior vaccinations for this event.

BLOOD GLUCOSE NORMAL	COVID19 (COVID19 (MODERNA)) (1201)
Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.	No prior vaccinations for this event.

BLOOD GLUCOSE NORMAL	COVID19 (COVID19 (MODERNA)) (1201)
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar	No prior vaccinations for this event.

level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.

BLOOD GLUCOSE NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
BLOOD GLUCOSE NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21	No prior vaccinations for this event.

BLOOD GLUCOSE NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."		No prior vaccinations for this event.
BLOOD GLUCOSE NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Heart stopped; Could not swallow; This is a spontaneous report from a contactable nurse (patient's wife). An 85-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 21Jan2021 at a single dose for COVID-19 immunization. Medical history included blood pressure abnormal (verbatim: blood pressure) from an unknown date and unknown if ongoing, neuropathy from an unknown date and unknown if ongoing, weight issue from an unknown date and unknown if ongoing, diabetes from an unknown date and unknown if ongoing, walker user from an unknown date and unknown if ongoing. Concomitant medications included insulin aspart (NOVOLOG) taken for diabetes from an unspecified date to an unspecified date; and he was taking a long acting one as well. The patient previously received the influenza vaccine (MANUFACTURER		No prior vaccinations for this event.

UNKNOWN) for immunization on unknown dates (""had flu shots before with no reactions and everything, nothing before""). On 24Jan2021, the patient's heart stopped (death, medically significant), and could not swallow (medically significant). The clinical course was reported as follows: The patient's wife stated the patient was taking insulin aspart (NOVOLOG) and he was taking a long acting one as well. The reporter, the patient's wife and a retired registered nurse (RN) stated, her husband (patient) just died and she thought he died from the COVID vaccine (later clarified the reason of death was-heart stopped). The patient had the vaccine on 21Jan2021, which was on a Thursday, and he was fine. On the following Sunday around 1:30 (on 24Jan2021), the patient was feeling a little weak, however, the patient's wife thought maybe his blood sugar was low. The patient's wife checked, and the patient's blood sugar was 91. The patient's wife went to get some yogurt to feed him in order to get his blood sugar up a little; ""which was a normal thing for him, it was not that low for him."" Then, suddenly, the patient fell, and the patient's wife could not get a pulse or anything. The patient's wife called an unspecified number and she started compressions; however, he was dead. The patient's wife stated the patient just had his heart test, a three hour long one, and it was ""perfect three weeks ago."" The patient had just gone to the doctor the other day and his blood pressure was ""fine and everything."" The patient's wife stated that other than his diabetes, ""which he had for (sentence incomplete)."" Regarding lab tests, the patient's wife stated, ""No, he had it before but not in the last two weeks. He was going for one because we just went to the doctor last week and he was going to call yesterday to make the appointment request to get his blood work done. Blood work has been good except his A1C was always high, but other than that everything was good"" (as reported). Regarding causality, the patient's wife stated, ""I do, because he was fine until about half an hour before he died. He said to me, I feel a little weak today and then I was talking to him that your upper body strength is really good and then I said, we just have to work on your weight a little more because he did have neuropathy. And then, I went out of the room and all of a sudden I just heard him fall and that is when I just went in to check his blood sugar and it was 91 and I got him yogurt and he started eating that and then that was it, he started spitting it out and he said, I could not swallow and that was it, he just died."" The patient's wife further added, ""I just wanted other people to know that things like this happen and I am sure it was from that because he was healthy as could be. He was walking with his walker, the day before outside and he felt fine."" The clinical outcome of the event, heart stopped, was fatal. The clinical outcome of the event, could not swallow, was

unknown. The patient died on 24Jan2021 due to ""heart stopped."" An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: Heart stopped"

BLOOD LACTATE DEHYDROGENASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more	No prior vaccinations for this event.

subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is

unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

	BLOOD LACTATE DEHYDROGENASE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received dose #1 of COVID-19 vaccine (Pfizer-BioNTech) on 12/18/20 and dose #2 (Pfizer-BioNTech) on 1/8/21. On 1/30, patient was evaluated at urgent care due to back pain. No bloodwork done; metronidazole prescribed for 7 days. On 2/8, patient was admitted to outside hospital due to ongoing symptom progression. At time of admission, hgb 5 g/dL and plt 9k. Per Dr. (hematology/oncology), pt with schistocytes, LDH 1500, and elevated reticulocyte count consistent with thrombotic thrombocytopenic purpura (TTP). SCr >2 mg/dL. Patient immediately treated with plasma exchange and steroids, however continued to decline. Patient expired on 2/14/21.		No prior vaccinations for this event.
	BLOOD LACTIC ACID	**COVID19 (COVID19 (MODERNA)) (1201)**
Moderna Vaccine Lot 029K20A Patient received second dose of vaccine on 2/2/21. Within 30 minutes patient had a near syncopal episode. She felt lightheaded and shortly after had episode of nonbloody vomiting. Hypotensive 81/69 and started on levophed. Alert and orientated. Lungs clear, abdomen benign on admission. Patient had no reaction when received first dose of the vaccine. Patient developed worsening		No prior vaccinations for this event.

shortness of breath, tachypnea, Afib with RVR, hypotension and required intubation and multiple pressors.

	BLOOD LACTIC ACID	**COVID19 (COVID19 (MODERNA)) (1201)**
Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127		No prior vaccinations for this event.
	BLOOD LACTIC ACID	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).		No prior vaccinations for this event.
	BLOOD LACTIC ACID	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of		No prior vaccinations for this event.

vomiting and dry heaving.

	BLOOD LACTIC ACID	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.		No prior vaccinations for this event.

	BLOOD LACTIC ACID	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death ""cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its components or a severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed.		No prior vaccinations for this event.

MDs recommending hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative status. 1/29 Pt passed away."

BLOOD LACTIC ACID	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.

BLOOD LACTIC ACID	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.	No prior vaccinations for this event.

BLOOD LACTIC ACID DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.	No prior vaccinations for this event.
BLOOD LACTIC ACID INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.	No prior vaccinations for this event.
BLOOD LACTIC ACID INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.	No prior vaccinations for this event.
BLOOD LACTIC ACID INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until	No prior vaccinations for this event.

family could be reached and decision was made to stop resuscitation.

BLOOD LACTIC ACID INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the

No prior vaccinations for this event.

decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

BLOOD LACTIC ACID INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.	No prior vaccinations for this event.
BLOOD LACTIC ACID INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and	No prior vaccinations for this event.

pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs

COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

BLOOD LACTIC ACID INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he

No prior vaccinations for this event.

passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending.

Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."		
	BLOOD LACTIC ACID INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.		No prior vaccinations for this event.
	BLOOD LACTIC ACID INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.		No prior vaccinations for this event.
	BLOOD LACTIC ACID INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-		No prior vaccinations for this event.

2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

BLOOD LACTIC ACID INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and	No prior vaccinations for

02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)

this event.

BLOOD LACTIC ACID INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider

No prior vaccinations for this event.

prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

BLOOD LACTIC ACID NORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.		No prior vaccinations for this event.
BLOOD LACTIC ACID NORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21		No prior vaccinations for this event.

based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

BLOOD LACTIC ACID NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis	No prior vaccinations for this event.

involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD MAGNESIUM DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

No prior vaccinations for this event.

BLOOD MAGNESIUM INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

BLOOD MAGNESIUM INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.		No prior vaccinations for this event.
BLOOD MAGNESIUM INCREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.		No prior vaccinations for this event.
BLOOD MAGNESIUM INCREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM		No prior vaccinations for this event.

	BLOOD MAGNESIUM NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.		No prior vaccinations for this event.
	BLOOD METHAEMOGLOBIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.
	BLOOD PH DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt started complaining of chest heaviness and shortness of breath on the afternoon of 1/21/21. EMS was called to the patients home and she was found to have an O2 sat in the 70's. She was admitted to hospital and found to have a proBNP of 5000. She tested negative for Covid-19. She was determined to be in acute-on-chronic heart failure and was referred for hospice care. She passed away on the evening of 1/24/21.		No prior vaccinations for this event.
	BLOOD PH DECREASED	**COVID19 (COVID19**

	(MODERNA)) (1201)
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.
BLOOD PH DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.

BLOOD PH DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200

No prior vaccinations for this event.

IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD PH INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

BLOOD PH INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1-12-21 Resident is complaining of heart pain. Resident blood pressure is 228/105. 1-22-21 Dx UTI 1-13-21 His nurse called MD at approximately 0645, reported to him that it was reported to this nurse that resident has not slept in 2 days and night, has an increased blood pressure, reports severe pain in lower back, and

No prior vaccinations for this event.

appears to be uncomfortable Resident is able to verbalize his pain and where it is at, but is unable to explain the quality of the pain or give a number on the 0/10 pain scale.

BLOOD PHOSPHORUS INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	No prior vaccinations for this event.
BLOOD POTASSIUM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
BLOOD POTASSIUM DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**

Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.

No prior vaccinations for this event.

BLOOD POTASSIUM DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.

No prior vaccinations for this event.

BLOOD POTASSIUM DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

BLOOD POTASSIUM DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile

No prior vaccinations for this event.

stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

BLOOD POTASSIUM DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21	No prior vaccinations for this event.
BLOOD POTASSIUM INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.	No prior vaccinations for this event.
BLOOD POTASSIUM INCREASED	**COVID19 (COVID19**

	(MODERNA)) (1201)
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.	No prior vaccinations for this event.
BLOOD POTASSIUM INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident c/o nausea evening of 1/29 (nausea common for her post dialysis), had a large emesis at approx 2220, 0030 (unusual for resident to vomit)- received Zofran per order. Skin cool and damp, Blood sugar 147 (checked due to h/o diabetes and poor intake). At approx 230am Blood pressured checked and noted to be 52/29. Resident transferred to ER, intubated and transferred to higher level of care where she passed away on 1/30 at 736pm. Resident's medical notes indicated likely shock, cardiogenic in nature, sepsis (source unknown) along with a multitude of other co-morbidities that resident has.	No prior vaccinations for this event.
BLOOD POTASSIUM INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29	No prior vaccinations for this event.
BLOOD POTASSIUM INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presents to ER with increased weakness, hypoxia, history of COPD, but not oxygen dependent.,	No prior vaccinations

hypotension. Acute Kidney failure noted in labs, not previously diagnosed , new hyperkalemia. BP 73/39, HR 67. dopamine initiated, and switched to Levophed. Oxygen Sat 86%, requiring 10 L O2. Transferred from this critical access hospital to another Hospital. Expires later 2-13-2021	for this event.	
BLOOD POTASSIUM INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.	No prior vaccinations for this event.	
BLOOD POTASSIUM INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.	No prior vaccinations for this event.	
BLOOD POTASSIUM INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**

Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

No prior vaccinations for this event.

BLOOD POTASSIUM INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death within thirty days of vaccine. Multiple co-morbidities and placed on hospice 12/28/20.

No prior vaccinations for this event.

BLOOD POTASSIUM INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)

No prior vaccinations for this event.

BLOOD POTASSIUM NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs.

No prior vaccinations for this event.

Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.

BLOOD POTASSIUM NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.

No prior vaccinations for this event.

BLOOD POTASSIUM NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

"Patient had COVID vaccination on 2/3 with no adverse s/s before leaving unit. Upon coming to treatment Friday 2/5 he reported to the RN that he had fallen on thursday 2/4 due to ""getting up fast"" did not hit head or hurt anything per RN discussion. Began treatment without difficulty. About 3/4 way through treatment was talking with staff and became unresponsive - code was called and pt expired after 30 minute resuscitation efforts."

No prior vaccinations for this event.

BLOOD POTASSIUM NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

BLOOD POTASSIUM NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
While at counseling appointment on February 17 patient had witnessed sudden cardiac arrest and was not able to be resuscitated. She was pronounced dead at 12:09. At the time of death her glucose was about 500.	No prior vaccinations for this event.
BLOOD POTASSIUM NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration	No prior vaccinations for this event.
BLOOD POTASSIUM NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR	No prior vaccinations for this event.

resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

	BLOOD POTASSIUM NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.		No prior vaccinations for this event.

	BLOOD POTASSIUM NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021		No prior vaccinations for this event.

	BLOOD POTASSIUM NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.		No prior vaccinations for this event.

BLOOD POTASSIUM NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.

No prior vaccinations for this event.

BLOOD POTASSIUM NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency

No prior vaccinations for this event.

department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD POTASSIUM NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia,

No prior vaccinations for this event.

COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into

Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

BLOOD PRESSURE ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient received vaccine at Public Health Clinic. Patient ended up having a seizure 3 days later and ended up in the hospital. Found to have right lobe pneumonia and low depakote level. Patient noted to have multiple seizures at hospital, issues with stabilizing HR and BP, and passed away on 1/20/21.

No prior vaccinations for this event.

BLOOD PRESSURE ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"The resident received is vaccine around 11:00 am and tolerated it without any difficulty or immediate adverse effects. He was at therapy from 12:36 pm until 1:22 pm when he stated he was too tired and could not do anymore. The therapist took him back to his room at that time and he got into bed himself but stated his legs felt heavy. At 1:50 pm the CNA answered his call light and found he had taken himself to the bathroom. She stated that when he went to get back into the bed it was ""abnormal"" how he was getting into it so she assisted him. At that time he quit breathing and she called a RN into the room immediately. He was found without a pulse, respirations, or blood pressure at 1:54 pm. He was a DNR."

No prior vaccinations for this event.

BLOOD PRESSURE DECREASED

COVID19 (COVID19

	(MODERNA)) (1201)
This patient has been under hospice care for over 2 years at the nursing home. She has had a steady decline with gradual weight loss. She was totally dependent in her care needs. She received the vaccine on 1/2/2021 as part of the facility vaccination campaign. No adverse events noted initially. On 1/3/2021 at 6:06 pm, she was noted on vital sign checks (done every 4 hours for first 72 hours after vaccination) with BP 64/52 but otherwise asymptomatic. Subsequent BP improved. On 1/4/2021 at 4:45 am, pt found with respiratory rate of 30 with otherwise normal vital signs. Tachypnea persisted, so she received liquid morphine 2.5 mg without improvement. Supplemental oxygen was applied. Tachypnea persisted. She had poor oral intake after that point had persistent tachypnea and worsening hypoxemia despite clear lungs on exam. She remained under hospice care and comfort measures were continued. No blood testing or imaging tests were done. She required increasing amounts of oxygen, became hypotensive, and died peacefully on 1/8/2021 at 7:45 pm.	No prior vaccinations for this event.
BLOOD PRESSURE DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.	No prior vaccinations for this event.
BLOOD PRESSURE DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had Covid-19 in October of 2020. He recovered. He received the vaccination on 12/30/2020 with no complaints. On 01-05-2021 it was noted to he was incontinent of urine and bilateral lower extremity edema. Lab work was completed showed acute kidney injury. He had decreased blood pressure and oxygen	No prior vaccinations for this event.

saturations on 01-06-2021 He was admitted to the hospital with rapid progression of symptoms and suggested multi-system failure. He had a long cardiac history. On 01-14-2021 he passed away with a diagnosis of Cardiomyopathic CHF, A.Fib contributory.		
	BLOOD PRESSURE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021		No prior vaccinations for this event.
	BLOOD PRESSURE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Legs started swelling and shortness of breath Thursday January 21 2021 Was rushed to hospital with kidney failure and fluid build up around lungs and entire body Blood pressure dropped and had multiple organ failure		No prior vaccinations for this event.
	BLOOD PRESSURE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"The day after the 2nd shot, patient developed blisters on his lips and mouth. The care facility said that he had a nut allergy -- but he had never been allergic to nuts. He stopped eating and drinking and his BP had dropped to 60/40. By Jan 16th they called to say he was dying and he passed away on 1/18/21. Patient had COVID19 from Oct 29th - early November. By Nov 21st he had lost 40 lbs. He was 6'3"" and had gone from 189lbs to 149 lbs with COVID. By Nov 21st when we could visit, he had		Shingles - Glaxo 8/22/2020, resulted in hospitalization and LTC.

recovered from COVID, but was very thin and weak. He could not bathroom alone and kept falling. He didn't seem to have a bad reaction to the 1st COVID shot, But he immediately reacted to the 2nd shot and passed away within 6 days."

	BLOOD PRESSURE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.		No prior vaccinations for this event.
	BLOOD PRESSURE FLUCTUATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.		No prior vaccinations for this event.
	BLOOD PRESSURE FLUCTUATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in		No prior vaccinations for

BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		this event.
	BLOOD PRESSURE IMMEASURABLE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.		No prior vaccinations for this event.
	BLOOD PRESSURE IMMEASURABLE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received the 2nd dose of the Covid vaccine approximately around 1105 by pharmacy through the pharmacy LTC partnership vaccination program. Resident had no adverse effects until around 8:00 pm she began complaining of body aches, and chills, Tylenol was given at this time. Around 9:30pm resident was sleeping in bed. Around 12:00 am the CNA called nurse into room to assess resident as the resident stated she did not feel good. Temperature at that time was 102.2, and vomiting. RN came to assess @ 1220 am		No prior vaccinations for this event.

She was noted to be vomiting, diaphoretic, pale and having trouble breathing. Temp was 97.3 after vomting, Pulse 53, Resp 20, o2 sats were 40-45%, unable to obtain Blood pressure, Applied 5 L of oxygen at this time and had LPN call 911 immediately. Resident was repsonsive and able to follow staff members instructions but was only answering yes or no simple questions at the time time of assessment. Paramedics arrived at 0040 and resident was sent to Hospital. @ 0130 ER nurse called to nursing facility to notify resident had coded in the ER and passed away @ 0110.

BLOOD PRESSURE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Rapid decline in health status, Elevated BP&P, posturing, loss of consciousness, Glasgow coma Scale 4 starting 2/1/2021, Deceased 2/3/21	No prior vaccinations for this event.
BLOOD PRESSURE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was seen at 0710 he was sleeping but at normal cognitive behavior Patient was again assessed at 0720 where he was noted to be unresponsive, BP 180/100s, HR 230s, he was a DNR therefore not CPR was administered. EMS arrived at facility patient was noted to be in full cardiac and respiratory arrest. Time of death 0735	No prior vaccinations for this event.
BLOOD PRESSURE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
"The patient came to the Emergency Room at approx 3:30 am on 02/03/2021 with pain in right arm (same arm the COVID vaccine had been administered in approx 12 hours earlier) and feeling generally unwell. Patient was concerned about possibility of gout flare or that something was wrong with her arm. Elevated blood pressure was noted; this was attributed to anxiety. She was evaluated, given 500 mg Tylenol, and discharged since the pain was decreasing and blood pressure was stabilized. Patient instructed to follow-up	No prior vaccinations for this event.

with physician. The next day, on 02/04/2021, the patient arrived at the Emergency Room by ambulance; cardiac arrest was the chief complaint. The patient's daughter stated the patient had been ""feeling generally poor and then suddenly collapsed."" Daughter described ""gurgling respirations"" and being unresponsive. 911 was called, police arrived within 5 minutes and initiated CPR. Epinephrine, atropine, lidocaine and bicarb administered after arrival to Emergency Room. Shockable rhythm never demonstrated. Patient never recovered spontaneous respiration or movement. The death was called at 23:04. Coronary artery disease with cardiac arrest is the cause from the ER records; the coroner is putting COVID-19 vaccination in Part 1 of the death certificate."

BLOOD PRESSURE INCREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1-12-21 Resident is complaining of heart pain. Resident blood pressure is 228/105. 1-22-21 Dx UTI 1-13-21 His nurse called MD at approximately 0645, reported to him that it was reported to this nurse that resident has not slept in 2 days and night, has an increased blood pressure, reports severe pain in lower back, and appears to be uncomfortable Resident is able to verbalize his pain and where it is at, but is unable to explain the quality of the pain or give a number on the 0/10 pain scale. No prior vaccinations for this event.

BLOOD PRESSURE INCREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Unresponsive, Increase BP and H. Hospital Dx Renal Failure No prior vaccinations for this event.

BLOOD PRESSURE INCREASED **COVID19 (COVID19 (UNKNOWN)) (1202)**

5 days after receiving his COVID vaccination the patient had a spontaneous (nontraumatic) subarachnoid hemorrhage which was fatal. The patient had previously been stable on his coumadin dosing with therapeutic No prior vaccinations

INRs for the past several months per his wife. At time of presentation his blood pressure in the ER was elevated to 223/94 and his INR was risen to 3.1	for this event.
BLOOD PRESSURE MEASUREMENT	**COVID19 (COVID19 (MODERNA)) (1201)**
No pulse and no heart beat; couldn't wake him up; passed away; A spontaneous report was received from a daughter concerning a 84-year old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) experienced no pulse or heartbeat, couldn't wake him up and passed away. The patient's medical history, as provided by the reporter, included high blood pressure and prostate cancer. No relevant concomitant medications were reported. On 19 Jan 2021, the patient had a blood pressure reading of 133/84 at a cardiology visit. On 13 Feb 2021, approximately 3 hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (batch number 031M20A) intramuscularly for prophylaxis of COVID-19 infection. On 13 Feb 2021 at 3:30 pm, the patient could not be woken up and was found with no pulse or heartbeat. Action taken with the drug in response to the events was not applicable. The outcome of the events, no pulse or heartbeat and couldn't wake him up, were not provided. The patient died on 13 Feb 2021. The cause of death was unknown.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. The patient's medical history of high blood pressure and prostate cancer remains the risk factors. The cause of death was unknown. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death	No prior vaccinations for this event.
BLOOD PRESSURE MEASUREMENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Blood pressure went down until he died; Couldn't hear his heartbeat; neck was sweating; He was cold; Couldn't get up; Death; Sick; immediately very tired; he was tired; Hands were shaking; Slept for too long; A spontaneous report was received on 18 Feb 2021 from a consumer concerning a 81-years-old, male patient who received Moderna's COVID-19 vaccine and developed immediately very tired, hands were shaking,	No prior vaccinations for this event.

neck was sweating, was cold, sick, couldn't get up, couldn't hear his heartbeat and blood pressure went down until he died. Patients' medical history, as provided by patient's spouse, was emergency room(ER) admission in November 2020 because he had a congested chest (he had fluid around his heart). At that time, they gave him pills for kidney function. Other concomitant medication reported was Coumadin, blood thinner. Two weeks before receiving the vaccine, patient's EKG was normal. On 11 Feb 2021, in the morning, patient received their first of two planned doses of mRNA-1273(BATCH/LOT # 007M20A) probably in the right arm for the prophylaxis of COVID-19 infection. On 11 Feb 2021, approximately after 15 minutes of receiving vaccine, they left and patient was immediately very tired, his hands were shaking. So, patient's spouse made them down sleep for too long. On Friday, 12 Feb 2021 she tried to pick him up, but he was tired, exhausted, and sick. On Saturday, 13 Feb 2021, she brought him a coffee and he couldn't hold it because his hands were shaking, so she gave him the coffee and then made him pee on the bed because he couldn't get up. At lunch time she made him eat something and he fell sleep again. His wife was hanging around him all day and around 7:30pm she realized that he was cold, and his neck was sweating, she couldn't hear his heartbeat. So, she called emergency services and when they arrived, her husband's blood pressure went down until he died. Treatment for the events were not provided. Action taken with mRNA-1273 was not applicable. Patient was pronounced dead on 13 Feb 2021 20:00. The cause of death was not provided. The plans for an autopsy were not provided. The events of blood pressure went down until he died and couldn't hear his heartbeat were fatal. The outcome for the remaining events were unknown.; Reporter's Comments: This case concerns an 81 year old, male patient, who experienced a serious event of death among others, 2 days after receiving mRNA- 1273 (Lot# 007M20A). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

BLOOD PRESSURE SYSTOLIC DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s No prior vaccinations for

he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.	this event.
BLOOD SMEAR TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37,	No prior vaccinations for this event.

she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

	BLOOD SODIUM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
	BLOOD SODIUM DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.		No prior vaccinations for this event.
	BLOOD SODIUM DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He		No prior vaccinations for this

was admitted to the hospital and treated for worsening AKI and hypotension.		event.
BLOOD SODIUM DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.		No prior vaccinations for this event.
BLOOD SODIUM DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.		No prior vaccinations for this event.
BLOOD SODIUM DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.		No prior vaccinations for this event.

BLOOD SODIUM DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**	
"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."		No prior vaccinations for this event.
BLOOD SODIUM DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**	
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.
BLOOD SODIUM DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.		No prior vaccinations for this event.
BLOOD SODIUM DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH))**	

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or

No prior vaccinations for this event.

definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD SODIUM DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and ACLS guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and ACLS guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is

No prior vaccinations for this event.

a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

BLOOD SODIUM INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.	No prior vaccinations for this event.
BLOOD SODIUM INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21	No prior vaccinations for this event.

BLOOD SODIUM INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death within thirty days of vaccine. Multiple co-morbidities and placed on hospice 12/28/20.

No prior vaccinations for this event.

BLOOD SODIUM INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing.

No prior vaccinations for this event.

Supervisor called and pronounced resident deceased.

	BLOOD SODIUM NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient had COVID vaccination on 2/3 with no adverse s/s before leaving unit. Upon coming to treatment Friday 2/5 he reported to the RN that he had fallen on thursday 2/4 due to ""getting up fast"" did not hit head or hurt anything per RN discussion. Began treatment without difficulty. About 3/4 way through treatment was talking with staff and became unresponsive - code was called and pt expired after 30 minute resuscitation efforts."		No prior vaccinations for this event.
	BLOOD SODIUM NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident getting rehab therapy in the facility and has a long history of Parkinson's Disease. On 01/29/21, he received the COVID vaccine on left deltoid, resident was recently hospitalized due to Pneumonia and was on antibiotic IV and was recently placed on GT feeding due to severe dysphagia from his Parkinson's disease. On 01/31/21, started having increased congestion. On 02/02/21, started having increased temperature and WBC went up >20,000 on 02/03/21, started on Vancomycin IV on 02/04/21 but was transferred to the hospital. Facility was notified today (02/18/21) that resident expired in the hospital.		No prior vaccinations for this event.
	BLOOD SODIUM NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus		No prior vaccinations for this event.

in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

BLOOD SODIUM NORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506		No prior vaccinations for this event.

BLOOD SODIUM NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p		No prior vaccinations for

multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	**BLOOD SODIUM NORMAL**	this event. **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	**BLOOD SODIUM NORMAL**	No prior vaccinations for this event. **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.	**BLOOD SODIUM NORMAL**	No prior vaccinations for this event. **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	**BLOOD SODIUM NORMAL**	No prior vaccinations for this event. **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status:

No prior vaccinations for this event.

SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD SODIUM NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have

No prior vaccinations for this event.

intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

BLOOD TEST	COVID19 (COVID19 (MODERNA)) (1201)
Patient received COVID-19 (Moderna) vaccine from the Health Department on afternoon of January 8, 2021 and went to sleep approximately 2300 that night. Was found unresponsive in bed the following morning and pronounced dead at 1336 on January 9, 2021	No prior vaccinations for this event.

BLOOD TEST	COVID19 (COVID19 (MODERNA)) (1201)
High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death	No prior vaccinations for this event.

BLOOD TEST	COVID19 (COVID19 (MODERNA)) (1201)
Started feeling unwell; Headaches; Body aches; Chest pain; Didn't had wishes to eat; Diarrhea; COVID-19 pneumonia; A spontaneous report was received from a consumer concerning a 69-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced COVID-19 pneumonia, feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea The patient's medical history high blood pressure which was controlled with medication. Concomitant product use included nifedipine and fenofibrate. On 20-JAN-2021, approximately a week and a half or two prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number 030L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. A week and a half or two later the patient stated feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea for which patient was hospitalized on 06-FEB-2021. Since everything seemed to be fine the patient was discharged on an unknown date in FEB-2021 however, patient's family was not notified that it was a late reaction to the vaccine's first dose. Later, due to shortness of breath he was hospitalized again on 08-FEB-2021 and was diagnosed for pneumonia and was intubated on the same day. Due to COVID-19 situation patient's family could not be in the facilities and that there wasn't any follow up of the patient given to the family, so family did not have much information. During the first hospitalization(06-FEB-2021) the patient had a blood test which showed a normal result and was tested for COVID-19 and Influenza, both were negative. During second hospitalization (08-FEB-2021) the hospital said that the patient was stable. The patient's family did not know the results of the tests conducted at the time. The action taken with the vaccine in response to the events is not applicable. The outcome of COVID-19 pneumonia was fatal. The patient died on 14 Feb 2021 The cause of death was reported as COVID-19 related pneumonia. The autopsy was not done.; Reporter's Comments: Very limited information regarding this event has been provided at this time. The cause of death was reported as COVID-19 related pneumonia. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the events are assessed as unlikely related. Further information has been requested.; Reported Cause(s) of Death: COVID-19 pneumonia	No prior vaccinations for this event.

BLOOD TEST

COVID19 (COVID19 (MODERNA)) (1201)

Case passed away on 2/28/21. During post vaccination monitoring, case did not have any adverse reactions. When writer spoke to him on 2/26/21 to schedule his second dose, he sounded well.

No prior vaccinations for this event.

BLOOD TEST

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident was hospitalized for confusion, and hypotension and increased weakness; resident proceeded to have a NSTEMI and died on 5th day in hospital on 1/31/2021.

No prior vaccinations for this event.

BLOOD TEST ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

in addition to above, pt had the following diagnosis: portal HTN, abnormal blood chem, essential tremor, depressive disorder, abnormal glucose tolerance test, hyperlipidemia, hypothyroidism, insomnia, localized osteoarthrosis, calculus of kidney, pancytopenia, odule on liver, hepatocellular CA, hyotension, hypovolemia, hepatorenal syndrome additional meds: zoloft, aldactone, thiamine,demadex, ultram, kenalog, vitamins, bactroban ung

No prior vaccinations for this event.

BLOOD TEST ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

My mom only had site soreness after her covid vaccine on 1/21 which resolved within a couple days. However, she died in the early morning hours of 1/25, she was fine the day before, no sign of injury. We found her collapsed on the ground and although we tried cpr she was already dead. She had gone to the hospital on 12/28 for shortness of breath, angina and symptomatic anemia, her ekg was unchanged and

No prior vaccinations for this event.

blood work normal except for anemia. The cardiologist did not think a cardiac cath was needed. Her shortness of breath improved with a blood transfusion and a dose of lasix (no heart failure).

BLOOD THYROID STIMULATING HORMONE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of	No prior vaccinations for this event.

45%.

BLOOD THYROID STIMULATING HORMONE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
BLOOD THYROID STIMULATING HORMONE NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.		
BLOOD TRIGLYCERIDES INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**	
While at counseling appointment on February 17 patient had witnessed sudden cardiac arrest and was not able to be resuscitated. She was pronounced dead at 12:09. At the time of death her glucose was about 500.		No prior vaccinations for this event.
BLOOD UREA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported		No prior vaccinations

left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		for this event.
BLOOD UREA ABNORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"		No prior vaccinations for this event.
BLOOD UREA DECREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"		No prior vaccinations for this event.
BLOOD UREA INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital		No prior vaccinations

signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics	for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.	No prior vaccinations for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**

Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.	No prior vaccinations for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.	No prior vaccinations for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.	No prior vaccinations for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient	No prior vaccinations for this event.

who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face, increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

BLOOD UREA INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope.

No prior vaccinations for this event.

ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.

BLOOD UREA INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Resident getting rehab therapy in the facility and has a long history of Parkinson's Disease. On 01/29/21, he received the COVID vaccine on left deltoid, resident was recently hospitalized due to Pneumonia and was on antibiotic IV and was recently placed on GT feeding due to severe dysphagia from his Parkinson's disease. On 01/31/21, started having increased congestion. On 02/02/21, started having increased temperature and WBC went up >20,000 on 02/03/21, started on Vancomycin IV on 02/04/21 but was transferred to the hospital. Facility was notified today (02/18/21) that resident expired in the hospital.

No prior vaccinations for this event.

BLOOD UREA INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

No prior vaccinations for this event.

BLOOD UREA INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
While at counseling appointment on February 17 patient had witnessed sudden cardiac arrest and was not able to be resuscitated. She was pronounced dead at 12:09. At the time of death her glucose was about 500.	No prior vaccinations for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration	No prior vaccinations for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed	No prior vaccinations for this event.

respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

BLOOD UREA INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

No prior vaccinations for this event.

BLOOD UREA INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay

No prior vaccinations for this event.

has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21

BLOOD UREA INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.

No prior vaccinations for this event.

BLOOD UREA INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"

No prior vaccinations for this event.

BLOOD UREA INCREASED

COVID19 (COVID19 (PFIZER-

	BIONTECH)) (1200)
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.	No prior vaccinations for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/5/2021 resident noted to be azotemic. Creatinine up to 3.8 and BUN in 80's. He was started on NS hydration. On 2/7/2021 he was noted without VS, per MD notes, possible VF arrest, renal failure; death unclear exact cause.	No prior vaccinations for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite.	No prior vaccinations for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP	No prior vaccinations for this event.

that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small

bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

BLOOD UREA INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart	No prior vaccinations for this event.

failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

BLOOD UREA INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.

No prior vaccinations for this event.

BLOOD UREA INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death on 1/31/2021 multiple comorbidities No prior vaccinations for this event.

BLOOD UREA INCREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support.

No prior vaccinations for this event.

Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

BLOOD UREA INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.

No prior vaccinations for this event.

BLOOD UREA INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death on same day as vaccination No prior vaccinations for this event.

BLOOD UREA INCREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death within thirty days of vaccine. Multiple co-morbidities and placed on hospice 12/28/20.

No prior vaccinations for this event.

BLOOD UREA INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM

No prior vaccinations for this event.

	BLOOD UREA INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21- N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.		No prior vaccinations for this event.
	BLOOD UREA INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)	No prior vaccinations for this event.
BLOOD UREA INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
BLOOD UREA NITROGEN/CREATININE RATIO	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
BLOOD UREA NITROGEN/CREATININE RATIO	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia	No prior vaccinations for this event.

(80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

BLOOD UREA NITROGEN/CREATININE RATIO INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT	No prior vaccinations for this event.

scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2

through

BLOOD UREA NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**	
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.	No prior vaccinations for this event.	
BLOOD UREA NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**	
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.	
BLOOD UREA NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.	

BLOOD UREA NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	No prior vaccinations for this event.
BLOOD URINE	**COVID19 (COVID19 (MODERNA)) (1201)**
loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21	No prior vaccinations for this event.

based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

BLOOD URINE ABSENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with

No prior vaccinations for this event.

bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

BLOOD URINE PRESENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29	No prior vaccinations for this event.
BLOOD URINE PRESENT	**COVID19 (COVID19 (MODERNA)) (1201)**
"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."	No prior vaccinations for this event.
BLUE TOE SYNDROME	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on	No prior vaccinations for this event.

17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away

BODY TEMPERATURE

COVID19 (COVID19 (MODERNA)) (1201)

High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and

No prior vaccinations for this event.

mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

BODY TEMPERATURE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

approxmately 1:30 Pm the resident passed away; This is a spontaneous report from a Pfizer sponsored program. A non-contactable consumer reported that a female patient of an unspecified age (reported as 85 without unit) received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL0140), intramuscular at left arm on 29Dec2020 11:29 at single dose for COVID-19 immunization. Medical history included dementia, aphasia, type 2 diabetes mellitus (DM), iron deficiency, asthenia, osteoporosis, polyneuropathy, anxiety, Major depressive disorder (MDD). Concomitant medication included gabapentin, memantine. The patient had allergies to codiene, phenobarbital, penicillin. The vaccine was administrated with no immediate adverse reaction at 11:29. Vaccine screening questions were completed and resident was not feeling sick and temperature was 98F. At approximately 13:30 on 29Dec2020, the resident passed away. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further

No prior vaccinations for this event.

information is expected. ; Reported Cause(s) of Death: approxmately 1:30 Pm the resident passed away

BODY TEMPERATURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches,	No prior vaccinations for this event.

diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on

10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

BODY TEMPERATURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with	No prior vaccinations for this event.

outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away

BODY TEMPERATURE ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Passed away; tired; nonresponsive; cold; difficulty breathing; swelling; sore arm; feeling weird and funny; A spontaneous report (United States) was received from a consumer concerning a 63 year old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and the patient experienced limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal and the patient passed away . Medical history included treatment for tuberculosis and dialysis. Concomitant medication included calcium acetate, Renvela, glipizide, omeprazole, aspirin, vitamin D, losartan, furosemide, rifampin, and Sensipar. On 14 Jan 2021, the patient received the first of their first planned doses of mRNA-1273 (lot number 030L20A) for prophylaxis of COVID-19 infection. On 13 Jan2021, the patient tested negative for COVID-19). On 16 Jan 2021, the patient experienced a sore arm, and feeling

No prior vaccinations for this event.

weird/funny. On 17Jan2021, the patient experienced difficulty breathing and swelling. On 18 Jan 2021, the patient declined dialysis, was tired and wanted to lay down. At 8 am, the patient was found nonresponsive and cold and is believed to have passed away around 4 am. The coroner tested the deceased for COVID-19 and the test was positive. No autopsy was reported. No death certificate was issued at the time of the report but the reporter believes it will list cause of death as COVID complications. Action taken with the mRNA-1273 was not applicable. The outcome of the events of limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal, was fatal. On 18 Jan 2021, the patient was died. Cause of death was COVID-19. Autopsy details were not provided.; Reporter's Comments: The events developed on four days after first dose of mRNA-1372. Dyspnea, unresponsive to stimuli, and death were consistent with infection in pandemic set up confounded by age of patient and refusal of dialysis Cause of death was reported as COVID-19. Autopsy details were not provided. Based on reporter's causality the events are assessed as unlikely related to mRNA-1273.; Reported Cause(s) of Death: COVID-19

BODY TEMPERATURE DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO WITHDRAWL EXTRME MEASURES

No prior vaccinations for this event.

BODY TEMPERATURE DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On the evening of 2/23/221 at 9:00 pm, resident reported feeling SOB, BP 80/44, Pulse 53, O2Sat 95% on 3L oxygen, hands cold, pulse weak. Temp 92.5F MD notified. EMS activated. EMS arrival and HR 20. Family

No prior vaccinations for this event.

refused transport to ER. Resident expired at 2:40 am on 2/24/21 Meds continued: duloextine, VITd2,hydralazine, synthroid, lisinopril, mag ox, folplex, pantoprazole, potassium chloride, ellipta, ensure, hydrocortisone cream, boost, deprox, xanax, morphine, lorazepam, tylenol, albuterol inhlation, ventolin inh.

BODY TEMPERATURE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics	No prior vaccinations for this event.

BODY TEMPERATURE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
"On 1/15/2021 at 1800, resident noted to be lethargic and shaking, stating ""I don't care."" repeatedly. C/O	No prior vaccinations

head and neck pain. T100.6. Given Tylenol with no relief of pain. Order received for Aleve and administered.. Assisted to bed as usual in evening. Monitored during night shift and noted to be resting comfortably/sleeping.. Noted agonal breathing at 4:10 AM 1/16/2021 , T 99.4, Absence of vital signs at 4:15AM 1/16/21 and death pronounced at 4:40AM 1/16/21." for this event.

BODY TEMPERATURE INCREASED **COVID19 (COVID19 (MODERNA)) (1201)**

hypoxia, secretions,cough, dyspnea Narrative: ALS patient on hospice with ongoing history of aspiration pna, receiving tube feeds. Developed incr in secretions, hypoxeia, temp and with recently noted clogged feeding tube. No prior vaccinations for this event.

BODY TEMPERATURE INCREASED **COVID19 (COVID19 (MODERNA)) (1201)**

Low Grade Temp, Persistent low back pain, Projectile Vomiting. No prior vaccinations for this event.

BODY TEMPERATURE INCREASED **COVID19 (COVID19 (MODERNA)) (1201)**

patient passed away 2 days after vaccine. patient had temperature, nausea, and vomiting after vaccine. No prior vaccinations for this event.

BODY TEMPERATURE INCREASED **COVID19 (COVID19 (MODERNA)) (1201)**

Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time No prior vaccinations for this event.

breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.

BODY TEMPERATURE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Resident reviewed for incident. Resident received the second dose of the Moderna Covid-19 vaccine lot# 016M20A Exp 5/2/2021 on 2/5/2021 from clinic through pharmacy. Resident had her temp/O2 taken on AM shift and was 98.6/93%, beginning PM shift 98.4/95%. A few hours later noted that resident to have chills and was shaking RN assessment completed and vitals taken resident noted to have temp of 102.2, oxygen 95%, pulse 110. Resident alert and oriented at that time and talking to staff. Reported findings to APNP with order to send to ER. 911 called, residents brother updated. Upon EMT arrival RN went down to residents room with EMT and resident had an emesis as resident was getting cleaned up resident went unresponsive. Pulse noted to still be present at that time, resident did briefly respond to sternal rub and then went unresponsive again. Resident full code and EMT transferred to gurney and said that if they lost a pulse in route that they would transfer to hospital B instead of hospital A being the closest facility. RN called brother and gave update. Facility notified from Hospital that resident had passed away.

No prior vaccinations for this event.

BODY TEMPERATURE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Resident getting rehab therapy in the facility and has a long history of Parkinson's Disease. On 01/29/21, he received the COVID vaccine on left deltoid, resident was recently hospitalized due to Pneumonia and was on antibiotic IV and was recently placed on GT feeding due to severe dysphagia from his Parkinson's disease. On 01/31/21, started having increased congestion. On 02/02/21, started having increased temperature and WBC went up >20,000 on 02/03/21, started on Vancomycin IV on 02/04/21 but was transferred to the hospital. Facility was notified today (02/18/21) that resident expired in the hospital.

No prior vaccinations for this event.

BODY TEMPERATURE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE,

No prior vaccinations for this event.

no acute PE.

	BODY TEMPERATURE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
1-25-2021- Phone call: pt had cold and cough prior to vaccine. cough worsened 1-28-2021 Phone call: pt requesting provider visit, cough is same and taking tessalon pearls 1-29-2021 Provider in office visit: pt complain of cough and SOB for 6 days. Getting worse. Temp 101.2, pulse ox 87%, BP 128/70. level of distress- leaning forward to breath. appeared ill. diffuse rales throughout both lung fields, more at bases. Diagnosis Pneumonia due to COVID 19 virus. Sent to ER		No prior vaccinations for this event.

	BODY TEMPERATURE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received Covid Vaccine, noted after 30 mins with labored breathing BP 161/77, HR 116, R 38, T 101.4,		No prior vaccinations for this event.

	BODY TEMPERATURE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021		No prior vaccinations for this event.

	BODY TEMPERATURE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had COVID in Sept. Minimal symptoms. Received 1st dose 1/18 without adverse reactions. Second dose on 2/8-had complaints of arm soreness several days after then appeared in usual state of health. On		No prior vaccinations for

2/14 @ 2 hours after having lunch, patient was found unresponsive with Respirations 60, pulse 130, PO 84%, blood pressure 105/68. Patient with lots of white foam coming out of mouth. Temperature to 101.3. Patient DNR B and family deferred transfer, wanted comfort measures only. Nursing received order for MSIR. Patient continued with temps in 99-100 range with tylenol suppositories. Patient passed on 2/16.		this event.
	BODY TEMPERATURE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received the 2nd dose of the Covid vaccine approximately around 1105 by pharmacy through the pharmacy LTC partnership vaccination program. Resident had no adverse effects until around 8:00 pm she began complaining of body aches, and chills, Tylenol was given at this time. Around 9:30pm resident was sleeping in bed. Around 12:00 am the CNA called nurse into room to assess resident as the resident stated she did not feel good. Temperature at that time was 102.2, and vomiting. RN came to assess @ 1220 am She was noted to be vomiting, diaphoretic, pale and having trouble breathing. Temp was 97.3 after vomting, Pulse 53, Resp 20, o2 sats were 40-45%, unable to obtain Blood pressure, Applied 5 L of oxygen at this time and had LPN call 911 immediately. Resident was repsonsive and able to follow staff members instructions but was only answering yes or no simple questions at the time time of assessment. Paramedics arrived at 0040 and resident was sent to Hospital. @ 0130 ER nurse called to nursing facility to notify resident had coded in the ER and passed away @ 0110.		No prior vaccinations for this event.
	BODY TEMPERATURE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased		No prior vaccinations for this event.

use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

BODY TEMPERATURE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100%

No prior vaccinations for this event.

on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

BONE FRAGMENTATION

COVID19 (COVID19 (MODERNA)) (1201)

On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene when EMS arrived. Autopsy showed a left temporal subdural hematoma.

No prior vaccinations for this event.

	BORDETELLA TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.		No prior vaccinations for this event.
	BRADYCARDIA	**COVID19 (COVID19 (MODERNA)) (1201)**
No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.		No prior vaccinations for this event.
	BRADYCARDIA	**COVID19 (COVID19 (MODERNA)) (1201)**
ON 1/21/2020 RESIDENT WAS EXPERINCING CHILLS AND LOOSE STOOLS. FOLLOWING THIS EPISODE BECAME UNRESPONSIVE, PALE, DIAPHORETIC AND BRADYCARDIC. PALLIATIVE CARE		No prior vaccinations for this event.

WAS PROVIDED. RESIDENT PASSED AWAY APPROX. 10 HOURS LATER.

	BRADYCARDIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presented to ER via EMS at 1556 3 days after receiving vaccine. pt was breathing approximately 50 times a minutes and o2 sats in the 70's upon arrival. NP decided to intubate, Rocuronium and Versed given. Pt became bradycardic and 1 amp of Atropine was given without improvement. No pulse felt, CPR started per ACLS protocol. 7 Epi's given. Time of death- 1632. After TOD pt was swabbed for COVID-19 and the results were positive.		No prior vaccinations for this event.
	BRADYCARDIA	**COVID19 (COVID19 (MODERNA)) (1201)**
6 days after vaccine developed bloody diarrhea. Thought to have ischemic colitis but negative evaluation. became hypotensive bradycardic placed on ventilator. Subsequently was poorly responsive and eventually coded once more and succumbed		No prior vaccinations for this event.
	BRADYCARDIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed		No prior vaccinations for this event.

respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

	BRADYCARDIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.		No prior vaccinations for this event.
	BRADYCARDIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began with vomiting and diarrhea. C/O chest pain. Bradycardia. Hypotension. 2 seizures in 45 minutes after not having one in years. We gave fluids. Gave Zofran. Comfort measures. Pt passed at midnight. Was completely fine one day before. Had minimal issues with COVID though did have a pneumonia that was treated w ATB early on and resolved.		No prior vaccinations for this event.
	BRADYCARDIA	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

No prior vaccinations for this event.

BRADYKINESIA

COVID19 (COVID19 (MODERNA)) (1201)

Since I was not with my husband I can only tell you what was told to me. He walked out of the store toward our car. Someone watched him, concerned, because he was walking very slowly (normally has a slow gait because of leg braces and toe amputations so I don't know if it was unusually slow). The woman saw him fall and she ran to help-administered CPR immediately-and told me he died instantly. Medics tried to resuscitate and failed to bring a pulse. (My husband left our home around 11:15 to drop a package off at

No prior vaccinations for this event.

store. The store is one mile from our home. At around 12:30 a deputy came to my door and when I saw him my knees buckled. I knew something horrible happened.

	BRAIN DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."		No prior vaccinations for this event.
	BRAIN DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Cardiac arrest within 1 hour Patient had the second vaccine approximately 2 pm on Tuesday Jan 12th He works at the extended care community and was in good health that morning with no complaints. He waited 10-15 minutes at the vaccine admin site and then told them he felt fine and was ready to get back to work. He then was found unresponsive at 3 pm within an hour of the 2nd vaccine. EMS called immediately worked on him 30 minutes in field then 30 minutes at ER was able to put him on life support yet deemed Brain dead 1-14-21 and pronounced dead an hour or so later		No prior vaccinations for this event.
	BRAIN HERNIATION	**COVID19 (COVID19 (MODERNA)) (1201)**

From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021

No prior vaccinations for this event.

BRAIN HYPOXIA

COVID19 (COVID19 (MODERNA)) (1201)

Passed away; Found unconscious; Coma; Lack of oxygen to the brain; A spontaneous report was received from a consumer, concerning his mother, a 71-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and passed away, prior to death, patient experienced lack of oxygen to the brain and was found unconscious and went to coma. The patient's medical history reported included seizures. Concomitant medications included phenobarbital, lamotrigine and levetiracetam. On 27 Jan 2021, approximately six days prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (lot number: 030L20A) intramuscularly for prophylaxis of COVID-19 infection. On 01 Feb 2021 at 4 am, the patient was found to be unconscious on the couch, hence she was rushed to the hospital with lack of oxygen to the brain. Later, she went into a coma, hence she was in hospital for 30 hours and then was transferred to a different hospital for a second opinion on 06-Feb-2021, where she was passed away at 02:20 PM. Treatment information was not provided Action taken with mRNA-1273 in response to the events were not applicable. The outcome of events, lack of oxygen to the brain, found unconscious and coma were considered unknown. The outcome of event passed away was fatal as she died on 06 Feb 2021 at 2:20 pm. The cause of death was not provided. Plans for an autopsy were unknown.; Reporter's Comments: This is a case of 71-year-old female subject with a history of seizures who died 6 days after receiving first dose of vaccine. Very limited information has been provided at this time. Further information has been

No prior vaccinations for this event.

requested.; Reported Cause(s) of Death: Passed away

BRAIN INJURY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal tunnel and sent her home. The morning or March 18th , 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.	No prior vaccinations for this event.
BRAIN NATRIURETIC PEPTIDE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/5/2021 resident noted to be azotemic. Creatinine up to 3.8 and BUN in 80's. He was started on NS hydration. On 2/7/2021 he was noted without VS, per MD notes, possible VF arrest, renal failure; death unclear exact cause.	No prior vaccinations for this event.
BRAIN NATRIURETIC PEPTIDE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.	No prior vaccinations for this event.

BRAIN NATRIURETIC PEPTIDE INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29	No prior vaccinations for this event.	
BRAIN NATRIURETIC PEPTIDE INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presents to ER with increased weakness, hypoxia, history of COPD, but not oxygen dependent., hypotension. Acute Kidney failure noted in labs, not previously diagnosed , new hyperkalemia. BP 73/39, HR 67. dopamine initiated, and switched to Levophed. Oxygen Sat 86%, requiring 10 L O2. Transferred from this critical access hospital to another Hospital. Expires later 2-13-2021	No prior vaccinations for this event.	
BRAIN NATRIURETIC PEPTIDE INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).	No prior vaccinations for this event.	
BRAIN NATRIURETIC PEPTIDE INCREASED		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Cardiac Arrest Narrative: No prior vaccinations for this event.

BRAIN NATRIURETIC PEPTIDE INCREASED COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.

No prior vaccinations for this event.

BRAIN NATRIURETIC PEPTIDE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.

No prior vaccinations for this event.

BRAIN NATRIURETIC PEPTIDE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and

No prior vaccinations for this event.

creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

BRAIN NATRIURETIC PEPTIDE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.	No prior vaccinations for this event.

BRAIN NATRIURETIC PEPTIDE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use	No prior vaccinations for this event.

Authorization (EUA)

	BRAIN OEDEMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."		No prior vaccinations for this event.
	BRAIN STEM HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were		No prior vaccinations

lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice, memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200 mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation: tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed, metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by

for this event.

mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral

patchy opacities

BRAIN STEM SYNDROME	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice, memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200 mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation: tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed,	No prior vaccinations for this event.

metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional

information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral patchy opacities

BREATH SOUNDS ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

"The patient came to the Emergency Room at approx 3:30 am on 02/03/2021 with pain in right arm (same arm the COVID vaccine had been administered in approx 12 hours earlier) and feeling generally unwell. Patient was concerned about possibility of gout flare or that something was wrong with her arm. Elevated blood pressure was noted; this was attributed to anxiety. She was evaluated, given 500 mg Tylenol, and discharged since the pain was decreasing and blood pressure was stabilized. Patient instructed to follow-up with physician. The next day, on 02/04/2021, the patient arrived at the Emergency Room by ambulance; cardiac arrest was the chief complaint. The patient's daughter stated the patient had been ""feeling generally poor and then suddenly collapsed."" Daughter described ""gurgling respirations"" and being unresponsive. 911 was called, police arrived within 5 minutes and initiated CPR. Epinephrine, atropine, lidocaine and bicarb administered after arrival to Emergency Room. Shockable rhythm never demonstrated. Patient never recovered spontaneous respiration or movement. The death was called at 23:04. Coronary artery disease with cardiac arrest is the cause from the ER records; the coroner is putting COVID-19 vaccination in Part 1 of the death certificate."

No prior vaccinations for this event.

BREATH SOUNDS ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

3:07 pm lung sounds diminished oxygen sats 68%, oxygen applied Oxygen sats remained low for next 36 hours (patient on Hospice care) expired 6:22 am 1-8-21	No prior vaccinations for this event.
BREATH SOUNDS ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021	No prior vaccinations for this event.
BREATH SOUNDS ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
REPORTING ONLY AS RESIDENT EXPIRED ON 1/17/2021 3 DAYS AFTER. S/S HYPOXIA/CONGESTED LUNG SOUNDS	No prior vaccinations for this event.
BREATH SOUNDS ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After being observed for approximately 20 minutes and patient walked to her car without assistance I was called to assess the patient in the parking lot for troubles breathing. EMS was called as I made my way outside. Upon my arrival patient was leaning out of the car and stating that she could not breath. She was able to tell me that she was allergic to penicillin. Oxygen was immediately placed on the patient with minimal relief. Lung sounds were coarse throughout. She then began to vomit about every 20-30 seconds. Epipen was administered in the right leg with no relief. Patient continued to complain of troubles breathing and vomiting. A second epipen was administered in the patients right arm again with no relief. A few minutes later patient was given racemic epinephrine through the oxygen mask. There appeared to be mild improvement in her breathing as she appeared more comfortable, but still complaining of shortness of	No prior vaccinations for this event.

breath and vomiting. When EMS arrived patient was unable to transport herself to the stretcher. When EMS and clinical staff transferred patient to the stretcher she became unresponsive. She appeared to still be breathing. She did not respond to verbal stimuli. Per ED report large amount of fluid was suctioned from the patients lungs following intubation in the ambulance. When patient arrived to the ED she was extubated and re-intubated without difficulty and further fluid was suctioned. At that time patient was found to be in PEA, shock was delivered. Shortly thereafter no cardiac activity was found and patient pronounced dead.

BREATH SOUNDS ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
He started vomiting 2 days later. we suspect he was having stool issues as well. he vomited blood at some point over the weekend. there was black vomit right before he passed. from 2am-6am he was wheezing and rattling and then he passed at approximately 6am 3/1/2021 at home. EMS did come and try to revive him and were unsuccessful.	No prior vaccinations for this event.
BREATH SOUNDS ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6	No prior vaccinations for this event.

mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (

BRONCHIAL SECRETION RETENTION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."	No prior vaccinations for this event.

BRONCHOSCOPY ABNORMAL	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and	No prior vaccinations for this event.

tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"		
BULBAR PALSY		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.		No prior vaccinations for this event.
BUNDLE BRANCH BLOCK LEFT		**COVID19 (COVID19 (MODERNA)) (1201)**
2/7/2021 at 0630, resident found in recliner without pulse or respirations. Resident had not been found		No prior vaccinations for this

to have any adverse reactions to the vaccine between the time of the vaccine on 2/4 until found deceased on 2/7.	event.	
BUNDLE BRANCH BLOCK RIGHT		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/9/2021 observed with elevated respirations of 38-42 per minute, BP manually 72/50. pulse is jumping rapidly between 110-16 bpm. oxygen sat 76% RA, resident refusing oxygen at first attempt, allowed oxygen to be placed, is now 84% on 4L. resident shaking head yes that he is hurting, and yes that he would take medication for pain. Dr. notified, branch block. Received order for morphine 2mg per hr as needed for elevated respirations and pain. Dr. also gave orders to D/C Tamsulosin and finasteride. Resident continue with decreased O2 sats and elevated respirations. Absence of vital signs on 1/10/21 at 826PM.	No prior vaccinations for this event.	
C-REACTIVE PROTEIN INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.	No prior vaccinations for this event.	
C-REACTIVE PROTEIN INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up	No prior vaccinations for this event.	

with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.

C-REACTIVE PROTEIN INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.

No prior vaccinations for this event.

C-REACTIVE PROTEIN INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.

No prior vaccinations for this event.

C-REACTIVE PROTEIN INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Pt presents to ER with increased weakness, hypoxia, history of COPD, but not oxygen dependent., hypotension. Acute Kidney failure noted in labs, not previously diagnosed , new hyperkalemia. BP 73/39, HR 67. dopamine initiated, and switched to Levophed. Oxygen Sat 86%, requiring 10 L O2. Transferred from this

No prior vaccinations for this event.

critical access hospital to another Hospital. Expires later 2-13-2021

C-REACTIVE PROTEIN INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).		No prior vaccinations for this event.

C-REACTIVE PROTEIN INCREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-		No prior vaccinations for this event.

dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in

setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

C-REACTIVE PROTEIN INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.

No prior vaccinations for this event.

C-REACTIVE PROTEIN NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

No prior vaccinations for this event.

C-REACTIVE PROTEIN NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the

No prior vaccinations for this event.

emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

CARBON DIOXIDE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
CARBON DIOXIDE DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.		No prior vaccinations for this event.
CARBON DIOXIDE DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.		No prior vaccinations for this event.
CARBON DIOXIDE DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
CARBON DIOXIDE DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506	No prior vaccinations for this event.
CARBON DIOXIDE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities,	No prior vaccinations for

c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper this event.

lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

CARBON DIOXIDE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
CARBON DIOXIDE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.	No prior vaccinations for this event.
CARBON DIOXIDE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

No prior vaccinations for this event.

CARBON DIOXIDE NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

"Patient had COVID vaccination on 2/3 with no adverse s/s before leaving unit. Upon coming to treatment Friday 2/5 he reported to the RN that he had fallen on thursday 2/4 due to ""getting up fast"" did not hit head or hurt anything per RN discussion. Began treatment without difficulty. About 3/4 way through

No prior vaccinations for this event.

treatment was talking with staff and became unresponsive - code was called and pt expired after 30 minute resuscitation efforts."

CARBON DIOXIDE NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.

CARBON DIOXIDE NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	No prior vaccinations for this event.

CARBON DIOXIDE NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.

CARBON DIOXIDE NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures

No prior vaccinations for this event.

consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

CARBOXYHAEMOGLOBIN DECREASED **COVID19 (COVID19 (MODERNA)) (1201)**

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

Two days post vaccine patient went into cardiac arrest and passed away. No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were

No prior vaccinations for this event.

she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.

CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient was found ""acting abnormal"" on 1/9/2021 at 1215. VS HR 20-30's. EMS activated. EMS arrived and patient was found pulseless in PEA/ asystole, CPR and ACLS initiated and then transported to the MC. Unsuccessful resuscitation and expired on 1/09/2021 at 1348. Clinical impression Cardiopulmonary arrest."	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient suffered a cardiac arrest and was unable to give details about her symptoms. Per husband, patient did not complain of any symptoms after vaccine administration. She began seizing without warning which was complicated by cardiac arrest of uncertain etiology	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to our Emergency Department via EMS in full code status; asystole. Patient expired. Per nursing, husband stated patient awoke this AM and reported pain in back between shoulders and in bilateral shoulders. Patient then went unresponsive and husband called EMS.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient had severe shortness of breath resulting in cardiac arrest on the 5th day after the vaccine. Shortness of breath started 12 hours after injection. On the 5th day, the patient was discovered to also have	No prior vaccinations

a rash throughout his body, but it is unknown when this rash started.

for this event.

CARDIAC ARREST

COVID19 (COVID19 (MODERNA)) (1201)

Presented to Urgent Care for weakness and confusion, transferred to ED, patient had a cardiac arrest and was unable to be resuscitated

No prior vaccinations for this event.

CARDIAC ARREST

COVID19 (COVID19 (MODERNA)) (1201)

Narrative: Symptoms: & Cardiac Arrest; Death Treatment: EPINEPHRINE No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

Cardiac arrest Narrative: No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

My dad got the Moderna Vaccine on Tuesday, January 12, 2021 in his left arm at the Mall injection site for the Health Department. He was told that the side effects could mean his arm hurting, tiredness, headache, and even a low grade fever. Additionally, the site informed us both (as I was with him to get the injection) that this was all normal and not to seek medical attention unless these symptoms last longer than 72 hours. That evening, my dad was experiencing all of those symptoms, and went to bed at 7pm. A little after 10am on Wednesday, January 13, 2021, when he awoke, my dad went to the bathroom vomiting. This was where he collapsed and went into cardiac arrest. Fire/Rescue was dispatched about 10:30am after my mom started CPR. County Fire Rescue EMTs and Paramedics continued CPR and other attempts at reviving him all the way to Hospital Emergency Department. He was pronounced dead at 12:14pm on Wednesday, January 13, 2021. We have no doubt my dad, following the instructions of the injection facility, thought he was just

No prior vaccinations for this event.

experiencing the side effects of the vaccine. He had no chance. Had this injection been done in the RIGHT arm, perhaps he could have recognized the arm numbness being that of an impending heart attack. We really miss Dad. He served this country with distinction for over 50 years, and we believe his country failed him.

	CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
"Pt. woke up the next morning after vaccination and ""didn't feel well"", described by wife as fatigue, no energy. At approximately 2 PM, he vomited. His wife checked on him at 4:20 PM and he wasn't breathing sitting in his chair. EMS squad was called but when they arrived he was asystole and mottling present. Did not start CPR since he was already gone too long. Pronounced by coroner on scene."		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
CARDIAC ARREST THAT LEAD TO DEATH - IT WAS REPORTED BY EMS THAT THE PT HAD RECEIVED THE VACCINE ABOUT 30 MINS PRIOR. HE ARRIVED HOME, BECAME SHORT OF BREATH & COLLAPSED. 911 WAS CALLED AND HE WAS TRANSPORTED VIA EMS TO HOSPITAL (16:17) WHERE HE LATER EXPIRED (23:01).		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
sudden cardiac arrest No prior vaccinations for this event.		
CARDIAC ARREST COVID19 (COVID19 (MODERNA)) (1201)		
Patient presented to the Emergency Department complaining of chest pain, pale, cool diaphoretic, and hypotensive. The patient was discovered to have a large saddle pulmonary embolism, went into cardiac arrest		No prior vaccinations

and expired. Of note, the patient received her second Moderna COVID vaccine on 1/23, which would place her first one approximately 12/25 if she received them at the appropriate interval. This information is from the patient's daughter and the ED record, the information is not available in CAIR. Per the daughter, the patient started feeling ill on 1/21, improved on 1/25, and then acutely worsened on 1/27, resulting in the ED visit.	for this event.
CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless and breathless and was pronounced. Autopsy currently pending.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
93 y/o with complex medical history (severe COPD on oxygen, diastolic CHF, CKD3, myelofibrosis, marginal zone lymphoma of spleen with recent progression and no active treatment, chronic anemia, afib, CAD, pulmonary artery hypertension, h/o bladder cancer, hypertension, hypothyroidism, h/o bilateral PE, sick sinus syndrome s/p pacemaker, h/o Hodgkin's disease). Has had multiple hospitalizations over the last 3 months for dyspnea, most recently in 12/2020. Enrolled in palliative care. Has had multiple transfusions (most recently 01/13/21) for his chronic anemia due to myelofibrosis, and recently started on darbepoetin. No documented history of anaphylaxis to medications or prior vaccinations. He received COVID19 vaccine (Moderna) on 01/16/21. He passed away suddenly at home on 01/17/21. Symptoms: & cardiac arrest Treatment:	No prior vaccinations for this event.

CARDIAC ARREST	COVID19 (COVID19 (MODERNA)) (1201)
Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021and felt poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM CHLORIDE 1000 MG ONCE	No prior vaccinations for this event.

CARDIAC ARREST	COVID19 (COVID19 (MODERNA)) (1201)
Cardiac arrest; Pain on her upper right chest; Lot of pain in lower abdomen; Pain underneath arm; Thought it was muscle aches; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed upper right chest pain and underneath the arm, severe abdominal pain, muscle aches and cardiac arrest. The patient's medical history was not provided Concomitant product use was not provided by the reporter. On 14 Jan 2021, approximately five days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the arm for prophylaxis of COVID-19 infection. On 19 Jan 2021, the patient developed upper right chest pain and pain underneath the arm. They thought it was muscle aches. Sometime later, the patient developed a lot of pain in the lower abdomen. The called emergency services and an ambulance arrived but the patient then suffered cardiac arrest. Treatment for the event included tramadol. Action taken with mRNA-1273 in response to the events was not applicable due to the patient was died. The patient died	No prior vaccinations for this event.

on 19 Jan 2021. The cause of death was reported as cardiac arrest. Autopsy were not provided.; Reporter's Comments: Company Comment: This case concerns a 92-year-old female patient who experienced unexpected serious events of cardiac arrest, upper right chest pain and underneath the arm, severe abdominal pain, muscle aches. The event occurred 5 days after the administration of the first dose of the vaccine mRNA-1273 vaccine (Lot #: unknown, expiration date-unknown). Although a temporal association exist between the events and the administration of the vaccine, in the absence of critical details such as the patient's medical history, any diagnostic test or autopsy result, adequate evaluation and assessment cannot be established. Main field defaults to æpossibly related' for all events.; Reported Cause(s) of Death: Cardiac arrest		
	CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
"85 year old patient with multiple medical problems. PEA/asystolic arrest 5 days after receiving vaccine, hospitalized. Patient died on 2/1/2021. It is not clear whether the vaccine administration led to the patient's death or not. ""...healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event)"""		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was seen at 0710 he was sleeping but at normal cognitive behavior Patient was again assessed at 0720 where he was noted to be unresponsive, BP 180/100s, HR 230s, he was a DNR therefore not CPR was administered. EMS arrived at facility patient was noted to be in full cardiac and respiratory arrest. Time of death 0735		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**

CARDIAC ARREST, DEATH Narrative: The patient presents to the emergency department in cardiopulmonary arrest. CPR was continued upon arrival. The Combi tube was removed and an endotracheal tube was placed without complications. ROSC was obtained multiple times but the patient continued to go into PEA. The patient was seen in the emergency department by both critical care and Cardiology. EKG shows ST elevations, but the patient was unstable to go to catheterization. The patient had 1 episode of asystole. Despite best efforts and multiple attempts we were unable to resuscitate the patient. Time of death 1253 on 1/24/21.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Received Covid vaccine in am. Last seen by family at 17:30 pm and observed to be well. About an hour later he collapsed, unresponsive. A 911 call was initiated at 18:29. Paramedics arrived to find the patient in cardiac arrest. CPR/ACLS was initiated, but resuscitation was unsuccessful. Pt. was transported to MC where he was pronounced dead at 19:32. There was no sing of an injection site reaction, nor of allergic reaction..	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Cardiac arrest resulting in death on the third day post vaccine administration, 0224. Reported syncopal event post toileting. Rescue measures attempted but not successful. Time of death 0358, 02/06/2021.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Sudden death 2/7/21 @ 0309 Started acute encephalopathy & required intubation Soon after intubation went into cardiac arrest Likely severe acidosis.	No prior vaccinations for this event.

	CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient found down at home with agonal respirations and per EMS asystole, received 2 rounds of epi at her house with return of spontaneous pulses, lost pulse again in route to ER and another round of epi was given, CPR in progress when arrived at hospital. Prior to this patient's husband states he heard her fall in the bathroom but did not immediately check on her as he states that this has happened before. He checked on her 10 min later and that's when he found her unconscious. Daughter called 911 and she began CPR. No previous complaints of headache, chest pain, back pain, fever or chills. Husband states patient was drinking that evening which is not unusual for her. Patient died at hospital.		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
He had not been feeling well after his second Covid vaccination (on 01/23/2021) and was found unresponsive in his room at the nursing home (late evening on 02/02/2021). He was taken to a hospital where they did tests and he had pneumonia and kidney failure, but he was being transferred to a larger hospital when he arrested and died (02/03/2021)		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to		No prior vaccinations for this event.

asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.

CARDIAC ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

the following morning the patient became unresponsive while taking a shower, became asystolic and died despite about an hour of ACLS and 8 rounds of epi

No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

Patient died of cardiac arrest on 01/21/2021 No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

Patient had the first Moderna Covid vaccine on Thursday 1/21/2021. She had a bit of sore arm on that day and the day after. On Saturday 1/23/2021, she had a fever of 100.5 F (11AM), nausea, light headache and chills. The temperature went down after she took ibuprofen. Patient's husband enrolled her to V-Safe to report all the adverse effects she experienced. On Sunday 1/24/2021, her temperature was 98.3F. She still had nausea and no appetite. She and her husband watched a football game in their bedroom upstairs. Husband noticed that his wife was pacing around the room many times. At 7Pm, Husband went downstairs for dinner but she refused to come down to eat. He went upstairs around 8pm, TV was still on. He turned off TV and went down stairs again thinking his wife felt as sleep while watching TV. He went back upstairs for bed around 10:30 PM. Husband said his wife had a deviated septum so she would snore very loudly when asleep. He didn?t hear her snoring so he went to check on her and found her not responsive. Husband called emergency services. Paramedic came at 10:45 and said patient was passed. Husband sent many texts to V-safe after that to report the incident. No response was received from V-safe. Patient?s doctor told her husband that she died due to cardiac arrest.

No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

Received first 1/15/2021 with no adverse reaction. Received 2nd dose 2/9 @ 0846 with no adverse reaction or report of feeling ill. Traveled to store and arrived approx. 2 hours after receiving vaccine. Daughter stated patient felt well and had to go to the restroom to have BM. Collapsed in bathroom. Transported by ambulance to Hospital @ 1439 in cardiac arrest. Was in PEA and went in v fib back to PEA. Resuscitation efforts initiated and patient expired with time noted at hospital records at 15:11. No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

Developed vomiting, seizure and cardiac arrest, V Fib No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

Vaccine given in clinic per protocol - patient monitored for 15 minutes, no adverse reactions noted at the time. Patient stated he felt fine following 15 minute monitoring time. Patient left facility- it was later reported that pt had a fall at home. Upon review of pt's medical record - Pt's wife had to initiate CPR and call EMS for transportation and life saving measures enroute to the Emergency Room. Pt was intubated as pt was in asystole upon arrival to the ER, ACLS was continued, pt was noted to have a traumatic brain injury from his fall at home, and pt was pronounced dead at 1620. No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

Short version The patient has long-standing health issues. The patient received the first dose of Moderna COVID-19 vaccine on 1/16/2021 (unknown location). The patient suffered an event in his home on 1/24/2021. CPR and treatment was begun and he was transported to the ED. He was pronounced dead in the ED at No prior vaccinations for this event.

0846. Long version 70-year-old male with past medical history of CAD with pacemaker, A. fib, COPD, hypertension/hyperlipidemia presenting in cardiac arrest. 911 call at 0724. Per EMS, patient was witnessed by family to have seizure-like activity and then collapsed and became unresponsive. Patient was noted by family to be pulseless and CPR was started right away. Patient received two doses of epi by police were on scene first (AED defibrillation x2) and six doses of epi (plus 6 more AED shocks) by EMS when they arrived. Patient had CPR performed for 45 minutes prior to arriving at the hospital. On route, patient had episodes of paced rhythm and V. fib. Patient received one amp of bicarb and one amp of calcium en route. Patient also received 300 mg of amiodarone en route. Arrived in ED at 0810 Patient received ongoing compressions, shocks and additional medications (epinephrine x6, lidocaine IV, sodium bicarbonate) until time of death called at 0846 in the ED.

CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.	No prior vaccinations for this event.

CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped	No prior vaccinations for this event.

with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive MI, PE or ruptured AAA"". Death certificate notes indicate ""signficant conditions contributing to death after cardiac arrest; ASCVD""."

	CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Per EMS/Hospital report patient had difficulty breathing and cardiac arrest with prolonged CPR (greater than 45 mins in the ER) who was resuscitated. Family subsequently arrived including son and daughter and all family members were in the ER room are in agreement that patient would not want further aggressive cares given her extremely poor prognosis in light of chronic debilitation with numerous medical issues and now a very long period of CPR. Hospital Course After updating family they stated patient would not want further aggressive cares given her grim prognosis and chronic severe and debilitating medical issues. She continued to have myoclonic jerking. She was extubated to comfort cares in the ER and did not pass immediately therefore brought to a room. She received comfort cares and passed away at 0450 with family present.		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient fell the day after receiving the Moderna COVID-19 vaccine. She broke her hip in this fall. During surgery to correct the broken hip, she went in to sudden and unexpected cardiac arrest. The anesthetist did not notice any ST changes or A fib; dysrhythmia was very unexpected. The patient had a DNR. She died at 13:00 on 02/07/2021. Causes of death are listed as 1. Cardiac Arrest 2. Recent hip fracture with hip placement 3. History of Breast Cancer 4. Hypothyroid and 5. Dementia		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
"The patient came to the Emergency Room at approx 3:30 am on 02/03/2021 with pain in right arm (same		No prior vaccinations

arm the COVID vaccine had been administered in approx 12 hours earlier) and feeling generally unwell. Patient was concerned about possibility of gout flare or that something was wrong with her arm. Elevated blood pressure was noted; this was attributed to anxiety. She was evaluated, given 500 mg Tylenol, and discharged since the pain was decreasing and blood pressure was stabilized. Patient instructed to follow-up with physician. The next day, on 02/04/2021, the patient arrived at the Emergency Room by ambulance; cardiac arrest was the chief complaint. The patient's daughter stated the patient had been ""feeling generally poor and then suddenly collapsed."" Daughter described ""gurgling respirations"" and being unresponsive. 911 was called, police arrived within 5 minutes and initiated CPR. Epinephrine, atropine, lidocaine and bicarb administered after arrival to Emergency Room. Shockable rhythm never demonstrated. Patient never recovered spontaneous respiration or movement. The death was called at 23:04. Coronary artery disease with cardiac arrest is the cause from the ER records; the coroner is putting COVID-19 vaccination in Part 1 of the death certificate."	for this event.	
CARDIAC ARREST		**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.	No prior vaccinations for this event.	
CARDIAC ARREST		**COVID19 (COVID19 (MODERNA)) (1201)**

Patient collapsed and could not be revived. There was no prior warning. She was otherwise in good condition for her age. The death was listed as probable cardiac arrest but no autopsy was performed. Since it occurred so close to the vaccine shot I thought someone may want to know.	No prior vaccinations for this event.	
CARDIAC ARREST		**COVID19 (COVID19 (MODERNA)) (1201)**
unknown if related to vaccine. patient received 2nd vaccine at 0830, observed 15 minutes, discharged, arrested at 0915 upon entering her home. vaccine was administered by DOH at their community location. patient was pronounced lifeless in the ED.	No prior vaccinations for this event.	
CARDIAC ARREST		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was found unconscious without a pulse. Patient remained in asystole without pulse or respirations despite CPR.	No prior vaccinations for this event.	
CARDIAC ARREST		**COVID19 (COVID19 (MODERNA)) (1201)**
"Was given vaccine around 1:30Pm on 2-11-2021. He and his wife waited in the building for 15 minutes and then left. he denied complaint. (He was waiting to have both Covid shots before he went to cardiologist Re: CAD.) He had an alarm going off in his house, was going to basement to check it out. Police officer heard alarm, came into house, & heard a thud when Doc fell. He was in PEA (Pulseless Electrical Activity) when brought into ER. Given 5 ""rounds of Epinephrine with no response."	No prior vaccinations for this event.	
CARDIAC ARREST		**COVID19 (COVID19 (MODERNA)) (1201)**

Patient passed away Saturday at 14:04pm. Patient's wife reports his death was sudden, he passed away sitting in his chair his heart just stopped she said. They tried to perform CPR, 911 was called and paramedics arrived at the scene and he was given medication but never had any return of vital signs and so his death was called at the scene. Wife reports he was not ill, did not have any symptoms prior to the event. They are not going to be doing a autopsy. She wanted us to know based on timing that there may be some possible correlation with his COVID19 vaccine. He obtained the vaccine on 02/09/2021 - wife reports he had no symptoms, not even arm soreness after the vaccine. Had no fever, shortness of breath. Did not complain of chest pain. We can update chart to reflect the patient is deceased and lets make a card for the family.

No prior vaccinations for this event.

CARDIAC ARREST

COVID19 (COVID19 (MODERNA)) (1201)

Per family, patient has been feeling sick since he was vaccinated, patient went to ER on 02/15/2021, and after few hours at ER patient passed away.

No prior vaccinations for this event.

CARDIAC ARREST

COVID19 (COVID19 (MODERNA)) (1201)

While at counseling appointment on February 17 patient had witnessed sudden cardiac arrest and was not able to be resuscitated. She was pronounced dead at 12:09. At the time of death her glucose was about 500.

No prior vaccinations for this event.

CARDIAC ARREST

COVID19 (COVID19 (MODERNA)) (1201)

cardiac arrest, death: 2/21/21 No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

On January 1, 2021, patient was admitted to Medical Center with COVID. Tested positive on January 2, 2021. Spent 10 days in hospital. Once recovered from pneumonia and fever gone, on January 10, 2021, she was transferred to Rehabilitation Center for continued treatment. She spent 16 days there. She developed UTI and CDIF infections and was on/off oxygen. She started physical therapy. She was scheduled to be released to go home on January 27, 2021. On January 26, 2021, the day before going home, Rehabilitation Center gave her the Moderna vaccine. On January 27, the day she went home, she started feeling very weak and couldn't walk. My dad tried lifting her and they both fell to the ground. My dad called 911 and she was taken to Medical Center, with high fever and possible stroke symptoms (which later was negative). Two days later, she had difficulty breathing and was put on a ventilator. She was on a ventilator for about three days. They took it off and she slowly started recovering. The doctors did all kinds of tests (blood clot in lung, heart, etc.) and all was negative. The only thing they could trace it to was an adverse reaction to the vaccine. After spending 11 days at hospital and treating her for various infections, her heart stopped and she passed away suddenly.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
"""Feeling Hot"" without fever and nausea 10 hours post vaccine and resolved within 1 hour. Seizure, Hypotension, Unresponsive followed shortly by cardiac arrest and pulseless electrical activity 21 hours post vaccine. Pronounced dead 22 hours post vaccine"	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
2-24-21 patient with development of cough, fatigue, increasing on chronic disability worsening debility and falls. scheduled for office visit 2-25.21 0900 call from spouse 0210 am patient was not breathing and lvad alarming low flow alarm on arrival of ems confirm asystolic not breathing and dead	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19**

(MODERNA)) (1201)

Cardiac Arrest No prior vaccinations for this event.

CARDIAC ARREST COVID19 (COVID19 (MODERNA)) (1201)

My grandpa got his second covid vaccine on Thursday. Saturday he complained of stiff neck. Sunday he had low grade fever, nausea and vomiting, chills, and mild headache. He was feeling bad enough to call squad at 3 pm. The paramedics did evaluation and thought he was just experiencing normal side effects from vaccine and felt no need to transport to hospital so my grandpa decided to stay home and just rest. At 2 am that same night he went into cardiac arrest and was not able to be brought back

No prior vaccinations for this event.

CARDIAC ARREST

COVID19 (COVID19 (MODERNA)) (1201)

No pulse and no heart beat; couldn't wake him up; passed away; A spontaneous report was received from a daughter concerning a 84-year old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) experienced no pulse or heartbeat, couldn't wake him up and passed away. The patient's medical history, as provided by the reporter, included high blood pressure and prostate cancer. No relevant concomitant medications were reported. On 19 Jan 2021, the patient had a blood pressure reading of 133/84 at a cardiology visit. On 13 Feb 2021, approximately 3 hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (batch number 031M20A) intramuscularly for prophylaxis of COVID-19 infection. On 13 Feb 2021 at 3:30 pm, the patient could not be woken up and was found with no pulse or heartbeat. Action taken with the drug in response to the events was not applicable. The outcome of the events, no pulse or heartbeat and couldn't wake him up, were not provided. The patient died on 13 Feb 2021. The cause of death was unknown.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. The patient's medical history of high blood pressure and prostate cancer remains the risk factors. The cause of death was unknown. Further information has been requested.;

No prior vaccinations for this event.

Reported Cause(s) of Death: Unknown cause of death

CARDIAC ARREST

COVID19 (COVID19 (MODERNA)) (1201)

Unwitnessed Cardiac arrest. ACLS protocols were performed. Cessation of resuscitation was called in the field by Dr.

No prior vaccinations for this event.

CARDIAC ARREST

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident received vaccine per pharmacy at the facility at 5 pm. Approximately 6:45 resident found unresponsive and EMS contacted. Upon EMS arrival at facility, resident went into cardiac arrest, code initiated by EMS and transported to hospital. Resident expired at hospital at approximately 8 pm

No prior vaccinations for this event.

CARDIAC ARREST

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.

No prior vaccinations for this event.

CARDIAC ARREST

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
coughing up blood, significant hemoptysis -- > cardiac arrest. started day after vaccine but likely related to ongoing progression of lung cancer	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The patient had an apparent cardiac arrest on 12/23/20 and was admitted to the ICU. He was taken off of life support on 12/30/20. He had known cardiac disease.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Three hours after receiving COVID 19 vaccination, Patient oxygen level decreased to a critical level and went into cardiac arrest. Staff performed full code but was unable to bring back patient from cardiac arrest.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Cardiac Arrest; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; Patient was found pulseless and breathless 20 minutes following the vaccine administration.;	No prior vaccinations

This is a spontaneous report from a contactable other healthcare professional (HCP). A 66-year-old female patient (pregnant at the time of vaccination: no) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284) via intramuscular at left arm on 11Jan2021 12:15 PM at single dose for COVID-19 immunization. Medical history included diastolic CHF, spinal stenosis, morbid obesity, epilepsy, pulmonary hypertension and COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19). The patient received medication within 2 weeks of vaccination included amiodarone, melatonin, venlafaxine hydrochloride (EFFEXOR), ibuprofen, aripiprazole (ABILIFY), lisinopril, cranberry capsules, diltiazem, paracetamol (TYLENOL), famotidine, furosemide (LASIX [FUROSEMIDE]), ipratropium bromide, salbutamol sulfate (IPRATROPIUM/ALBUTEROL), buspirone, senna alexandrina leaf (SENNA [SENNA ALEXANDRINA LEAF]), polyethylene glycol 3350 and morphine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient used took Penicillin, propranolol, quetiapine, topiramate, Lamictal and had allergy to them. Patient used took the first dose of BNT162B2 (lot number: EJ1685) via intramuscular at right arm on 21Dec2020 12:00 PM at single dose for COVID-19 immunization. Since the vaccination, the patient been tested for COVID-19 (Sars-cov-2 PCR) via nasal swab on 06Jan2021, covid test result was negative. Patient was found pulseless and breathless 20 minutes following the vaccine administration (11Jan2021 12:30 AM). MD found no signs of anaphylaxis. Patient died on 11Jan2021 12:30 AM because of cardiac arrest. No treatment received for the events. Outcome of pulseless and breathless was unknown. the autopsy was performed, and autopsy remarks was unknown. Autopsy-determined cause of death was unknown. It was reported as non-serious, not results in death, Life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.; Sender's Comments: Based on the available information this patient had multiple underlying medical conditions including morbid obesity, diastolic CHF, epilepsy, pulmonary hypertension and COVID-19 diagnosed prior to vaccination. All these conditions more likely contributed to patients cardiac arrest resulting in death. However, based on a close temporal association (""Patient was found pulseless and breathless 20 minutes following the second dose of BNT162B2 vaccine administration, contributory role of BNT162B2 vaccine to the onset of reported events cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part for this event.

of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Cardiac arrest; Autopsy-determined Cause(s) of Death: autopsy remarks was unknown. Autopsy-determined cause of death was unknown"

	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
54 y/o M with PMH of HTN, HLD, Alcoholic Cirrhosis, Aortic Valve Stenosis, and angina BIBA as a Medical Alert for cardiac arrest noted PTA. Per EMS, the patient called because he was having constant, diffuse abdominal pain x 1 day that radiated to his chest. On scene, the patient had a witnessed arrest with EMS starting CPR. He was given 3 rounds of epi without ROSC. Pt had no associated shockable rhythm. Of note, pt's wife, had noted pt had received covid vaccine the prior day.		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On day due for 2nd dose, Patient was found unresponsive at work in the hospital. Patient pupils were fixed and dilated. Full ACLS was initiated for 55 minutes with multiple rounds of bicarb, calcium chloride, magnesium, and epinephrine. Patient was intubated. Patient continued into V. Fib arrest and was shocked multiple times.		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident expired on 12/30/20, dx cardiac arrest. No prior vaccinations for this event.

CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Cardiac arrest within 1 hour Patient had the second vaccine approximately 2 pm on Tuesday Jan 12th He works at the extended care community and was in good health that morning with no complaints. He waited 10-15 minutes at the vaccine admin site and then told them he felt fine and was ready to get back to work. He then was found unresponsive at 3 pm within an hour of the 2nd vaccine. EMS called immediately worked on him 30 minutes in field then 30 minutes at ER was able to put him on life support yet deemed Brain dead 1-14-21 and pronounced dead an hour or so later		No prior vaccinations for this event.
CARDIAC ARREST		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.		No prior vaccinations for this event.
CARDIAC ARREST		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
She had the first dose of Pfizer vaccine at the Campus on Friday 1/15 at 4:30 pm. After the vaccine, she had no new symptoms or signs of vaccine reaction and MD friend reports that he checked her pulse which was not elevated from baseline. On 1/16, she awakened and continued to feel at her recent baseline. However, in the early afternoon, she complained of headache, nausea/epigastric pain, and chest		No prior vaccinations for this event.

heaviness. These apparently were not unusual symptoms for her to feel intermittently. Per her niece, who has a home O2 sat device, her 02 sat that morning was 97 with a HR of 87 irregularly irregular. She was afebrile. (continue on page 2)

	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient developed 104.4 temp approximately 48 hours after being given the vaccine. I treated him with antibiotics, IV fluids, cooling methods. CXR does show a new right perihilar infiltrate. However, his fever came down within the next 24-48 hours. Unfortunately, he suffered a cardiac arrest on 1/21/21 in the early morning and expired.		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

This is a 94-year-old male who is brought in by ambulance after being found on the floor with unknown downtime. He was in asystole upon EMS arrival. He remains in asystole. No advanced airway is in place. The patient is getting compressions from Lucas device upon arrival. It was reported that he was last talked to by family at 2 PM. The patient got his SARS-CoV-2 vaccination this morning. The patient is evaluated emergently. CPR was ongoing with 3 rounds of epinephrine given. The patient remains in asystole. He has rigor mortis. The patient's pupils are fixed and dilated. The patient has compressions paused and ultrasound is used to evaluate for cardiac activity. None is detected. The patient has no electrical activity on monitor. The patient's time of death is 2113.

No prior vaccinations for this event.

CARDIAC ARREST

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Cardiac Arrest Narrative: No prior vaccinations for this event.

CARDIAC ARREST COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

reported causes of death :circulatory collapse; asystole; reported causes of death :circulatory collapse; asystole; This is a spontaneous report from a Pfizer-sponsored program received from the Regulatory Authority-WEB GB-MHRA-WEBCOVID-20201214111558, satety Report unique Identifier GB-MHRA-ADR 24542972 and EU-EC-10007191566 received via Regulatory Authority 908245. A contactable pharmacist and three consumers reported that an adult female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 13Dec2020 at a single dose for COVID-19 vaccination. The patient's medical history was not reported. Concomitant medications included acetylsalicylic acid, amiloride HCl, allopurinol, desogestrel, furosemide, levothyroxine, sildenafil, and spironolactone. The patient experienced circulatory collapse and asystole on 13Dec2020. The patient died due to asystole and circulatory collapse on 13Dec2020. It was unknown if an autopsy was performed. No follow-up attempts are possible, information about lot/batch number cannot be obtained. No

No prior vaccinations for this event.

further information Is expected.; Sender's Comments: The information available is limited and does not allow a meaningful case evaluation. However, based solely on a close chronological association (same day) a causal relationship between events circulatory collapse and cardiac arrest and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: reported causes of death :circulatory collapse; asystole; reported causes of death :circulatory collapse; asystole

CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
decedent had shortness of breath and hypoxia, cardiac arrested in front of the EMS crew, ACLS initiated, arrived in the Hospital ED asystole and pronounced dead	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"CC:full arrest HPI:HPI and ROS limited due to patient's condition. History is via EMS, medical record, and son. Per Son patient had Covid vaccine on Saturday morning. Slept all day Sunday. Woke up Sunday night a bit ""like coming out of a deep sleep per son, around 10 pm. Shortly after that patient was having a hard time breathing. Emergency called. Arrested around the time EMS arrived. King airway, I/O and CPR initiated. Patient has been in v fib. Was shocked multiple times, given 4 rounds of epi, bicarb and amiodarone. ACLS continued on arrival. Multiple rounds of epi, and attempted defib. Patient given epi, bicarb. Rhythms included fine v fib, asystole, and PEA. Unrecoverable with no cardiac motion. Time of	No prior vaccinations for this event.

death 11:50 pm."

CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

cardiac arrest - no warning signs No prior vaccinations for this event.

CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient arrived at ER with complaints of CPR in progress. Per EMS, patient became short of breath while performing yard work on 1/26/2021. At arrival, patient was in fine v fib with a total of 6 shocks delivered along with 300 mg amiodarone followed by 150 mg amiodarone, 1 amp epinephrine and 2 epinephrine drips adminstered en route to ED. CPR initiated at 1755 and EMS reports asystole at 1829. TOD 1909 pronounced by ED DO Dx: Cardiac arrest	No prior vaccinations for this event.

CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per EMS, the patient was last seen walking and talking to wife 10 minutes prior to EMS arrival. EMS reports via patients wife, that patient was upstairs to change for his doctor appointment then patient's wife found him down. The patient received his COVID-19 vaccine on 1/25/21. EMS states they gave 5 rounds of EPI then patient moved into vfib then was shocked once but returned to asystole. In ED, the patient initially in asystole CPR was started immediately. The patient was given 3 rounds EPI, 1 round bicarb. The patient stayed in PEA throughout. Patient was given tPA. Patient continued to be in asystole and time of death was called at 11:35 am.	No prior vaccinations for this event.

	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client was being treated with antibiotics by her PCP for diverticulitis flare up. It had not been resolved on the date of her death which occurred 01/27/21, She was found unresponsive by staff, 911 contacted, and paramedics pronounced her deceased at 7:48 AM. After consultation with PCP manner of death was noted as cardiac arrest. PCP was to sign off on death certificate.		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was an 87 y/o female admitted for septic shock. She was started on and eventually maxed on 3 pressors. CT abd showed colonic obstruction with dilatation of large and small bowel. Patient was made DNR in the ED. Palliative care consulted on case. Family opted for comfort care. Patient was asystole on monitor. No spontaneous breath/cardiac sounds ausculted. Patient did not withdraw to pain. Pupils fixed and dilated. She was pronounced and 1230 on 1/28/21		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Cardiac arrest on 1/24/21 in the early morning hours then passed away on 1/25/21 around 1:51am in the hospital		No prior vaccinations for this event.
	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

After being observed for approximately 20 minutes and patient walked to her car without assistance I was called to assess the patient in the parking lot for troubles breathing. EMS was called as I made my way outside. Upon my arrival patient was leaning out of the car and stating that she could not breath. She was able to tell me that she was allergic to penicillin. Oxygen was immediately placed on the patient with minimal relief. Lung sounds were coarse throughout. She then began to vomit about every 20-30 seconds. Epipen was administered in the right leg with no relief. Patient continued to complain of troubles breathing and vomiting. A second epipen was administered in the patients right arm again with no relief. A few minutes later patient was given racemic epinephrine through the oxygen mask. There appeared to be mild improvement in her breathing as she appeared more comfortable, but still complaining of shortness of breath and vomiting. When EMS arrived patient was unable to transport herself to the stretcher. When EMS and clinical staff transferred patient to the stretcher she became unresponsive. She appeared to still be breathing. She did not respond to verbal stimuli. Per ED report large amount of fluid was suctioned from the patients lungs following intubation in the ambulance. When patient arrived to the ED she was extubated and re-intubated without difficulty and further fluid was suctioned. At that time patient was found to be in PEA, shock was delivered. Shortly thereafter no cardiac activity was found and patient pronounced dead.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/28/2021- Seen by FNP for indigestion, chest pressure and palpitations. EKG reviewed and referral made to Cardiology. 1/29/2021-1800 Presented to ED in cardiac arrest-onset PTA. Patient was found unresponsive by his wife at their home. The last known well was at 1530 when she called him on the phone. The patient was pronounced at ~1850.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

she was injected, sh stopped eating and talking, the doctor watched her for 2 days. had her transported to the hospital. i was told she had tested positive for COVID 2 times once at the home and once at the hospital. with in 2 DAYS at the hospital she wa on a ventilator 2 days later she died. i talked with the rehab center and confirmed she tested negative for COVID on Dec 27th 2020 and was given the Vaccine on the 29th Dec 202 was in the hospital 4 day later, was on a ventilator 4 days after that then died a few day later as her heart stopped beating. all the while i had POA and was not contacted by Hospital staff until after they had made the next step.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Heart stopped; Could not swallow; This is a spontaneous report from a contactable nurse (patient's wife). An 85-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 21Jan2021 at a single dose for COVID-19 immunization. Medical history included blood pressure abnormal (verbatim: blood pressure) from an unknown date and unknown if ongoing, neuropathy from an unknown date and unknown if ongoing, weight issue from an unknown date and unknown if ongoing, diabetes from an unknown date and unknown if ongoing, walker user from an unknown date and unknown if ongoing. Concomitant medications included insulin aspart (NOVOLOG) taken for diabetes from an unspecified date to an unspecified date; and he was taking a long acting one as well. The patient previously received the influenza vaccine (MANUFACTURER UNKNOWN) for immunization on unknown dates (""had flu shots before with no reactions and everything, nothing before""). On 24Jan2021, the patient's heart stopped (death, medically significant), and could not swallow (medically significant). The clinical course was reported as follows: The patient's wife stated the patient was taking insulin aspart (NOVOLOG) and he was taking a long acting one as well. The reporter, the patient's wife and a retired registered nurse (RN) stated, her husband (patient) just died and she thought he died from the COVID vaccine (later clarified the reason of death was-heart stopped). The patient had the vaccine on 21Jan2021, which was on a Thursday, and he was fine. On the following Sunday around 1:30	No prior vaccinations for this event.

(on 24Jan2021), the patient was feeling a little weak, however, the patient's wife thought maybe his blood sugar was low. The patient's wife checked, and the patient's blood sugar was 91. The patient's wife went to get some yogurt to feed him in order to get his blood sugar up a little; ""which was a normal thing for him, it was not that low for him."" Then, suddenly, the patient fell, and the patient's wife could not get a pulse or anything. The patient's wife called an unspecified number and she started compressions; however, he was dead. The patient's wife stated the patient just had his heart test, a three hour long one, and it was ""perfect three weeks ago."" The patient had just gone to the doctor the other day and his blood pressure was ""fine and everything."" The patient's wife stated that other than his diabetes, ""which he had for (sentence incomplete)."" Regarding lab tests, the patient's wife stated, ""No, he had it before but not in the last two weeks. He was going for one because we just went to the doctor last week and he was going to call yesterday to make the appointment request to get his blood work done. Blood work has been good except his A1C was always high, but other than that everything was good"" (as reported). Regarding causality, the patient's wife stated, ""I do, because he was fine until about half an hour before he died. He said to me, I feel a little weak today and then I was talking to him that your upper body strength is really good and then I said, we just have to work on your weight a little more because he did have neuropathy. And then, I went out of the room and all of a sudden I just heard him fall and that is when I just went in to check his blood sugar and it was 91 and I got him yogurt and he started eating that and then that was it, he started spitting it out and he said, I could not swallow and that was it, he just died."" The patient's wife further added, ""I just wanted other people to know that things like this happen and I am sure it was from that because he was healthy as could be. He was walking with his walker, the day before outside and he felt fine."" The clinical outcome of the event, heart stopped, was fatal. The clinical outcome of the event, could not swallow, was unknown. The patient died on 24Jan2021 due to ""heart stopped."" An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: Heart stopped"

CARDIAC ARREST

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Cardiac arrest; Patient transported by EMS to hospital 11:00pm on 01/29/2021. Patient received vaccine on 01/25/2021. Patient expired 01/30/2021 within the hour into the new day after midnight on 01/30/2021. Patient was feeling well prior to and any chronic health conditions were well controlled. Sudden cardiac arrest 4 days after receiving the vaccine. Details given by patients husband/POA.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient noted to have irregular breathing in bed and unable to arouse. Provided life saving measures in the field x 30 minutes and transferred to hospital. Noted to have heart arrhythmia which suspected to cause cardiac arrest.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient expired. Per Emergency MD note: ""This is a 72-year-old male with what sounds like diabetes, atrial fibrillation, and hypertension who presents via EMS in cardiac arrest. It sounds like he received his Covid vaccine last week. Initially he had some mild effects from it. However over the last day or so he has felt very unwell. He apparently called his wife today and told her that he was not feeling well and so she returned home. Shortly thereafter he attempted to get up from his chair. He then collapsed and fell forward onto his face. Sounds like his wife had some difficulty rolling him over to perform CPR. When EMS arrived they found him in PEA. He received a total of 5 rounds of epinephrine. At some point they did have return of spontaneous circulation. However just prior to arriving in the emergency department they lost pulses again. The patient was intubated with an 8 oh endotracheal tube prior to arrival."""	No prior vaccinations for this event.

	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."		No prior vaccinations for this event.

	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/5/2021 resident noted to be azotemic. Creatinine up to 3.8 and BUN in 80's. He was started on NS hydration. On 2/7/2021 he was noted without VS, per MD notes, possible VF arrest, renal failure;		No prior vaccinations for this event.

death unclear exact cause.

CARDIAC ARREST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical	No prior vaccinations for this event.

consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

CARDIAC ARREST

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and ACLS guidelines initiated. Patient was found to be in PEA, and

No prior vaccinations for this event.

according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and ACLS guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mother died suddenly on February 3rd. She went into shock/cardiac arrest and appeared to have internal bleeding. No autopsy has been performed. Unsure if it was related to the COVID vaccine.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he	No prior vaccinations for this event.

passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending.

Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
For the two days prior to presentation the patient had been complaining of chest pain, his breathing seemed to be labored Monday. He and the family thought the pain was due to shingles as he carried this diagnosis from a month ago. Patient had also received the COVID vaccine 2 days prior to presentation and assumed he was feeling unwell due to the vaccine. Family wanted to take him to the hospital yesterday and earlier today but he refused. She left him in his home earlier this afternoon prior to presentation and returned to check on him finding him unresponsive and apneic at which time EMS was activated. #cardiac arrest -- suspect primary cardiac given collateral from family at home, consider hypoxemia which was corrected with advanced airway and 100% FiO2, patient clinically euvolemic and with soft brown stool in diaper not suggestive of GI hemorrhage, attempt to address acidosis with CPR and bicarbonate, not hypoglycemia, on bedside ultrasound FAST neg and no pericardial effusion suggestive of tamponade and +lung sliding bil not spontaneous pneumothorax Assessment/Diagnosis: -cardiac arrest, cause unspecified		No prior vaccinations for this event.

	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt suffered Cardiac Arrest and respiratory arrest on 2/9/21 and passed away at a local hospital. He had multiple health conditions likely contributing to this. he arrested at home and CPR was attempted and unsuccessful. Pt received his Covid vaccine #1 on 1/27/21. No issues were noted after vaccine and was due for his 2nd dose next week. However, we were notified he passed away on 2/9/21. Very likely death		No prior vaccinations for this event.

not at all related to vaccine but wanted to document as patient was in the middle of the covid vaccine series.

CARDIAC ARREST **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

New onset dizziness with hypotension, tachycardia, and vomiting blood. Sent to ER - told he went into cardiac arrest and died. No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

PATIENT ARRIVED TO ED ON 2/9 IN FULL CARDIAC ARREST No prior vaccinations for this event.

CARDIAC ARREST **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

My dad received the Pfizer vaccination on 2/5/21. He was admitted into the hospital the next day for C-Diff bacterial infection. He had been on dialysis treatments for kidney failure treatment since 2017 and had recently been diagnosed with stage 3 colon cancer in June 2020. He had completed his final treatment of chemotherapy on 2/4/21 and several weeks prior had been determined cancer free. On Tuesday 2/9/21 he was released from the hospital and went home. Early Thursday morning 2/11/21 @ approximately 1:30 am CST his eyes rolled back in head and he stopped breathing and was non responsive. My mother called 911 and attempted CPR. Paramedics arrived and were able to successfully get a pulse then transferred him to the hospital. He was put on a ventilator @ the hospital and then transferred to a different hospital a few hours later. He lost pulse/heartbeat several times @ the 2nd hospital he was transferred to. We were not allowed to travel with him or see him b/c of all of the COVID restrictions. We were communicating with the ICU doctor by phone who ultimately communicated to us that there was nothing further that could be done

No prior vaccinations for this event.

to save his life. He subsequently passed away @ approximately 8:55 am CST on 2/11/21.

	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was found with no pulse no heart rate by a staff member around 11 pm. Earlier that day seen by myself for fatigue, sorethroat, nausea.		No prior vaccinations for this event.

	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No symptoms or signs on the day 1st dose of vaccine was received (2/11/2021). 3 days later, (2/14/2021) patient experienced chills for approximately 6 hours, followed by severe (visible) chest spasms, and then cardiac arrest. 911 was called upon witnessing chest spasms, but cardiac arrest/death occurred before patient could be transported to the hospital.		No prior vaccinations for this event.

	CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of		No prior vaccinations for this event.

patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
02/07/21 through 2/13/21 slightly fatiqued, took all his prescribed medications, ate breakfast, lunch and dinner was drinking eight 10 oz bottles of water. On 02/14/21 was very tired had a difficult time breathing after taking the normal meds. He took a breathing treatment with his prescribed Ipratropium Bromide and Albuterol Sulfate via home nebulizer. This did not improve his breathing. He was very weak and breathing was labored. 911 was called by wife. 911EMTchecked pulse and breathing. Informed him they would give him a breathing treatment.He started to go limp. EMT's got him to Ambulance and to Medical Center to the ER. Heroics done. He died. Pulmonary and Cardiac Arrest	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

"He collapsed due to a cardiac arrest on Friday 15Jan and passed away on 19Jan; He collapsed due to a cardiac arrest on Friday 15Jan and passed away on 19Jan; his cardiac arrest was caused by an arrhythmia; This is a spontaneous report from contactable pharmacist via Pfizer Sales Representative. A 45-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not reported), via an unspecified route of administration on 11Jan2021 at single dose for covid-19 immunisation. Patient had a long history of congenital heart issues. He had been stable and closely monitored for the past 20 years. He had no history of arrhythmia. The patient's concomitant medications were not reported. Patient collapsed due to a cardiac arrest on Friday 15Jan2021 and passed away on 19Jan2021. The doctors feel that his cardiac arrest was caused by an arrhythmia. Reporter reported this through the v safe app. And received a message stating reporter would be contacted by the cdc. After patient passed away reporter replied stop to v safe. But still had not been contacted by anyone. This may or may not be related. Reporter have no way of knowing. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported ""collapsed due to a cardiac arrest"", ""cardiac arrest was caused by an arrhythmia"" and the administration of COVID-19 vaccine, BNT162B2, based on the reasonable temporal association. The patient's pre-existing long history of congenital heart issues might have provided alternative explanations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: He collapsed due to a cardiac arrest on Friday 15Jan and passed away on 19Jan; his cardiac arrest was caused by an arrhythmia; He collapsed due to a cardiac arrest on Friday 15Jan and passed away on 19Jan"

No prior vaccinations for this event.

CARDIAC ARREST

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
1/26 /2021 - pt went to ER for chest pain 2/9/2021 - pt received Pfizer COVID vaccine 1st dose 2/17/2021 - cardiac arrest with death	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had an unwitnessed cardiac arrest while outside walking his dog. AED in the field initially advised shock and was shocked 3 times without effect. At the time EMS ALS arrived, patient was in PEA arrest. He was transferred to Hospital with CPR in progress. Time of death called at 1857.	No prior vaccinations for this event.
CARDIAC ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion; On 21Feb he went to the ER after vomiting and passing out; On 21Feb he went to the ER after vomiting and passing out; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; fever; headache; stomach upset; This is a spontaneous report from a contactable consumer reporting for the father: A 75-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EL3428) at single dose at left arm on 03Feb2021 for Covid-19 immunisation. Medical history included type 2 diabetes mellitus. No known allergies. The patient had not experienced Covid-19 prior vaccination. Concomitant medication in 2 weeks included amitriptyline hydrochloride (manufacturer unknown) 10 mg, atorvastatin (manufacturer unknown) 20 mg, dutasteride (manufacturer unknown) 0.5 mg, linaclotide (LINZESS) 290 mcg, gabapentin (manufacturer unknown) 300 mg, montelukast (manufacturer unknown) 10 mg, ramipril (manufacturer unknown) 5 mg, insulin degludec (TRESIBA) 100 unit/ml, liraglutide (VICTOZA) 18 mg/3ml solution. No other vaccine in 4 weeks. The patient experienced cardiac arrest due to pericardial effusion on 21Feb2021 14:15, fever on 13Feb2021, headache on 13Feb2021,	No prior vaccinations for this event.

stomach upset on 13Feb2021, on 19feb, he began to feel ill again with a fever, he felt worse on 20feb on 19Feb2021, on 21feb he went to the ER after vomiting and passing out on 21Feb2021. Events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of cardiac arrest due to pericardial effusion. Course of events: In Feb2021, 10 days after his 1st injection, the patient developed fever, headache, and stomach upset. He went for a rapid Covid-19 test (nasal swab) and it was negative on 11Feb2021. The doctor told him he might be having a delayed reaction to the vaccination. After a couple of days, he improved. On 19Feb2021, he began to feel ill again with a fever. He felt worse on 20Feb2021. On 21Feb2021 he went to the ER after vomiting and passing out and received treatment: IV fluids, diagnostic testing at ER. Rapid Covid test (nasal swab) at ER came back negative again on 21Feb2021. His heart arrested suddenly and he could not be resuscitated. CT scan results, that came back after death, showed Covid like pneumonia and pericardial effusion. The patient died on 21Feb2021 14:15. Cause of death was cardiac arrest due to pericardial effusion. An autopsy was not performed. The outcome of cardiac arrest due to pericardial effusion was fatal, of fever, headache, stomach upset was recovering, of he began to feel ill again with a fever, he felt worse was not recovered, of he went to the ER after vomiting and passing out was unknown.; Reported Cause(s) of Death: cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion

CARDIAC ARREST **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Cardiac arrest- death No prior vaccinations for this event.

CARDIAC ARREST COVID19 (COVID19 (UNKNOWN)) (1202)

COVID 19 vaccine, unknown which company Chronically ill in a skilled nursing facility found diaphoretic, hypotensive, hypoxia to 85% arrived to Emergency dept in cardiac arrest Died within 65 minutes of nursing finding patient in distress Wife felt it may have been related to vaccine date of vaccination 1/6/20 hx covid 19

No prior vaccinations for this event.

PNA in April 2020

CARDIAC ARREST	COVID19 (COVID19 (UNKNOWN)) (1202)
Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2 diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated) then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and was intubated. Transported to hospital. SARS CoV-2 and influenza negative.	No prior vaccinations for this event.

CARDIAC ASSISTANCE DEVICE USER	COVID19 (COVID19 (MODERNA)) (1201)
Short version The patient has long-standing health issues. The patient received the first dose of Moderna COVID-19 vaccine on 1/16/2021 (unknown location). The patient suffered an event in his home on 1/24/2021. CPR and treatment was begun and he was transported to the ED. He was pronounced dead in the ED at 0846. Long version 70-year-old male with past medical history of CAD with pacemaker, A. fib, COPD, hypertension/hyperlipidemia presenting in cardiac arrest. 911 call at 0724. Per EMS, patient was witnessed by family to have seizure-like activity and then collapsed and became unresponsive. Patient was noted by family to be pulseless and CPR was started right away. Patient received two doses of epi by police were on scene first (AED defibrillation x2) and six doses of epi (plus 6 more AED shocks) by EMS when they arrived. Patient had CPR performed for 45 minutes prior to arriving at the hospital. On route, patient had episodes of paced rhythm and V. fib. Patient received one amp of bicarb and one amp of calcium en route. Patient also received 300 mg of amiodarone en route. Arrived in ED at 0810 Patient received ongoing compressions, shocks and additional medications (epinephrine x6, lidocaine IV, sodium bicarbonate) until time of death called at 0846 in	No prior vaccinations for this event.

the ED.

CARDIAC DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
On 3/2/2021, clinic was notified by patient's family that patient had deceased on 2/28/2021 from a heart attack. Unsure of any relation to the Moderna vaccine but reporting for due diligence.	No prior vaccinations for this event.
CARDIAC DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
"1-2-2021 10:30 PM Complained Right arm/back hurt - took Tylenol 1-3-2021 Complained Right arm hurt, dizzy 1-4-2021 Felt better - did laundry, daughter found her deceased at 3:30 pm. Dr. at hospital said it was ""cardiac event"" according to death certificate."	No prior vaccinations for this event.
CARDIAC DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccination at 14:20 2/26/21. Was observed until discharged at 15:15. Discharged per wheel chair to lobby in alert/stable condition, to wait on bus to take him home. At 18:00 his neighbor heard him fall, could not get patient to answer phone, found him unresponsive. Neighbor called 9-1-1, ambulance personnel could not revive patient. Coroner's office ruled his death as Natural Causes due to Hypertension, Cardiac disease, Diabetes, ESRD. There were no indication of anaphylactic reaction noted when I questioned the coroner's office. The Coroner's office/EMS were aware the patient had received the Moderna COVID 19 vaccination that day.	No prior vaccinations for this event.
CARDIAC DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**

Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse		No prior vaccinations for this event.
CARDIAC DISORDER		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Cardiac event, 2 days after vaccination, patient expired. No prior vaccinations for this event.		
CARDIAC DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
The patient had an apparent cardiac arrest on 12/23/20 and was admitted to the ICU. He was taken off of life support on 12/30/20. He had known cardiac disease.		No prior vaccinations for this event.
CARDIAC DISORDER		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No symptoms or signs on the day 1st dose of vaccine was received (2/11/2021). 3 days later, (2/14/2021)		No prior vaccinations for

patient experienced chills for approximately 6 hours, followed by severe (visible) chest spasms, and then cardiac arrest. 911 was called upon witnessing chest spasms, but cardiac arrest/death occurred before patient could be transported to the hospital.	this event.	
CARDIAC DISORDER		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
blood clot; death cause: Heart Problems; tired; nauseous; This is a spontaneous report from a contactable consumer. An 81-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number EL3248), via an unspecified route of administration at single dose in the left arm on 19Jan2021 14:00 for covid-19 immunisation. Medical history included heart problems, pacemaker. Concomitant medication included heparin. The patient experienced death cause: heart problems on 20Jan2021, blood clot on an unspecified date with outcome of unknown that required hospitalization, tired on 19Jan2021 with outcome of unknown, nauseous on 19Jan2021 with outcome of unknown. The patient was hospitalized for blood clot from 16Jan2021 to 18Jan2021. The patient died on 20Jan2021. An autopsy was not performed. The events were described as follows: The patient was tired and nauseous about 3 hours after her vaccine. She had been in the hospital 16Jan2021 to 18Jan2021 for a blood clot. The patient died at her home on 20Jan2021 between 4 and 7 pm. No treatment required. The vaccine was administered at Hospital Facility. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19.; Reported Cause(s) of Death: death cause: Heart Problems	No prior vaccinations for this event.	
CARDIAC FAILURE		**COVID19 (COVID19 (MODERNA)) (1201)**
EARLY SUNDAY MORNING THE PATIENT BEGAN VOMITTING AND SHORT OF BREATH AND CHEST AND BACK PAIN. SHE CODED WHEN SHE GOT IN THE ER AND LATER PASSED AWAY THE MONDAY. DIAGNOSIS WAS PNEUMONIA AND HEART FAILURE PER STEP DAUGHTER.	No prior vaccinations for this event.	

CARDIAC FAILURE **COVID19 (COVID19 (MODERNA)) (1201)**

Stomach upset, sudden heart failure, death No prior vaccinations for this event.

CARDIAC FAILURE **COVID19 (COVID19 (MODERNA)) (1201)**

Blood pressure went down until he died; Couldn't hear his heartbeat; neck was sweating; He was cold; Couldn't get up; Death; Sick; immediately very tired; he was tired; Hands were shaking; Slept for too long; A spontaneous report was received on 18 Feb 2021 from a consumer concerning a 81-years-old, male patient who received Moderna's COVID-19 vaccine and developed immediately very tired, hands were shaking, neck was sweating, was cold, sick, couldn't get up, couldn't hear his heartbeat and blood pressure went down until he died. Patients' medical history, as provided by patient's spouse, was emergency room(ER) admission in November 2020 because he had a congested chest (he had fluid around his heart). At that time, they gave him pills for kidney function. Other concomitant medication reported was Coumadin, blood thinner. Two weeks before receiving the vaccine, patient's EKG was normal. On 11 Feb 2021, in the morning, patient received their first of two planned doses of mRNA-1273(BATCH/LOT # 007M20A) probably in the right arm for the prophylaxis of COVID-19 infection. On 11 Feb 2021, approximately after 15 minutes of receiving vaccine, they left and patient was immediately very tired, his hands were shaking. So, patient's spouse made them down sleep for too long. On Friday, 12 Feb 2021 she tried to pick him up, but he was tired, exhausted, and sick. On Saturday, 13 Feb 2021, she brought him a coffee and he couldn't hold it because his hands were shaking, so she gave him the coffee and then made him pee on the bed because he couldn't get up. At lunch time she made him eat something and he fell sleep again. His wife was hanging around him all day and around 7:30pm she realized that he was cold, and his neck was sweating, she couldn't hear his heartbeat. So, she called emergency services and when they arrived, her husband's blood pressure went down until he died. Treatment for the events were not provided. Action taken with mRNA-1273 was not applicable. Patient was pronounced dead on 13 Feb 2021 20:00. The cause of death was not provided. The plans for an autopsy were not provided. The events of blood pressure went down until he died and couldn't hear his heartbeat were fatal.

No prior vaccinations for this event.

The outcome for the remaining events were unknown.; Reporter's Comments: This case concerns an 81 year old, male patient, who experienced a serious event of death among others, 2 days after receiving mRNA-1273 (Lot# 007M20A). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

CARDIAC FAILURE

COVID19 (COVID19 (MODERNA)) (1201)

Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse

No prior vaccinations for this event.

CARDIAC FAILURE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

She started having breathing problems/heart attack appearance. on 1/22/21 and went to the ER. Upon admittance was told it was an anaphylactic shock from the Covid shot. They kept her in ICU and released

No prior vaccinations for this event.

her 1/23/21. At 12:45 am on 1/24/21 she passed out and we called the ambulance. Hospital admitted her and worked through multiple organ failure issues and thought her numbers were under control. She was released on 1/27/21 and was driving on 1/28/21 around 4:15 pm and appears to have had heart failure and had a wreck. She passed away that day.

	CARDIAC FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident did not exhibit any side effects from the vaccine. Staff spoke with him in his room at approximately 7:20am and returned to his room just a few minutes later and he was unresponsive. When the RN got to the room he had CTB. Physician documented heart failure and end stage kidney disease on the death certificate.		No prior vaccinations for this event.
	CARDIAC FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient passed away from chronic respiratory failure with cardiogenic shock 24 hours from 2nd dose of vaccine. Patient with longstanding history of pulmonary HTN and heart failure with desire for comfort care only. Entering into VAERS out of abundance of caution.		No prior vaccinations for this event.
	CARDIAC FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
presumed cardiac failure; This is a spontaneous report from a contactable nurse. An 89-year-old female patient (not pregnant) received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm left on 10Feb2021 (at the age of 89 years) at single dose for		No prior vaccinations for this event.

COVID-19 immunization. The patient medical history included congestive heart failure, coronary artery disease, hypertension, hyperlipidemia, osteoarthritis, presence of prosthetic heart valve and allergies, all from an unknown date and unknown if ongoing. The patient's concomitant medication included amlodipine besilate/benazepril hydrochloride, amlodipine, acetylsalicylic acid (ASPIRIN E.C.), atorvastatin, benazepril, carvedilol, ubidecarenone (COQ10), furosemide, acetaminophen and potassium chloride. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0142), intramuscular at arm left on 20Jan2021 at single dose for COVID-19 immunization. The patient experienced presumed cardiac failure on 12Feb2021 at 03:30 with fatal outcome. The patient died on 12Feb2021. An autopsy was not performed.; Sender's Comments: Based on the current available information, the event Cardiac failure is most likely related to an intercurrent or underlying condition which is not related to the suspected drug BNT162B2. The patient medical history of congestive heart failure, coronary artery disease, hypertension, and hyperlipidemia provide plausible explanations for the event. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: presumed cardiac failure

CARDIAC FAILURE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air

No prior vaccinations for this event.

saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days

prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

CARDIAC FAILURE ACUTE	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt started complaining of chest heaviness and shortness of breath on the afternoon of 1/21/21. EMS was called to the patients home and she was found to have an O2 sat in the 70's. She was admitted to hospital and found to have a proBNP of 5000. She tested negative for Covid-19. She was determined to be in acute-on-chronic heart failure and was referred for hospice care. She passed away on the evening of 1/24/21.	No prior vaccinations for this event.

CARDIAC FAILURE ACUTE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of	No prior vaccinations for

COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021. this event.

CARDIAC FAILURE CHRONIC

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient did not have any adverse reaction to the COVID vaccine, but we were asked by our health dept to submit a VAERS report since the patient died between his first and second dose. Received Pfizer Dose #1 12/17/2020. No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Date of death 12/23/2020 from aspiration pneumonia complicated by end-stage heart failure and ischemic cardiomyopathy. Death was anticipated and not sudden.

No prior vaccinations for this event.

CARDIAC FAILURE CONGESTIVE

COVID19 (COVID19 (MODERNA)) (1201)

cough congestive heart failure death No prior vaccinations for this event.

CARDIAC FAILURE CONGESTIVE COVID19 (COVID19 (MODERNA)) (1201)

Fever 101.1, unresponsive episode. Transferred to Hospital on 1/28. Diagnosis there was anemia and CHF, aware that he had vaccine day prior. Transfused with 2 units pRBC's. Transferred back to Nursing Home on 1/30 and passed away 0140 1/31/2021

No prior vaccinations for this event.

CARDIAC FAILURE CONGESTIVE

COVID19 (COVID19

	(MODERNA)) (1201)
pt received vaccine on 2/3. early on 2/4 developed chest pain, dyspnea, and was seen in ED and diagnosed with acute exacerbation of CHF and NSTEMI type 2, and anemia. on 2/5 transfusion was started and pt developed worsening dyspnea and then PEA arrest. Pt achieved ROSC and was transferred to the cardiac intensive care unit where he required vasopressor support. he subsequently declined and died on 2/7	No prior vaccinations for this event.
CARDIAC FAILURE CONGESTIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had Covid-19 in October of 2020. He recovered. He received the vaccination on 12/30/2020 with no complaints. On 01-05-2021 it was noted to he was incontinent of urine and bilateral lower extremity edema. Lab work was completed showed acute kidney injury. He had decreased blood pressure and oxygen saturations on 01-06-2021 He was admitted to the hospital with rapid progression of symptoms and suggested multi-system failure. He had a long cardiac history. On 01-14-2021 he passed away with a diagnosis of Cardiomyopathic CHF, A.Fib contributory.	No prior vaccinations for this event.
CARDIAC FAILURE CONGESTIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"	No prior vaccinations for this event.

	CARDIAC FAILURE CONGESTIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration		No prior vaccinations for this event.
	CARDIAC FAILURE CONGESTIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
We do not believe that the patient's death was an adverse event from the vaccine. Patient received COVID vaccine from Pfizer Dose #1 12/19/2020 (lot # EK5730) and Dose #2 1/7/2021 (lot # EL1284). No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Patient died 1/10/2021 from chronic respiratory failure and congestive heart failure after recent aspiration pneumonia requiring hospitalization. Death was anticipated and not sudden. We were told to report his death to VAERS even though his death was anticipated and not related to his vaccination.		No prior vaccinations for this event.
	CARDIAC FAILURE CONGESTIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no		No prior vaccinations for this event.

hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50.

Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

CARDIAC FAILURE CONGESTIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

symptoms of ongoing congestive heart disease just progressed No prior vaccinations for this event.

CARDIAC FAILURE CONGESTIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	No prior vaccinations for this event.

CARDIAC FAILURE CONGESTIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.	No prior vaccinations for this event.

CARDIAC FAILURE CONGESTIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation,	No prior vaccinations for

elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.		this event.
	CARDIAC FAILURE CONGESTIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient passed away on 2/1/21 at the Health System. She was there for congestive heart failure (CHF) which had been a problem for her since contracting COVID-19 (symptoms began 10/29/20 and tested positive 10/30/20). She had been to see her medical provider several times after her isolation period as well as a few trips to the hospital for, what they called ""CHF flare-ups"". Her last hospitalization began on January 30, 2021. Her social worker reported on t1/31/21 that ""she would likely be returning in another day or two""."		No prior vaccinations for this event.
	CARDIAC PACEMAKER EVALUATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Had no immediate issues with the vaccine. He had returned from the hospital on 12/21 and had some concerns about his weight which were shared with his physician on 1/4/21. On 1/5/21 had a visit with his cardiologist for a pacemaker check. On 1/8/21 staff were called to his room, he was on the floor, bluish skin color. No vital signs found, no heart rhythm heard at 2200.		No prior vaccinations for this event.
	CARDIAC TAMPONADE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death on February 12, 2021 acute cardiac tamponade No prior vaccinations for this event.		

CARDIAC TELEMETRY **COVID19 (COVID19 (MODERNA)) (1201)**

Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29

No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST

COVID19 (COVID19 (MODERNA)) (1201)

syncopal episode - arrested - CPR - death No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

"Patient was found ""acting abnormal"" on 1/9/2021 at 1215. VS HR 20-30's. EMS activated. EMS arrived and patient was found pulseless in PEA/ asystole, CPR and ACLS initiated and then transported to the MC. Unsuccessful resuscitation and expired on 1/09/2021 at 1348. Clinical impression Cardiopulmonary arrest."

No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST

COVID19 (COVID19 (MODERNA)) (1201)

Patient had increased SOB while at home. EMS was called. Patient coded in the squad No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST **COVID19 (COVID19 (MODERNA)) (1201)**

about 20+ hours after vaccination resident was having hard time breathing, 911 was called. Resident coded multiple times at the facility after CPR she was taken to ICU. She coded again and was placed on life support. Due to her choice to not be on life support she passed on 11/26/2021.

No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST

COVID19 (COVID19

	(MODERNA)) (1201)
UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless and breathless and was pronounced. Autopsy currently pending.	No prior vaccinations for this event.
CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
6 days after vaccine developed bloody diarrhea. Thought to have ischemic colitis but negative evaluation. became hypotensive bradycardic placed on ventilator. Subsequently was poorly responsive and eventually coded once more and succumbed	No prior vaccinations for this event.
CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
PATIENT WAS IN CLINIC FOR 1ST CLINIC. WAS DISCHARGED BEFORE OUR 2ND CLINIC. HE CAME BACK TO OBTAIN HIS 2ND SHOT. WE WENT OUT TO THE CAR GAVE SHOT. THE NEXT DAY TO MY KNOWLEDGE, HE STARTED CODING AT HOME. AMBULANCE WAS CALLED AND HE CONTINUED TO CODE. THE AMBULANCE CREW TRIED CPR FOR 30 MINS WITH NO LUCK. PATIENT PASSED 2-3-21.	No prior vaccinations for this event.
CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**

CARDIAC ARREST, DEATH Narrative: The patient presents to the emergency department in cardiopulmonary arrest. CPR was continued upon arrival. The Combi tube was removed and an endotracheal tube was placed without complications. ROSC was obtained multiple times but the patient continued to go into PEA. The patient was seen in the emergency department by both critical care and Cardiology. EKG shows ST elevations, but the patient was unstable to go to catheterization. The patient had 1 episode of asystole. Despite best efforts and multiple attempts we were unable to resuscitate the patient. Time of death 1253 on 1/24/21.	No prior vaccinations for this event.
CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
EARLY SUNDAY MORNING THE PATIENT BEGAN VOMITTING AND SHORT OF BREATH AND CHEST AND BACK PAIN. SHE CODED WHEN SHE GOT IN THE ER AND LATER PASSED AWAY THE MONDAY. DIAGNOSIS WAS PNEUMONIA AND HEART FAILURE PER STEP DAUGHTER.	No prior vaccinations for this event.
CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
pt received vaccine on 2/3. early on 2/4 developed chest pain, dyspnea, and was seen in ED and diagnosed with acute exacerbation of CHF and NSTEMI type 2, and anemia. on 2/5 transfusion was started and pt developed worsening dyspnea and then PEA arrest. Pt achieved ROSC and was transferred to the cardiac intensive care unit where he required vasopressor support. he subsequently declined and died on 2/7	No prior vaccinations for this event.
CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended	No prior vaccinations for this event.

(although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident reviewed for incident. Resident received the second dose of the Moderna Covid-19 vaccine lot# 016M20A Exp 5/2/2021 on 2/5/2021 from clinic through pharmacy. Resident had her temp/O2 taken on AM shift and was 98.6/93%, beginning PM shift 98.4/95%. A few hours later noted that resident to have chills and was shaking RN assessment completed and vitals taken resident noted to have temp of 102.2, oxygen 95%, pulse 110. Resident alert and oriented at that time and talking to staff. Reported findings to APNP with order to send to ER. 911 called, residents brother updated. Upon EMT arrival RN went down to residents room with EMT and resident had an emesis as resident was getting cleaned up resident went unresponsive. Pulse noted to still be present at that time, resident did briefly respond to sternal rub and then went unresponsive again. Resident full code and EMT transferred to gurney and said that if they lost a pulse in route that they would transfer to hospital B instead of hospital A being the closest facility. RN called brother and gave update. Facility notified from Hospital that resident had passed away.	No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Cardiopulmonary arrest	No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST COVID19 (COVID19 (MODERNA)) (1201)

"Patient had COVID vaccination on 2/3 with no adverse s/s before leaving unit. Upon coming to treatment Friday 2/5 he reported to the RN that he had fallen on thursday 2/4 due to ""getting up fast"" did not hit head or hurt anything per RN discussion. Began treatment without difficulty. About 3/4 way through treatment was talking with staff and became unresponsive - code was called and pt expired after 30 minute resuscitation	No prior vaccinations for this event.

efforts."

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**

Pt. received vaccine on 2/3/2021. Coded at home on 2/17/2021. No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**

Code blue called at 11:00pm. Patient had code status of Do Not Resuscitate. No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**

911 called to patients house for trouble breathing and abdominal pain. Patient coded, wife presented DNR paperwork. Patient presented to Hospital DOA at 0958.

No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**

Patient received Covid Vaccine Moderna at 1145, multiple syncopal episodes at pharmacy, sent to ER. Outcome Death

No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported

No prior vaccinations for this event.

to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was	No prior vaccinations for

called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."

this event.

CARDIO-RESPIRATORY ARREST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
resident coded on 09Jan at 8am and expired; This is a spontaneous report from a contactable Other Health Professional. A 70-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140), intramuscularly in left arm on 05Jan2021 15:15 at single dose for COVID-19 immunization. Medical history included DM2(Type two diabetes mellitus), CHF(congestive heart failure), open wound, wound infection, heart failure. Allergies to medications, food, or other products: none. Concomitant medications included unspecified products (List of any other medications the patient received within 2 weeks of vaccination: yes). If the patient received any other vaccines within 4 weeks prior to the COVID vaccine: Unknown. Facility where the most recent COVID-19 vaccine was administered: Nursing Home/Senior Living Facility. The resident coded on 09Jan2021 at 8 AM and expired. The patient died on 09Jan2021. An autopsy was not performed. AE resulted in: patient died. Death cause: unknown at this time. Was treatment received for the adverse event: Unknown. Prior to vaccination, was the patient diagnosed with COVID-19: No. Since the vaccination, has the patient been tested for COVID-19: No. Serious: Yes. Seriousness criteria-Results in death: Yes. Seriousness criteria-Life threatening: No. Seriousness criteria-Caused/prolonged hospitalization: No. Seriousness criteria-Disabling/Incapacitating: No. Seriousness criteria-Congenital anomaly/birth defect: No.; Sender's Comments: The old patient had diabetes mellitus, congestive heart failure, open wound complicated by infection, all these pre-existing medical conditions contribute to the patient death. More information including complete medical history, concomitant	No prior vaccinations for this event.

medications and event term details especially death cause and autopsy results are needed for a full assessment of the case. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate; Reported Cause(s) of Death: resident coded on 09Jan at 8am and expired

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at	No prior vaccinations for this event.

time of this report."

	CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	resident coded and expired; This is a spontaneous report from a non-contactable consumer via Pfizer Sponsored Program. A 63-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EH9899) intramuscular at single dose at left arm on 28Dec2020 for Covid-19 immunisation. Medical history included no current Illness, no known allergies, but preexisting conditions: dysphagia, violent behaviors, depressive disorder, schizophrenia, aspiration, gastrooesophageal reflux disease (GERD), hyperlipidaemia, bipolar disorder, rectal bleeding, hypertension. The patient had no birth defect. Concomitant medication included asa (ASA) at 81mg, lisinopril (LISINOPRIL) at 10mg daily, ferrous sulfate (FERROUS SULFATE) at 325 (unit unknown), olanzapine (ZYPREXA) at 20mg, morniflumate (FLOMAX [MORNIFLUMATE]) at 0.4 (unit unknown), famotidine (FAMOTIDINE) at 20mg, ascorbic acid (VIT C), carbamazepine (CARBAMAZEPINE) at 250mg bid, valproate semisodium (DEPAKOTE) at 750mg bid, metformin (METFORMIN) at 1000 (unit unknown) bid, sertraline (SERTRALINE) at 100 (unit unknown) bid, albuterol [salbutamol] (ALBUTEROL [SALBUTAMOL]), buspirone hydrochloride (BUSPAR) at 10mg tid, polycarbophil calcium (FIBERCON). The patient died on 29Dec2020. The patient had no ER or Doctor visit and was not hospitalized. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: resident coded and expired	No prior vaccinations for this event.

	CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even	No prior vaccinations for this event.

on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."	No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"CC:full arrest HPI:HPI and ROS limited due to patient's condition. History is via EMS, medical record, and son. Per Son patient had Covid vaccine on Saturday morning. Slept all day Sunday. Woke up Sunday night a bit ""like coming out of a deep sleep per son, around 10 pm. Shortly after that patient was having a hard time breathing. Emergency called. Arrested around the time EMS arrived. King airway, I/O and CPR initiated. Patient has been in v fib. Was shocked multiple times, given 4 rounds of epi, bicarb and amiodarone. ACLS continued on arrival. Multiple rounds of epi, and attempted defib. Patient given epi, bicarb. Rhythms included fine v fib, asystole, and PEA. Unrecoverable with no cardiac motion. Time of death 11:50 pm."	No prior vaccinations for this event.
CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was an 87 y/o female admitted for septic shock. She was started on and eventually maxed on 3 pressors. CT abd showed colonic obstruction with dilatation of large and small bowel. Patient was made DNR in the ED. Palliative care consulted on case. Family opted for comfort care. Patient was asystole on monitor. No spontaneous breath/cardiac sounds ausculted. Patient did not withdraw to pain. Pupils fixed and dilated. She was pronounced and 1230 on 1/28/21	No prior vaccinations for this event.
CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident found unresponsive in room this am at approx. 9:30 am. Resident was observed eating breakfast around 8:45 am. Housekeeper reported seeing resident between breakfast and time found unresponsive. Resident had voiced no complaints. Code was initiated until EMS arrived and transported resident to hospital. Resident expired.	No prior vaccinations for this event.

	CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death Narrative: Pt attended arthritis clinic appt 0900; labs shortly after; rec'd vaccine in clinic ~ 1113; seen on surveillance camera walking to parking garage ~ 1145; medical center rec'd call from wife ~ 1900 that pt never returned home; police found vehicle running in parking garage, code called, pt obviously deceased by that time 1930, body sent to medical examiner for autopsy.		No prior vaccinations for this event.
	CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more		No prior vaccinations for this event.

hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was administered second dose of Pfizer vaccine in Nursing Home on 2/5/2021 around noon and was found unresponsive at 5:03AM the following day 2/6/2021. Patient arrived to Hospital in cardiopulmonary arrest and was pronounced dead.	No prior vaccinations for this event.

CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no	No prior vaccinations for this event.

peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

	CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.		No prior vaccinations for this event.
	CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Few minutes post vaccination, after moving to observation area via wheelchair, the patient complained of dizziness. She took glucose tabs she had brought with her. Staff wheeled her to Triage # 1. Her eyes rolled back in her head and she lost consciousness. Staff (paramedics on site) transferred her to gurney and started compressions. AED placed, V- Fib was rhythm, Shock # 1 given, CPR resumed. Shocked again. Fire truck and additional EMT arrived on site and took over care. Epinephrine was given 3 times via intra-osseous route, Amiodarone given intra-osseous route. Additional defibrillation with on site AED for a total of 6-7 times. Patient had good chest rise with ambu-bag, no airway obstruction or peri-oral edema noted. Code called at 12:40 PM.		No prior vaccinations for this event.

	CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia		No prior vaccinations for this event.
	CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received his first dose of Covid vaccine on Jan. 30, 2021. On Jan 31, 2021 at 6:08 AM, patient noted unresponsive per facility. Code blue was called and 911 dispatched. He expired in the ER.		No prior vaccinations for this event.
	CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received the 2nd dose of the Covid vaccine approximately around 1105 by pharmacy through the pharmacy LTC partnership vaccination program. Resident had no adverse effects until around 8:00 pm she began complaining of body aches, and chills, Tylenol was given at this time. Around 9:30pm resident was sleeping in bed. Around 12:00 am the CNA called nurse into room to assess resident as the resident stated she did not feel good. Temperature at that time was 102.2, and vomiting. RN came to assess @ 1220 am She was noted to be vomiting, diaphoretic, pale and having trouble breathing. Temp was 97.3 after vomting, Pulse 53, Resp 20, o2 sats were 40-45%, unable to obtain Blood pressure, Applied 5 L of oxygen at this time and had LPN call 911 immediately. Resident was repsonsive and able to follow staff members instructions but was only answering yes or no simple questions at the time time of assessment. Paramedics		No prior vaccinations for this event.

arrived at 0040 and resident was sent to Hospital. @ 0130 ER nurse called to nursing facility to notify resident had coded in the ER and passed away @ 0110.

CARDIO-RESPIRATORY ARREST

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to

No prior vaccinations for this event.

be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased	
CARDIO-RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received the vaccine around 11 am. He hadn't been feeling well (headache, dizziness) per report and initially called in to work. He then decided to come to work and was found down in a patient bathroom during his shift on our Facility while taking care of a patient (he was a nurse aid). Patient was coded and the team and was transferred to our Facility ED. He expired 3/3 2112	No prior vaccinations for this event.
CARDIO-RESPIRATORY DISTRESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Fever Feeling tired short of breath all night and morning after the vaccine My grandma had to be intubated and then passed away to a heart distress we think it was the vaccine because she was fine even with dialysis. When she got the vaccine it took hours and her health conditions changed.	No prior vaccinations for this event.
CARDIOGENIC SHOCK	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident c/o nausea evening of 1/29 (nausea common for her post dialysis), had a large emesis at approx 2220, 0030 (unusual for resident to vomit)- received Zofran per order. Skin cool and damp, Blood sugar 147 (checked due to h/o diabetes and poor intake). At approx 230am Blood pressured checked and noted to be 52/29. Resident transferred to ER, intubated and transferred to higher level of care where she passed away	No prior vaccinations for this event.

on 1/30 at 736pm. Resident's medical notes indicated likely shock, cardiogenic in nature, sepsis (source unknown) along with a multitude of other co-morbidities that resident has.

CARDIOGENIC SHOCK	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient passed away from chronic respiratory failure with cardiogenic shock 24 hours from 2nd dose of vaccine. Patient with longstanding history of pulmonary HTN and heart failure with desire for comfort care only. Entering into VAERS out of abundance of caution.	No prior vaccinations for this event.
CARDIOGENIC SHOCK	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Cardiogenic shock occurred on 2/10/2021, approximately 12 hours after patient received her 12th dose of pemetrexed/pembrolizumab and 4 days after COVID vaccine. Coronary angiography was done on 2/10/2021 and no significant coronary narrowing or blockage were noted. Baseline troponin on 2/10/21 was 0.02 and later on 2/10/21, troponins were 9.99 & 25.27. Creatinine increase from 1.2 to 3.4 within 24hours, and AST/ALT increased from 23 & 31 to 4,220 & 4,786 respectively on 2/11. Patient expired on 02/11/2021.	No prior vaccinations for this event.
CARDIOMEGALY	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis,	No prior vaccinations for this event.

bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.		
CARDIOMEGALY		**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"		No prior vaccinations for this event.
CARDIOMEGALY		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
right arm swelling immediately after injection. followed by bilateral lower leg edema, chills and body aches that continued daily at 2 weeks post immunization admin 2/4/21 treated with dexamethasone 6mg PO x 7 days- this resolved his s/s 2/13/21 patient passed away at facility		No prior vaccinations for this event.
CARDIOMYOPATHY		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had Covid-19 in October of 2020. He recovered. He received the vaccination on 12/30/2020 with no complaints. On 01-05-2021 it was noted to he was incontinent of urine and bilateral lower extremity edema. Lab work was completed showed acute kidney injury. He had decreased blood pressure and oxygen saturations on 01-06-2021 He was admitted to the hospital with rapid progression of symptoms and		No prior vaccinations for this event.

suggested multi-system failure. He had a long cardiac history. On 01-14-2021 he passed away with a diagnosis of Cardiomyopathic CHF, A.Fib contributory.

CARDIOMYOPATHY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.	No prior vaccinations for this event.
CARDIOVASCULAR DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
"My grandpa had a stroke on the 15th of February. He claimed he had been feeling ""off"" for a few days, but didn't say anything. A blood clot had formed in his brain. He was doing better and about to go to rehab to strength his right side of his body. On the 22nd he took a turn for the worst. He was having trouble breathing and they sedated and partially paralyzed him to put a tube in his mouth. I believe another blood clot had formed and oxygen wasn't properly going through his body. They could not stabilize him, and he passed away the same day."	No prior vaccinations for this event.

	CARDIOVERSION	**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation		No prior vaccinations for this event.
	CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt last seen at 1200 by nurse for ID band check. No visible signs of distress noted. Pt states ""I just want to be left alone"". 1230 nurse was called to pt room. Pt was noted unresponsive, no pulse and respiration noted. CPR started immediately, at 1239 first shock given. 1245 EMT took over, at 1319 EMT called time of death"		No prior vaccinations for this event.
	CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On day due for 2nd dose, Patient was found unresponsive at work in the hospital. Patient pupils were fixed and dilated. Full ACLS was initiated for 55 minutes with multiple rounds of bicarb, calcium chloride, magnesium, and epinephrine. Patient was intubated. Patient continued into V. Fib arrest and was shocked multiple times.		No prior vaccinations for this event.

	CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"CC:full arrest HPI:HPI and ROS limited due to patient's condition. History is via EMS, medical record, and son. Per Son patient had Covid vaccine on Saturday morning. Slept all day Sunday. Woke up Sunday night a bit ""like coming out of a deep sleep per son, around 10 pm. Shortly after that patient was having a hard time breathing. Emergency called. Arrested around the time EMS arrived. King airway, I/O and CPR initiated. Patient has been in v fib. Was shocked multiple times, given 4 rounds of epi, bicarb and amiodarone. ACLS continued on arrival. Multiple rounds of epi, and attempted defib. Patient given epi, bicarb. Rhythms included fine v fib, asystole, and PEA. Unrecoverable with no cardiac motion. Time of death 11:50 pm."		No prior vaccinations for this event.
	CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.		No prior vaccinations for this event.

	CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient arrived at ER with complaints of CPR in progress. Per EMS, patient became short of breath while performing yard work on 1/26/2021. At arrival, patient was in fine v fib with a total of 6 shocks delivered along with 300 mg amiodarone followed by 150 mg amiodarone, 1 amp epinephrine and 2 epinephrine drips adminstered en route to ED. CPR initiated at 1755 and EMS reports asystole at 1829. TOD 1909 pronounced by ED DO Dx: Cardiac arrest		No prior vaccinations for this event.
	CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per EMS, the patient was last seen walking and talking to wife 10 minutes prior to EMS arrival. EMS reports via patients wife, that patient was upstairs to change for his doctor appointment then patient's wife found him down. The patient received his COVID-19 vaccine on 1/25/21. EMS states they gave 5 rounds of EPI then patient moved into vfib then was shocked once but returned to asystole. In ED, the patient initially in asystole CPR was started immediately. The patient was given 3 rounds EPI, 1 round bicarb. The patient stayed in PEA throughout. Patient was given tPA. Patient continued to be in asystole and time of death was called at 11:35 am.		No prior vaccinations for this event.
	CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After being observed for approximately 20 minutes and patient walked to her car without assistance I was called to assess the patient in the parking lot for troubles breathing. EMS was called as I made my way outside. Upon my arrival patient was leaning out of the car and stating that she could not breath. She was		No prior vaccinations for this event.

able to tell me that she was allergic to penicillin. Oxygen was immediately placed on the patient with minimal relief. Lung sounds were coarse throughout. She then began to vomit about every 20-30 seconds. Epipen was administered in the right leg with no relief. Patient continued to complain of troubles breathing and vomiting. A second epipen was administered in the patients right arm again with no relief. A few minutes later patient was given racemic epinephrine through the oxygen mask. There appeared to be mild improvement in her breathing as she appeared more comfortable, but still complaining of shortness of breath and vomiting. When EMS arrived patient was unable to transport herself to the stretcher. When EMS and clinical staff transferred patient to the stretcher she became unresponsive. She appeared to still be breathing. She did not respond to verbal stimuli. Per ED report large amount of fluid was suctioned from the patients lungs following intubation in the ambulance. When patient arrived to the ED she was extubated and re-intubated without difficulty and further fluid was suctioned. At that time patient was found to be in PEA, shock was delivered. Shortly thereafter no cardiac activity was found and patient pronounced dead.

CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/28/2021- Seen by FNP for indigestion, chest pressure and palpitations. EKG reviewed and referral made to Cardiology. 1/29/2021-1800 Presented to ED in cardiac arrest-onset PTA. Patient was found unresponsive by his wife at their home. The last known well was at 1530 when she called him on the phone. The patient was pronounced at ~1850.	No prior vaccinations for this event.
CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received the vaccine at an outside healthcare facility on 2/11/21. At approximately 1 pm she screamed out and fell out of her chair. EMS was called and patient was found to be in Vfib. ACLS was	No prior vaccinations for this event.

performed for approximately 42 minutes prior to arrival at ED. At that time the patient had been pulseless for 25 minutes. Patient received 450 mg of amiodarone, epinephrine x7, sodium bicarbonate x2, and 7 AED shocks. In the ED 3 more doses of epinephrine were given, one more dose of sodium bicarbonate, and 5 additional shocks. ROSC was not achieved and time of death was called at 1416.		
	CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Few minutes post vaccination, after moving to observation area via wheelchair, the patient complained of dizziness. She took glucose tabs she had brought with her. Staff wheeled her to Triage # 1. Her eyes rolled back in her head and she lost consciousness. Staff (paramedics on site) transferred her to gurney and started compressions. AED placed, V- Fib was rhythm, Shock # 1 given, CPR resumed. Shocked again. Fire truck and additional EMT arrived on site and took over care. Epinephrine was given 3 times via intra-osseous route, Amiodarone given intra-osseous route. Additional defibrillation with on site AED for a total of 6-7 times. Patient had good chest rise with ambu-bag, no airway obstruction or peri-oral edema noted. Code called at 12:40 PM.		No prior vaccinations for this event.
	CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt received 2nd Pfizer BioNTech Covid 19 EUA vaccine @1:50 pm; Pt released from Observation @2:09 pm. Approximately 2:18 pm RN called to parking lot and observed pt having difficulties. Called for EMS & crash cart. Vitals taken 2:20 BP 83/55, no respirations noted, pt unresponsive. AED attached. EMS arrived 2:22 and took over care of pt. and transported @2:40 pm to Hospital. Per wife, pt has history of PE in Oct. 2020, HTN, diabetes with insulin pump, obesity, gastroparesis, home oxygen and uses motorized scooter. Wife also said pt had allergy to iodine not previously reported, and MD had stopped Zarelto subsequent to		No prior vaccinations for this event.

1st Pfizer vaccine 2/8/21 ""due to breathing difficulty"". Patient was unable to be resuscitated. Time of death 14:59."

CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had an unwitnessed cardiac arrest while outside walking his dog. AED in the field initially advised shock and was shocked 3 times without effect. At the time EMS ALS arrived, patient was in PEA arrest. He was transferred to Hospital with CPR in progress. Time of death called at 1857.	No prior vaccinations for this event.
CARDIOVERSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Presented to ED via EMS c/o increasing shortness of breath, O2 sat mid to high 80s on 4L. When EMS arrived , pt was in distress, intubated by EMS and transported to ED. Pt had a PEA arrest en route but resuscitated w/ return of spontaneous circulation after receiving a dose of epinephrine and chest compressions. Pt was hypotensive on arrival to ED. He was started on sepsis protocol , volume resuscitation and empiric antibiotics. Once stabilized, he was admitted to icu at hospital. Removed from respirator 2/22/21	No prior vaccinations for this event.
CATHETER SITE HAEMORRHAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of	No prior vaccinations for this event.

admission.

CATHETERISATION CARDIAC ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
"""Moderna COVID-19 Vaccine EUA"" It has been reported to me that pt. had gone into hospital for a heart catheterization on 1/12/2021. It was found during this procedure that pt. had suffered a MI. She was release to home the following day and passed away at her residence on 1/15/2021."	No prior vaccinations for this event.
CATHETERISATION VENOUS	**COVID19 (COVID19 (MODERNA)) (1201)**
2-24-21 patient with development of cough, fatigue, increasing on chronic disability worsening debility and falls. scheduled for office visit 2-25.21 0900 call from spouse 0210 am patient was not breathing and lvad alarming low flow alarm on arrival of ems confirm asystolic not breathing and dead	No prior vaccinations for this event.
CELLULITIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did	No prior vaccinations for this event.

not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse

CENTRAL VENOUS CATHETERISATION	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.	No prior vaccinations for this event.
CENTRAL VENOUS CATHETERISATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family,	No prior vaccinations for this event.

code blue not called. Patient expired at 01:53 on 1/19/21.

CEREBELLAR HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm No prior vaccinations for this event.	
CEREBRAL ARTERIOSCLEROSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No adverse reactions noted. Resident is on hospice for end of life care for terminal diagnosis cerebral atherosclerosis. Experiencing respiratory distress 2/10/2021 r/t to hospice prognosis.	No prior vaccinations for this event.
CEREBRAL ARTERY OCCLUSION	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of the MCA territory (TPA not recommended). CTA did show distal L M1/M2 occulsion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.	No prior vaccinations for this event.
CEREBRAL HAEMORRHAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received her first dose of the Moderna COVID-19 Vaccination on Saturday January 16th 2021 at approximately 12pm. She completed all necessary screening forms and was deemed to be at low risk for serious allergic reactions. She tolerated the vaccination well, and no complications or immediate adverse	No prior vaccinations for this event.

events occurred. She was observed for a full 15 mins per CDPHE/CDC guidelines and left the Clinic in stable condition after her observation period was complete. On the morning of Tuesday, January 19th, 2021, the patient was found unconscious and unresponsive by her husband. She was transferred by Ambulance to Hospital shortly thereafter. She was diagnosed with a brain bleed that was determined to be inoperable. She was transferred to other Hospital for higher level care. She was seen by neurosurgery and diagnosed with a ruptured aneurysm. She was treated in the ICU for 24 hours, at which point her team determined that the severity of her brain bleed would not respond to treatment. Supportive cares were withdrawn on Wednesday Jan 20th, and she passed away shortly thereafter.

CEREBRAL HAEMORRHAGE

COVID19 (COVID19 (MODERNA)) (1201)

1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.

No prior vaccinations for this event.

CEREBRAL HAEMORRHAGE

COVID19 (COVID19 (MODERNA)) (1201)

"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with

No prior vaccinations for this event.

the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

CEREBRAL HAEMORRHAGE **COVID19 (COVID19 (MODERNA)) (1201)**

Spontaneous intracerebral hemorrhage and death on 2/20/2021 No prior vaccinations for this event.

CEREBRAL HAEMORRHAGE **COVID19 (COVID19 (MODERNA)) (1201)**

From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021

No prior vaccinations for this event.

CEREBRAL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - anuerism lead to death approximately 14 hours after initial symptoms.	No prior vaccinations for this event.
CEREBRAL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Within 15 minutes of the injection, the individual became aphasia and stroke like symptoms. She was taken to the ER where she was later diagnosed with a cerebral hemorrhage and passed away.	No prior vaccinations for this event.
CEREBRAL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
BRAIN BLEED	No prior vaccinations for this event.

CEREBRAL HAEMORRHAGE COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Unsure if related to vaccine, but wanted to report event of death due to brain bleed on evening of administration of the vaccination.	No prior vaccinations for this event.
CEREBRAL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was found unresponsive on her kitchen floor about 9:45 AM on February 10, 2021 approximately 18	No prior vaccinations for

hours after receiving her first Covid-19 vaccination. Exact time of the event is unknown. She was known to get up between 6:30 and 7:30 AM. It appeared that she had not eaten breakfast nor taken any medication that morning. She was taken by ambulance to Medical Center where a CT scan showed an unrecoverable massive brain hemorrhage. She died at approximately 3:50 PM after the respirator was removed. She was sent to the local Medical Examiner afterwards.		this event.
	CEREBRAL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient and her husband are elderly, but healthy and live independently. Patient took blood pressure medicine 'off and on' according to family. She was 5'2"", 120 pounds and slim and healthy and active, so was her husband, though he had pulmonary fibrosis so they had been staying home and not attending church etc, and masking when they did go out to protect against covid disease. They were both vaccinated with covid Pfizer vaccine (dose #1) on Thursday Feb 11. (02/11/2021) Thursday night as they went to bed they checked in with each other on how they each felt. Patient said she felt totally fine, and her husband said his arm was a bit sore. Patient woke before her husband on Friday Feb 12, went downstairs and, from what the family can tell, fixed herself a snack, then sat on the sofa. Patient's husband found her deceased on the sofa. He called 911 and they asked him to do CPR until the paramedics arrived. Because of proximity to covid vaccine, the ME wanted to examine the body in the home and also ordered an autopsy. Autopsy was completed on the same day as death, Feb 12, 2021"		No prior vaccinations for this event.
	CEREBRAL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-		No prior vaccinations for this event.

19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

CEREBRAL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
CEREBRAL INFARCTION	**COVID19 (COVID19 (MODERNA)) (1201)**
"85 year old patient with multiple medical problems. PEA/asystolic arrest 5 days after receiving vaccine,	No prior vaccinations for

hospitalized. Patient died on 2/1/2021. It is not clear whether the vaccine administration led to the patient's death or not. ""...healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event)"""	this event.	
CEREBRAL INFARCTION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.	No prior vaccinations for this event.	
CEREBRAL INFARCTION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mother had a stroke on 28Jan2021 sometime after 9:30 AM the morning after getting the first dose of the Pfizer Covid vaccine; Cerebral infarction; This is a spontaneous report from a contactable consumer (reporting for mother). A 94-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date unknown as not available or provided to reporter at the time of report completion) via an unspecified route of administration on 27Jan2021 in right arm at single dose for COVID-19 immunization. Medical history included coronary artery disease and hypertension. There were no concomitant medications. The patient was not pregnant. No other vaccine was received in four weeks. The	No prior vaccinations for this event.	

patient did not have covid prior vaccination and not have covid tested post vaccination. The patient had a stroke on 28Jan2021 sometime after 9:30 AM the morning after getting the first dose of the Pfizer Covid vaccine and was hospitalized due to stroke for 6 days from Jan2021. The patient then experienced cerebral infarction in 2021 and died due to it on 04Feb2021. Treatment received for events stroke and cerebral infarction included tPA injection. The outcome of events stroke and cerebral infarction was fatal. An autopsy was not performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Cerebral infarction

CEREBRAL MASS EFFECT	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	No prior vaccinations for this event.
CEREBRAL SMALL VESSEL ISCHAEMIC DISEASE	**COVID19 (COVID19 (MODERNA)) (1201)**
"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable	No prior vaccinations for this event.

troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

CEREBRAL SMALL VESSEL ISCHAEMIC DISEASE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented with spontaneous IVH of small vessel origin with essentially no past medical history. She then acutely developed mesenteric ischemia. Died due to all dead small bowel which also appeared to be small vessel disease and not embolic/thrombotic. This process started one week after	No prior vaccinations for this event.
CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Staff walked into resident's room around 10:00am and noted resident's left side of his face was flaccid. Nurse was called and upon assessment resident noted to have an unequal hand grasp with left worse. He was able to talk but was mumbled and hard to understand. Physician, hospice, and family were notified. Resident had a stroke at 10:06 am on 1/8/2020. He lost all ability to use his left side. Resident passed away on 1/11/2020.	No prior vaccinations for this event.
CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19**

(MODERNA)) (1201)

Resident received Moderna vaccine on 12/23/2020 around 5 pm. At approximately 3:35 am on 12/25/2020, resident had a CVA and died on 1/1/2021 at 3:00 am.

No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT

COVID19 (COVID19 (MODERNA)) (1201)

Stroke, death

No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT COVID19 (COVID19 (MODERNA)) (1201)

My Mother was given the Covid Vaccine (1st Dose) on 12/28/2020. Later that night we received a call from the nursing facility that my Mother was having uncontrollable seizures and had to be transported to the nearby hospital. The ER doctor confirmed that my Mother had tested positive to Covid. She was treated for Covid and was on life support. A few days later we received a call that my Mother had a major stroke. She passed away on January 4, 2021

No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT

COVID19 (COVID19 (MODERNA)) (1201)

spoke with patient husband on Saturday 1/23 and he said that she had been in the hospital. that she had had a stroke, the MD's at the hospital told him that it was not contributed to the vaccine and that they were unsure even if the stroke had occurred prior to the vaccine or after. spoke with him again on 1-29 and he stated that she had passed away on 1/25/21

No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT

COVID19 (COVID19 (MODERNA)) (1201)

Patient had a CVA and passed away suddenly 1/10/21 No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT **COVID19 (COVID19 (MODERNA)) (1201)**

Rapid decline in health status, Elevated BP&P, posturing, loss of consciousness, Glasgow coma Scale 4 starting 2/1/2021, Deceased 2/3/21 No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT **COVID19 (COVID19 (MODERNA)) (1201)**

2/6/2021 stroke. 2/8/2021 he died No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT COVID19 (COVID19 (MODERNA)) (1201)

resident had a stroke, sent to the hospital and died 4 days later No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT **COVID19 (COVID19 (MODERNA)) (1201)**

Patient went into new-onset atrial fibrillation, resulting in a catastrophic stroke. Patient passed away on 2/11 as a result of the stroke. No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT **COVID19 (COVID19 (MODERNA)) (1201)**

Patient called son around 6:30am on 2/18/21. When son tried to contact patient around 8:30am, he was not able to get a hold of patient. Son sent someone over to check on patient. They found patient on the floor. He was coherent at first but then lost consciousness. It believed he experienced a stroke sometime around 8:30-9:00am of 2/18/21. Patient was taken to hospital and then transferred to another hospital. He was put in a medically induced coma. He passed between 4:00 and 4:30 pm on 02/19/21. No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT **COVID19 (COVID19 (MODERNA)) (1201)**

I was notified on 2/22/21 that this patient passed away over the weekend. I do not know the details, nor can I confirm anything beyond what I was told. I believe the death occurred on 2/20/21 due to a massive stroke. No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT **COVID19 (COVID19 (MODERNA)) (1201)**

Patient suffered a stroke and passed away No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT **COVID19 (COVID19 (MODERNA)) (1201)**

"My grandpa had a stroke on the 15th of February. He claimed he had been feeling ""off"" for a few days, but didn't say anything. A blood clot had formed in his brain. He was doing better and about to go to rehab to strength his right side of his body. On the 22nd he took a turn for the worst. He was having trouble breathing and they sedated and partially paralyzed him to put a tube in his mouth. I believe another blood clot had formed and oxygen wasn't properly going through his body. They could not stabilize him, and he passed away the same day." No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT **COVID19 (COVID19 (MODERNA)) (1201)**

The medical facility did not treat patient as her primary care, but were informed that she passed away on 15 February 2021 of a stroke. I do not have further information on the medical aspect of this as we were not her treating provider but did administer the vaccine on 12 February. No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT	COVID19 (COVID19 (MODERNA)) (1201)
Patient received Covid Vaccine Moderna at 1145, multiple syncopal episodes at pharmacy, sent to ER. Outcome Death	No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT	COVID19 (COVID19 (MODERNA)) (1201)
I am the patient's daughter as well as an RN-BSN. My mother was given the Moderna vaccine on Feb 11, 2021 and on Feb 15, 2021 she had a CVA and MI. She was found on her apt. floor unconscious. She was transferred to the Hospital by ambulance where a CT scan and other tests were done. It was determined she had a stroke and heart attack. My mother was in great health, took no medications, and lived alone in her apt. before this incident. The medical professionals determined she would not recover so she was admitted to hospice and died on Feb. 21, 2021. I believe there is a relationship between the vaccine and the CVA and MI.	No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT	COVID19 (COVID19 (MODERNA)) (1201)
Massive stroke; A spontaneous report was received from a consumer (patient's daughter), concerning an 85-year-old female patient, who received Moderna COVID-19 vaccine and death occurred in two days. The patient's medical history was not provided. No relevant concomitant medications were reported. No information on allergies. She states that her mother was physically and mentally healthy before vaccination. On 29-JAN-2021, prior to the onset of events, the patient received her first of two planned doses of covid-19 vaccine for the prophylaxis of Covid-19 infection. There were no complaints on any side effects from the patient for 6 hours after vaccination. Next day, she was found unresponsive on her bed by her neighbor after they were sent to check on her by her daughter. Her heart was beating, and she was breathing at that time, but did not have consciousness. According to her daughter, the patient had a massive stroke in her sleep sometime between 8:pm on 29-JAN-2021 and 9:30 am on 30-JAN-2021. Her life saving measures were	No prior vaccinations for this event.

taken out at 1:15 am on 31-JAN-2021 and she died approximately at 1:45am. No information available on hospitalization and treatment received with this event. It is not known whether autopsy was done. Action taken with 2nd dose of Moderna Covid-19 vaccine was not applicable. The outcome of the event stroke is fatal.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the onset date of the event of stoke, a causal relationship cannot be excluded. Patient's elderly age is considered a risk factor.; Reported Cause(s) of Death: Massive stroke

CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Has underlying dementia and often with difficulty eating. 1 week after immunization she developed a stroke with left sided weakness and difficulty swallowing. Comfort measures instituted. Not sure if this is related to the vaccine, but thought I should report	No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE	No prior vaccinations for this event.

STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.

CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Within 15 minutes of the injection, the individual became aphasia and stroke like symptoms. She was taken to the ER where she was later diagnosed with a cerebral hemorrhage and passed away.	No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
SON SAID PATIENT WAS FOUND UNRESPONSIVE AND CALLED 911	No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient with history advanced vascular dementia, hypertensive cerebrovascular disease and stroke, T2DM. Received her second dose of Pfizer COVID-19 vaccine at approximately 14:00 and was reported to have expired at home at 20:55. Dr. (Medical Director) spoke with patient's son/caregiver 2/4/21. Son reports that patient was in her usual health yesterday morning, deemed well enough by son to travel for vaccination. He reports she had no bothersome symptoms after either first or second vaccinations. Specifically denied rash, wheeze, and difficulty breathing. Son was with patient throughout the day. In the evening, when preparing for bed, he noted she became suddenly unresponsive in a similar fashion as she has done several times in past years. While in all previous such episodes she recovered within minutes, last evening she did not regain consciousness, experiences a brief period of labored breathing, and died. Patient's son called 911 and the patient's body was brought to the medical examiners. The medical examiner declined to proceed with autopsy. Patient's son is not interested in autopsy. Patient's son reports confidence that his mother's underlying hypertensive/diabetic cardiovascular disease is the natural cause of	No prior vaccinations for this event.

her death. Other Relevant Hx: Symptoms: & Death Treatment:

CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
her arm was sore but no other adverse reactions until Saturday, Feburary 6th 2021 she had stroke between 4 and 6pm. She died within 6 to 7 hours later.	No prior vaccinations for this event.
CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient admitted to hospital evening of 2/7/21 with acute ischemic stroke and received tenectaplase. Diagnosis Left MCA stroke. Reporting event given was just over 24 hours after first COVID vaccine dose.	No prior vaccinations for this event.
CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Had a stroke 3 days after round one of Covid vaccine and subsequently died the next week due to complications of stroke. Upon admission to hospital, was in afib.	No prior vaccinations for this event.
CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Adverse reaction to the vaccine started with variable weakness beginning 1/29/2021. On 1/30/21 around 8:30pm, he needed assistance in the bathroom related to weakness and had what was later identified as a stroke with left side weakness and slurred speech. In accordance with his wishes, he had care at home. Due	No prior vaccinations for this event.

to his advanced age and frailty, a CT scan was not pursued. The 325 mg of aspirin that he was previously taking daily was discontinued. After the stroke, he needed total care. Hospice was established at home. Nursing assistant care was delivered by daughter. Death followed 9 days later (2/9/2021).

	CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Stroke; This is a spontaneous report from a contactable consumer. A 94-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 16Jan2021, at single dose, for COVID-19 immunisation. Medical history included ongoing hypertension (took medication). Patient did not have COVID-19 prior to vaccination. Concomitant included unspecified medication for hypertension. The patient experienced stroke on 31Jan2021. The patient was brought to the emergency room and hospitalized due to the event on 31Jan2021. No therapeutic measures were taken as a result of the event. The patient underwent lab tests and procedures which included COVID-19 virus test: negative in Feb2021 (a week before report); investigation: brain bleed and discovered she had a stroke (on unknown date in 2021). The patient died on 03Feb2021 due to stroke and old age. An autopsy was not performed. Patient's family did not attribute her death to the vaccine at all. The information on the Lot/Batch number has been requested.; Reported Cause(s) of Death: stroke; Old age		No prior vaccinations for this event.

	CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient woke up on the morning of 2/6 with symptoms of a stroke. Rushed to hospital where clot found in brain. Recovered from initial stroke but then had another major stroke on 2/8 and never recovered.		No prior vaccinations for this event.

	CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19**

(PFIZER-BIONTECH)) (1200)

On the 25th he was home alone, he called 911 and let them know he thought he was having a stroke. EMS arrived and transported him to Hospital. It was massive stroke, he was not able to comprehend anything, he was put into Hospice the following day and passed away on the 27th. There was no autopsy preformed.

No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death after stroke .

No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

stroke; This is a spontaneous report from a contactable consumer reported for father. An 87-year-old male patient received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: el9261) via an unspecified route of administration on 22Jan2021 at 10:45 AM at single dose for covid-19 immunisation. Medical history was unknown. Concomitant medications included other medications in two weeks in medical records. The patient had no other vaccine in four weeks. The patient had a stroke around 9 pm after receiving vaccine on same day (22Jan2021). At 10:50 that morning, he died on 27Jan2021. AE resulted in emergency room/department or urgent care, hospitalization. The patient had hospitalization for 5 days. The patient had no Covid prior vaccination, no Covid tested post vaccination, no known allergies. The patient had other medical history (unspecified). It was unknown whether the autopsy was performed. Outcome of the event was fatal.; Reported Cause(s) of Death: stroke

No prior vaccinations for this event.

CEREBROVASCULAR ACCIDENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

My mother had a stroke on 28Jan2021 sometime after 9:30 AM the morning after getting the first dose of the Pfizer Covid vaccine; Cerebral infarction; This is a spontaneous report from a contactable consumer (reporting for mother). A 94-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date unknown as not available or provided to reporter at the time of report completion) via an unspecified route of administration on 27Jan2021 in right arm at single dose for COVID-19 immunization. Medical history included coronary artery disease and hypertension. There were no concomitant medications. The patient was not pregnant. No other vaccine was received in four weeks. The patient did not have covid prior vaccination and not have covid tested post vaccination. The patient had a stroke on 28Jan2021 sometime after 9:30 AM the morning after getting the first dose of the Pfizer Covid vaccine and was hospitalized due to stroke for 6 days from Jan2021. The patient then experienced cerebral infarction in 2021 and died due to it on 04Feb2021. Treatment received for events stroke and cerebral infarction included tPA injection. The outcome of events stroke and cerebral infarction was fatal. An autopsy was not performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Cerebral infarction	No prior vaccinations for this event.
CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Cardiac Event MI or Stroke; Cardiac Event MI or Stroke; This is a spontaneous report from a contactable consumer (Son in law). A 73-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at left arm on 17Feb2021 14:00 at single dose for covid-19 immunisation. Medical history included atrial fibrillation (AFib), prostate cancer Survivor. Concomitant medication included alirocumab (PRALUENT), escitalopram oxalate (LEXAPRO), apixaban (ELIQUIS), nitroglycerin and Ca channel blocker. The patient received the first dose of BNT162B2 on an unknown date for covid-19 immunisation. The patient experienced cardiac event myocardial infarction (MI) or stroke on 17Feb2021. Adverse event result in Doctor or other healthcare professional office/clinic visit. It was unknown if treatment received for the events. Prior to vaccination, the	No prior vaccinations for this event.

patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for COVID-19. The patient died on 19Feb2021. It was unknown if an autopsy was performed. The outcome of the events was fatal. The reporter didn't know if this was associated or not. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Cardiac Event MI or Stroke; Cardiac Event MI or Stroke		
	CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal tunnel and sent her home. The morning or March 18th , 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.		No prior vaccinations for this event.
	CEREBROVASCULAR ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Developed acute facial droop and slurred speech 2h after 1st dose of the vaccine on 2/17, found with R MCA stroke. Then became unresponsive on 2/27 and was found with an acute L MCA stroke. Was transferred from another hospital, was not a candidate for intervention, and was made comfort and died on 2/28		No prior vaccinations for this event.
	CHEMOTHERAPY	**COVID19 (COVID19 (MODERNA)) (1201)**
chills 1 day after vaccine administration; found dead by family 1/18/2021 Narrative: Per patient family report, patient said the next day after vaccination that he didn't feel well because of chills. Patient was found dead		No prior vaccinations for

at home by his family on January 18th. He was a 74yo man with castrate resistant prostate cancer and liver and bone metastases with rising PSA, status post intravenous chemotherapy 1/7/21 this event.

	CHEMOTHERAPY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg		No prior vaccinations for this event.

of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well.

Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure""""

CHEST DISCOMFORT		**COVID19 (COVID19 (MODERNA)) (1201)**
Clients wife reported on 1/18/2021, that her husband died unexpectedly the day after receiving the COVID 19 vaccine. I called and spoke with her. She stated that the client had started experienced some tightness in his chest the evening of 1/11/2021. She stated that it was normal for him to have the tightness in his chest if he got stressed. She stated that she found him on the garage floor on 1/12/2021 at 2120. He was taken by ambulance to the hospital. She stated that the hospital told her that his COPD had caused him to go into arrythmia.		No prior vaccinations for this event.
CHEST DISCOMFORT		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt started complaining of chest heaviness and shortness of breath on the afternoon of 1/21/21. EMS was called to the patients home and she was found to have an O2 sat in the 70's. She was admitted to hospital and found to have a proBNP of 5000. She tested negative for Covid-19. She was determined to be in acute-on-chronic heart failure and was referred for hospice care. She passed away on the evening of 1/24/21.		No prior vaccinations for this event.
CHEST DISCOMFORT		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

The day following the vaccine, the patient complained of throat issues and anxiety. This was not new... however . That evening he reported difficulty breathing and was placed on oxygen; a COVID test was performed and was negative. On 12/30/2020, patient complained of sternal pressure and was transferred to the hospital. The patient died 12/31/2020 and records obtained from the hospital indicated the patient died from a massive myocardial infarction.	No prior vaccinations for this event.
CHEST DISCOMFORT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
She had the first dose of Pfizer vaccine at the Campus on Friday 1/15 at 4:30 pm. After the vaccine, she had no new symptoms or signs of vaccine reaction and MD friend reports that he checked her pulse which was not elevated from baseline. On 1/16, she awakened and continued to feel at her recent baseline. However, in the early afternoon, she complained of headache, nausea/epigastric pain, and chest heaviness. These apparently were not unusual symptoms for her to feel intermittently. Per her niece, who has a home O2 sat device, her 02 sat that morning was 97 with a HR of 87 irregularly irregular. She was afebrile. (continue on page 2)	No prior vaccinations for this event.
CHEST DISCOMFORT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/28/2021- Seen by FNP for indigestion, chest pressure and palpitations. EKG reviewed and referral made to Cardiology. 1/29/2021-1800 Presented to ED in cardiac arrest-onset PTA. Patient was found unresponsive by his wife at their home. The last known well was at 1530 when she called him on the phone. The patient was pronounced at ~1850.	No prior vaccinations for this event.
CHEST DISCOMFORT	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

DEATH Narrative: Pt he reports he developed chills SOB body aches the same night as receiving the COVID vaccine on 1.26.2021-pt is currently reporting CheSt tightness and SOB Admitted to hosp: ICU with Bilateral Pulmonary Emboli, LLE DVT, NSTEMI, Arrhythmia.

No prior vaccinations for this event.

CHEST INJURY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.

No prior vaccinations for this event.

CHEST PAIN

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21

No prior vaccinations for this event.

CHEST PAIN

COVID19 (COVID19 (MODERNA)) (1201)

1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2

No prior vaccinations for this event.

with gram positive cocci in clusters growing after 9 hours.

	CHEST PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to the Emergency Department complaining of chest pain, pale, cool diaphoretic, and hypotensive. The patient was discovered to have a large saddle pulmonary embolism, went into cardiac arrest and expired. Of note, the patient received her second Moderna COVID vaccine on 1/23, which would place her first one approximately 12/25 if she received them at the appropriate interval. This information is from the patient's daughter and the ED record, the information is not available in CAIR. Per the daughter, the patient started feeling ill on 1/21, improved on 1/25, and then acutely worsened on 1/27, resulting in the ED visit.		No prior vaccinations for this event.
	CHEST PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Cardiac arrest; Pain on her upper right chest; Lot of pain in lower abdomen; Pain underneath arm; Thought it was muscle aches; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed upper right chest pain and underneath the arm, severe abdominal pain, muscle aches and cardiac arrest. The patient's medical history was not provided Concomitant product use was not provided by the reporter. On 14 Jan 2021, approximately five days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the arm for prophylaxis of COVID-19 infection. On 19 Jan 2021, the patient developed upper right chest pain and pain underneath the arm. They thought it was muscle aches. Sometime later, the patient developed a lot of pain in the lower abdomen. The called emergency services and an ambulance arrived but the patient then suffered cardiac arrest. Treatment for the event included tramadol. Action taken with mRNA-1273 in response to the events was not applicable due to the patient was died. The patient died on 19 Jan 2021. The cause of death was reported as cardiac arrest. Autopsy were not provided.; Reporter's Comments: Company Comment: This case concerns a 92-year-old female patient who experienced		No prior vaccinations for this event.

unexpected serious events of cardiac arrest, upper right chest pain and underneath the arm, severe abdominal pain, muscle aches. The event occurred 5 days after the administration of the first dose of the vaccine mRNA-1273 vaccine (Lot #: unknown, expiration date-unknown). Although a temporal association exist between the events and the administration of the vaccine, in the absence of critical details such as the patient's medical history, any diagnostic test or autopsy result, adequate evaluation and assessment cannot be established. Main field defaults to æpossibly related' for all events.; Reported Cause(s) of Death: Cardiac arrest		
	CHEST PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
EARLY SUNDAY MORNING THE PATIENT BEGAN VOMITTING AND SHORT OF BREATH AND CHEST AND BACK PAIN. SHE CODED WHEN SHE GOT IN THE ER AND LATER PASSED AWAY THE MONDAY. DIAGNOSIS WAS PNEUMONIA AND HEART FAILURE PER STEP DAUGHTER.		No prior vaccinations for this event.
	CHEST PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
pt received vaccine on 2/3. early on 2/4 developed chest pain, dyspnea, and was seen in ED and diagnosed with acute exacerbation of CHF and NSTEMI type 2, and anemia. on 2/5 transfusion was started and pt developed worsening dyspnea and then PEA arrest. Pt achieved ROSC and was transferred to the cardiac intensive care unit where he required vasopressor support. he subsequently declined and died on 2/7		No prior vaccinations for this event.
	CHEST PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
"The decedent experienced severe chest pain and dyspnea approximately nine days following the first series of the vaccine. He reported to family members that he was having a ""severe reaction"" to the vaccine and believed it was acute pericarditis due to the same symptoms he experienced prior. He reported that on 2/1/21		No prior vaccinations for this event.

around 0300 hours, the symptoms were the most severe and he was going to seek medical attention, but did not. He waited till the convenient store opened and purchased OTC Tylenol for relief of symptoms. He continued to have dyspnea and chest pain up until 2/9/21, when he called 911 complaining of chest pain and was found to have a STEMI; subsequently died at Hospital in the ER."

	CHEST PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt was hospitalized Jan 18, 2021 after he had fallen outside overnight and lay there approximately 12 hours until he was found. Hypothermic & rhabdomyolis diagnosis. Gradually improved w/ strength & mental status - was in swing bed @ hospital. He got his first Covid 19 shot on 2-8-21. Was fine @ 0300 on 2-9-21 and @ 0430 he was found unresponsive. Dx: probable arrythmia & pronounced dead @ 0454. Noted on pain scale @ 2/8/21 @ 21:11, clients pain was a 7/10 They offered pain med & he refused They repositioned & distracted him @ 2047 on 2/8/21 Pain had decreased to 3/10 and nothing given. Then @ 0300 check he was sleeping and @ 0430 unresponsive.		No prior vaccinations for this event.
	CHEST PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Started feeling unwell; Headaches; Body aches; Chest pain; Didn't had wishes to eat; Diarrhea; COVID-19 pneumonia; A spontaneous report was received from a consumer concerning a 69-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced COVID-19 pneumonia, feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea The patient's medical history high blood pressure which was controlled with medication. Concomitant product use included nifedipine and fenofibrate. On 20-JAN-2021, approximately a week and a half or two prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number 030L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. A week and a half or two later the patient stated feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea for which patient was hospitalized on		No prior vaccinations for this event.

06-FEB-2021. Since everything seemed to be fine the patient was discharged on an unknown date in FEB-2021 however, patient's family was not notified that it was a late reaction to the vaccine's first dose. Later, due to shortness of breath he was hospitalized again on 08-FEB-2021 and was diagnosed for pneumonia and was intubated on the same day. Due to COVID-19 situation patient's family could not be in the facilities and that there wasn't any follow up of the patient given to the family, so family did not have much information. During the first hospitalization(06-FEB-2021) the patient had a blood test which showed a normal result and was tested for COVID-19 and Influenza, both were negative. During second hospitalization (08-FEB-2021) the hospital said that the patient was stable. The patient's family did not know the results of the tests conducted at the time. The action taken with the vaccine in response to the events is not applicable. The outcome of COVID-19 pneumonia was fatal. The patient died on 14 Feb 2021 The cause of death was reported as COVID-19 related pneumonia. The autopsy was not done.; Reporter's Comments: Very limited information regarding this event has been provided at this time. The cause of death was reported as COVID-19 related pneumonia. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the events are assessed as unlikely related. Further information has been requested.; Reported Cause(s) of Death: COVID-19 pneumonia

	CHEST PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
on 2/218/2021 the patient was at home and developed chest pain. Patient was transported by family to urgent care then to the ED where the patient later died.		No prior vaccinations for this event.
	CHEST PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP		No prior vaccinations for this event.

Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation

CHEST PAIN

COVID19 (COVID19 (MODERNA)) (1201)

Chills; headache; extreme fatigue; gas or chest pain that was thought to be gas and went away Died 4 days later

No prior vaccinations for this event.

CHEST PAIN

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Fever, shortness of breath and chest pain that resulted in a heart attack a few hours after vaccination

No prior vaccinations for this event.

CHEST PAIN

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

54 y/o M with PMH of HTN, HLD, Alcoholic Cirrhosis, Aortic Valve Stenosis, and angina BIBA as a Medical Alert for cardiac arrest noted PTA. Per EMS, the patient called because he was having constant, diffuse abdominal pain x 1 day that radiated to his chest. On scene, the patient had a witnessed arrest with EMS starting CPR. He was given 3 rounds of epi without ROSC. Pt had no associated shockable rhythm. Of note, pt's wife, had noted pt had received covid vaccine the prior day.

No prior vaccinations for this event.

CHEST PAIN

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

No prior vaccinations for this event.

CHEST PAIN

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

she was hurting at her chest/ Chest pain; on her left arm hurt real bad that's what the clot on her left arm;

No prior vaccinations for

on her left arm hurt real bad that's what the clot on her left arm; She passed away; heart attack; This is a spontaneous report from a contactable consumer. An 87-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Jan2021 at single dose for COVID-19 immunisation. Medical history included diabetes mellitus, for which she was taking a pill like an hour before she would take her meal. On Monday (Jan2021) the patient experienced was hurting at her chest/ chest pain, her left arm hurt real bad as she had a blockage in her left arm/clot on her left arm, and they wanted to put in a stent and after the surgery it went well and she all go home in two days. The patient was hospitalized in Jan2021 due to the events. She had a heart attack and that the chamber between the dividers had a hole in it and her heart tissue was too thin so much thin she couldn't repair it. The patient passed away on 26Jan2021. The patient was tested negative for COVID-19 on unknown date. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: She passed away		this event.
	CHEST PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began with vomiting and diarrhea. C/O chest pain. Bradycardia. Hypotension. 2 seizures in 45 minutes after not having one in years. We gave fluids. Gave Zofran. Comfort measures. Pt passed at midnight. Was completely fine one day before. Had minimal issues with COVID though did have a pneumonia that was treated w ATB early on and resolved.		No prior vaccinations for this event.
	CHEST PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated at 11:30am. By 7pm he started presenting symptoms of fatigue, chest pain. Patient urinated and defecated in himself. Was not feeling well. Patient died at 10:30pm.		No prior vaccinations for this event.

CHEST PAIN

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off

No prior vaccinations for this event.

to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

CHEST PAIN

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

For the two days prior to presentation the patient had been complaining of chest pain, his breathing seemed to be labored Monday. He and the family thought the pain was due to shingles as he carried this diagnosis from a month ago. Patient had also received the COVID vaccine 2 days prior to presentation and assumed he was feeling unwell due to the vaccine. Family wanted to take him to the hospital yesterday and earlier today but he refused. She left him in his home earlier this afternoon prior to presentation and returned to check on him finding him unresponsive and apneic at which time EMS was activated. #cardiac arrest -- suspect primary cardiac given collateral from family at home, consider hypoxemia which was corrected with advanced airway and 100% FiO2, patient clinically euvolemic and with soft brown stool in diaper not

No prior vaccinations for this event.

suggestive of GI hemorrhage, attempt to address acidosis with CPR and bicarbonate, not hypoglycemia, on bedside ultrasound FAST neg and no pericardial effusion suggestive of tamponade and +lung sliding bil not spontaneous pneumothorax Assessment/Diagnosis: -cardiac arrest, cause unspecified

	CHEST PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of covid vaccine on 1/22/2021. Patient had no immediate reaction. Patient presented to the Emergency Department on 1/26/2021 c/o shortness of breath and chest pain. ECG showed a ST elevation myocardial infarction. Patient was treated and transferred to a cath lab where he died. Patient had significant coronary artery disease.		No prior vaccinations for this event.

	CHEST PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/26 /2021 - pt went to ER for chest pain 2/9/2021 - pt received Pfizer COVID vaccine 1st dose 2/17/2021 - cardiac arrest with death		No prior vaccinations for this event.

	CHEST PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
pulmonary edema; Low heart rate; chest pain; This is a spontaneous report from a contactable pharmacist. An 80-years-old male patient received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in left arm on 28Jan2021 at single dose for COVID-19 Immunisation. Medical history included dementia, high blood pressure, COVID prior vaccination. He had no known allergies. Concomitant medication included diltiazem hydrochloride (CARDIZEM), anastrozole (ARIMIDEX), simvastatin and lorazepam. Historical Vaccine included first dose of BNT162B2 (PFIZER-BIONTECH		No prior vaccinations for this event.

COVID-19 VACCINE) on 07Jan2021 (at the age of 80-years-old) at single dose for COVID-19 Immunization. There was no other vaccine received in four weeks. The patient experienced pulmonary edema, low heart rate and chest pain on 26Feb2021. The events resulted in hospitalization and patient died. The patient was hospitalized from 26Feb2021 for 1 day. Treatment received for the events included Epinephrine, morphine, nitroglycerine. The patient underwent lab tests and procedures which included Covid test Nasal Swab post vaccination on 26Feb2021 indicated Negative. The patient died on 26Feb2021. An autopsy was not performed. information on the lot/batch number has been requested.; Sender's Comments: Pulmonary edema, low heart rate, and chest pain, all reported as fatal, are deemed unrelated to BNT162B2 vaccine, being rather accidental occurrences, likely favored by the patient's age and by the mentioned high blood pressure, known risk factor for cardiovascular diseases. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Low heart rate; pulmonary edema; chest pain

CHEST TUBE INSERTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate	No prior vaccinations for this event.

cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

CHEST X-RAY

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21

No prior vaccinations for this event.

CHEST X-RAY

COVID19 (COVID19 (MODERNA)) (1201)

1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2

No prior vaccinations for this event.

with gram positive cocci in clusters growing after 9 hours.

CHEST X-RAY **COVID19 (COVID19 (MODERNA)) (1201)**

cough congestive heart failure death No prior vaccinations for this event.

CHEST X-RAY **COVID19 (COVID19 (MODERNA)) (1201)**

Patient developed Covid pneumonia dx 1/15/21, patient expired No prior vaccinations for this event.

CHEST X-RAY **COVID19 (COVID19 (MODERNA)) (1201)**

Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127 No prior vaccinations for this event.

CHEST X-RAY **COVID19 (COVID19 (MODERNA)) (1201)**

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient No prior vaccinations for this event.

was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

CHEST X-RAY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm No prior vaccinations for this event.

CHEST X-RAY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1st COVID immunization 1/7/2021, COIVD positive results on 1/16/21, 1/24/21 O2 sats decreased to 78%, 1/24/21 reveived the Bamlanivimab infusion 50 ml/hr. 1/24/20 chest x ray 1/24/21 She was sent to hospital and admitted. 1/27/2021 Expired	No prior vaccinations for this event.
CHEST X-RAY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Early in the shift on January 31 resident was noticed to be more tired than usual and was not eating well. Lung sounds were crackly and resident was found to be hypotensive. He was evaluated in emergency department. He was diagnosed with pneumonia. Received a loading dose of antibiotic and returned to facility.	No prior vaccinations for this event.
CHEST X-RAY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.	No prior vaccinations for this event.
CHEST X-RAY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.	No prior vaccinations for this event.
CHEST X-RAY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral	No prior vaccinations

patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice, memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200 mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation: tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed, metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every for this event.

morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral

patchy opacities

CHEST X-RAY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
within 24 hours after her second injection she developed chills, had a syncopal episode and had, difficulty breathing. this progressed over the next day when she had a second syncopal episode and her dyspnea and confusion worsened EMT was called and she was brought to the hospital. she was in flash pulmonary edema and with her history of severe aortic stenosis she was admitted to the cardiac icu. she had no prior history up to that time of pulmonary edema and was functioning without distress in her home. she had a history of covid in early april, manifesting primarily as severe confusion, from which she recovered.	No prior vaccinations for this event.
CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff.	No prior vaccinations for this event.

Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics

CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless and breathless and was pronounced. Autopsy currently pending.	No prior vaccinations for this event.

CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.	No prior vaccinations for this event.

	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.
	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face, increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious		No prior vaccinations for this event.

unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died		
	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29		No prior vaccinations for this event.
	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.		No prior vaccinations for this event.
	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**

"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"	No prior vaccinations for this event.
CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡	No prior vaccinations for this event.

enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

CHEST X-RAY ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

No prior vaccinations for this event.

CHEST X-RAY ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration

No prior vaccinations for this event.

CHEST X-RAY ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of

No prior vaccinations for this event.

breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

CHEST X-RAY ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Several days after vaccination his left arm turned red. He was taken to the hospital where he was

No prior vaccinations for

evaluated and admitted with a diagnosis of left axillary vein thrombosis. A chest X-ray was taken and he presented bibasilar atelectasis and pneumonia with pleural effusions.		this event.
	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient developed 104.4 temp approximately 48 hours after being given the vaccine. I treated him with antibiotics, IV fluids, cooling methods. CXR does show a new right perihilar infiltrate. However, his fever came down within the next 24-48 hours. Unfortunately, he suffered a cardiac arrest on 1/21/21 in the early morning and expired.		No prior vaccinations for this event.
	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some		No prior vaccinations for this event.

interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with

radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with	No prior vaccinations for this event.

LPN. Funeral Home called at 1900 and body released at 2000.

	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.		No prior vaccinations for this event.

	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
emesis bright yellow in color, liquid BM, increased respirations No prior vaccinations for this event.		

CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple		No prior vaccinations for this event.

aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Xrays showed covid Poss pockets all in her lungs on 15Jan; Xrays showed covid Poss pockets all in her lungs on 15Jan; This is a spontaneous report from a contactable consumer. An 85-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for covid-19 immunisation. Medical history included dementia. Concomitant medications were not reported. Patient popped hot 02Jan2021 along with 4 others on the hall she lived. Within 9 days 50+ patients were positive. All had the vaccine the same day. Patient was test positive on 02Jan2021. She was on day 12 of her quarantine when she started to get worse. She was unresponsive by	No prior vaccinations for this event.

16Jan2021 and passed 18Jan2021. We were with her from 14Jan2021 to 18Jan2021. But had not been allowed to visit with her since Mar2020. And what post treatment pairs well with it? Publicly we hear Remdesivir and Bamlanivimab but these patients only received a general antibiotic and some vitamins. Death cause was Xrays showed covid Poss pockets all in her lungs on 15Jan2021. No autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information; Reported Cause(s) of Death: Xrays showed covid Poss pockets all in her lungs on 15Jan

CHEST X-RAY ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the

No prior vaccinations for this event.

emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."		No prior vaccinations for this event.
	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
right arm swelling immediately after injection. followed by bilateral lower leg edema, chills and body aches		No prior vaccinations for

that continued daily at 2 weeks post immunization admin 2/4/21 treated with dexamethasone 6mg PO x 7 days- this resolved his s/s 2/13/21 patient passed away at facility		this event.
	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.		No prior vaccinations for this event.
	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.		No prior vaccinations for this event.
	CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low		No prior vaccinations for this event.

oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

CHEST X-RAY ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO WITHDRAWL EXTRME MEASURES

No prior vaccinations for this event.

CHEST X-RAY ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice, memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200 mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation:	No prior vaccinations for this event.

tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed, metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal

relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral patchy opacities		
CHEST X-RAY ABNORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.	No prior vaccinations for this event.	
CHEST X-RAY ABNORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-	No prior vaccinations for this event.	

2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

CHEST X-RAY ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 No prior vaccinations for

at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.

this event.

CHEST X-RAY ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)

No prior vaccinations for this event.

CHEST X-RAY ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed

No prior vaccinations for this event.

troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on

2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

CHEST X-RAY NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient recieved vaccine 1 of covid 19 i 1/19/2021. She felt poorly on 1/20/2021. She felt dizzy and fell at 3 AM on 1/23/2021. She felt poorly and did not know her son's name which was not normal. She went to ER on 1/24. She was assessed as not having fractures. She was going to be transferred to a skilled nursing facility. She was not having respiratory complaints. She was awaiting transfer when her O2 levels started dropping substantially. She declined aggressive intervention and she died within a few hours.

No prior vaccinations for this event.

CHEST X-RAY NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction

No prior vaccinations for this event.

to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

CHEST X-RAY NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Has underlying dementia and often with difficulty eating. 1 week after immunization she developed a stroke with left sided weakness and difficulty swallowing. Comfort measures instituted. Not sure if this is related to the vaccine, but thought I should report	No prior vaccinations for this event.
CHEST X-RAY NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.	No prior vaccinations for this event.

	CHEST X-RAY NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."		No prior vaccinations for this event.
	CHEST X-RAY NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank		No prior vaccinations for this event.

anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21		
	CHEST X-RAY NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1 fall after first dose on 1/8/2021 at 1930; no injuries; 4 falls after second dose on 1/14/21 at 1545, 1/15/21 at 1700, 1/21/21/at 1220 and 1/21/21 at 1330 all falls with no injuries. Started Ceftriaxone 1 GM IM daily for 5 dyas on 1/21/21 for UTI: E. Coli		No prior vaccinations for this event.
	CHEST X-RAY NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/21 - Resident complained of SOB. SPO2 66% on RA, vs 105/66-96-20 T98.2 O2 administered Pox 97% Binax test revealed (+) COVID results. Resident transferred to COVID wing. Family (HCP) updated and declined transfer to hospital Resident continued with fever, hypoxia and lethargy. Family elected CMO and Hospice notified. Resident died on 1/16/2021 @ 930AM.		No prior vaccinations for this event.
	CHILLS	**COVID19 (COVID19**

	(MODERNA)) (1201)
Resident had body aches, a low O2 sat and had chills starting on 12/30/20. He had stated that they had slightly improved. On 1/1/21 he sustained a fall with a diagnosis of a displaced hip fracture. On 1/2/21 during the NOC shift his O2 sat dropped again. He later went unresponsive and passed away.	No prior vaccinations for this event.
CHILLS	**COVID19 (COVID19 (MODERNA)) (1201)**
ON 1/21/2020 RESIDENT WAS EXPERINCING CHILLS AND LOOSE STOOLS. FOLLOWING THIS EPISODE BECAME UNRESPONSIVE, PALE, DIAPHORETIC AND BRADYCARDIC. PALLIATIVE CARE WAS PROVIDED. RESIDENT PASSED AWAY APPROX. 10 HOURS LATER.	No prior vaccinations for this event.
CHILLS	**COVID19 (COVID19 (MODERNA)) (1201)**
Death Narrative: Patient received the first COVID-19 dose on 12/23. Afterwards, patient complained of localized pain on L deltoid area where the vaccine was administered; his temperature was 98.1 F. On 12/26-27, staff reported that patient appeared more fatigued than usual and was shivering on 12/27, which seized after blanket was given. On 12/28, patient presented with fever (Tmax 100.2 F) and acetaminophen was administered for alleviation of fever. ADR was reported for the fever on 12/29. Patient continued to decline and was placed back on hospice care on 12/29; on 12/30. the symptoms reported on nursing note include erythema and pain on whole L arm. Lidocaine was applied. Patient's family and provider mutually agreed not to administer the second dose of vaccine. He continued to decline and was started on end-of-life care around 1/4 and passed on 1/20 1417.	No prior vaccinations for this event.
CHILLS	**COVID19 (COVID19 (MODERNA)) (1201)**

chills 1 day after vaccine administration; found dead by family 1/18/2021 Narrative: Per patient family report, patient said the next day after vaccination that he didn't feel well because of chills. Patient was found dead at home by his family on January 18th. He was a 74yo man with castrate resistant prostate cancer and liver and bone metastases with rising PSA, status post intravenous chemotherapy 1/7/21	No prior vaccinations for this event.	
CHILLS		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had the first Moderna Covid vaccine on Thursday 1/21/2021. She had a bit of sore arm on that day and the day after. On Saturday 1/23/2021, she had a fever of 100.5 F (11AM), nausea, light headache and chills. The temperature went down after she took ibuprofen. Patient's husband enrolled her to V-Safe to report all the adverse effects she experienced. On Sunday 1/24/2021, her temperature was 98.3F. She still had nausea and no appetite. She and her husband watched a football game in their bedroom upstairs. Husband noticed that his wife was pacing around the room many times. At 7Pm, Husband went downstairs for dinner but she refused to come down to eat. He went upstairs around 8pm, TV was still on. He turned off TV and went down stairs again thinking his wife felt as sleep while watching TV. He went back upstairs for bed around 10:30 PM. Husband said his wife had a deviated septum so she would snore very loudly when asleep. He didn?t hear her snoring so he went to check on her and found her not responsive. Husband called emergency services. Paramedic came at 10:45 and said patient was passed. Husband sent many texts to V-safe after that to report the incident. No response was received from V-safe. Patient?s doctor told her husband that she died due to cardiac arrest.	No prior vaccinations for this event.	
CHILLS		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident reviewed for incident. Resident received the second dose of the Moderna Covid-19 vaccine lot# 016M20A Exp 5/2/2021 on 2/5/2021 from clinic through pharmacy. Resident had her temp/O2 taken on AM shift and was 98.6/93%, beginning PM shift 98.4/95%. A few hours later noted that resident to have chills and	No prior vaccinations for this event.	

was shaking RN assessment completed and vitals taken resident noted to have temp of 102.2, oxygen 95%, pulse 110. Resident alert and oriented at that time and talking to staff. Reported findings to APNP with order to send to ER. 911 called, residents brother updated. Upon EMT arrival RN went down to residents room with EMT and resident had an emesis as resident was getting cleaned up resident went unresponsive. Pulse noted to still be present at that time, resident did briefly respond to sternal rub and then went unresponsive again. Resident full code and EMT transferred to gurney and said that if they lost a pulse in route that they would transfer to hospital B instead of hospital A being the closest facility. RN called brother and gave update. Facility notified from Hospital that resident had passed away.

CHILLS

COVID19 (COVID19 (MODERNA)) (1201)

2/10: Fever, fatigue, tylenol 2/11 @ 1300: pt made DNR, hospice consulted 2/11 @ 1800 decreased LOC, increased RR, fever, chills - 1/5L NS bolus IV, rectal tylenol. Refusing to eat/drink, PO morphine 2/12 @ 16:30, deceased at facility **resident was not doing well prior to vaccination

No prior vaccinations for this event.

CHILLS

COVID19 (COVID19 (MODERNA)) (1201)

Two days later passed away; difficulty breathing, shortness of breath; difficulty breathing, gurgling; Not feeling well; Achiness; Severe fever; Chills; A spontaneous report was received from a physician concerning a 56-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed fever, chills, achiness, shortness of breath, gurgling and unresponsive. The patient's medical history was not provided. Concomitant product use was not provided. On 19 Jan 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Lot 042L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. After receiving the vaccine on 19 Jan 2021, the patient experienced fever, chills, shortness of breath, gurgling and achiness. On 21 Jan 2021, the patient was found unresponsive. Emergency medical services were called to perform life saving measures however, they were

No prior vaccinations for this event.

unsuccessful. No further treatment information was provided. The patient died on 21 Jan 2021. The cause of death was reported as unknown. An autopsy was planned.; Reporter's Comments: This case concerns a 56-year-old, female, who experienced a serious event of death, with many other events after receiving second dose of mRNA-1273 (Lot# 042L20A). Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

	CHILLS	**COVID19 (COVID19 (MODERNA)) (1201)**
He had rigors starting 6 pm the day after the vaccination. He was treated with one 500 mg tylenol. He had increased wheezing but did not complain of SOB. At 0400 the next morning, he died.		No prior vaccinations for this event.
	CHILLS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient felt fine on Friday afternoon and evening after shot. Felt fine on Saturday until the afternoon when she started feeling fatigued and chilled. Decided to take a warm bath at about 6pm. Was found dead in bathtub at approximately 7pm with blisters on arms, legs, and face.		No prior vaccinations for this event.
	CHILLS	**COVID19 (COVID19 (MODERNA)) (1201)**
pt woke up at 0400 with fever, chills, and body aches progressing over 4 hours to the point when she became unresponsive. husband called 911, pt was declared dead at the time of EMS arrival around 1200		No prior vaccinations for this event.
	CHILLS	**COVID19 (COVID19 (MODERNA)) (1201)**
High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased;		No prior vaccinations

Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

for this event.

CHILLS	**COVID19 (COVID19 (MODERNA)) (1201)**

Fever, chills, fatigue, muscle aches, nausea, death 48 hours after injection No prior vaccinations for this event.

CHILLS	**COVID19 (COVID19 (MODERNA)) (1201)**

My grandpa got his second covid vaccine on Thursday. Saturday he complained of stiff neck. Sunday he had low grade fever, nausea and vomiting, chills, and mild headache. He was feeling bad enough to call squad at 3 pm. The paramedics did evaluation and thought he was just experiencing normal side effects from vaccine and felt no need to transport to hospital so my grandpa decided to stay home and just rest. At 2 am that same

No prior vaccinations for this event.

night he went into cardiac arrest and was not able to be brought back

	CHILLS	**COVID19 (COVID19 (MODERNA)) (1201)**
Beginning in the evening 2/19/21, fever/chills/fatigue; worsening of symptoms 2/20/21 with lethargy/lack of appetite/weakness; unable to arouse on 2/21/21 then breathing stopped, patient's spouse called 911 performed CPR, EMS continued for 15 min then while in ambulance to hospital where he was pronounced dead. Official time of death 2:20pm		No prior vaccinations for this event.
	CHILLS	**COVID19 (COVID19 (MODERNA)) (1201)**
Chills; headache; extreme fatigue; gas or chest pain that was thought to be gas and went away Died 4 days later		No prior vaccinations for this event.
	CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Jan 3 vaccine administered, jan 4 started headaches, vomiting, pain in the back of the neck, Headaches, chills, loss of speech,		No prior vaccinations for this event.
	CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Same day as vaccination given, developed pain went from arm up to shoulder, to back, to neck to head - right side of body; chills/body aches		No prior vaccinations for this event.

	CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver failure, pneumonia, and DIC>"		No prior vaccinations for this event.

	CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
24 hours after shot had high fever 101, chills, weakness, became listless, family called 911, client became unresponsive and died in the Emergency room.		No prior vaccinations for this event.

	CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/15: Pfizer vaccine dose 1 administered 1/16: Fever, chills 1/22: Sore throat, coughing w/white phlegm, taking Tylenol and Mucinex. Fever and chills from 1/16 subsided. Had telehealth consultation with PA. Per her notes, patient said he gets these symptoms annually, requested for an antibiotic. PA referred him for a COVID test. Ordered hydrocodone/chlorphen ER suspension for his cough and an antibiotic. Antibiotic was recommended if symptoms do not subside. 1/23: COVID test administered 1/25: Reported positive for COVID 1/26: Telehealth session w/PA: she informed patient of his positive test, advised to quarantine and seek medical help at hospital if symptoms worsen. Patient reported that his sore throat mostly subsided but is still coughing at night. Said that the pharmacy didn't receive the prescription order for the antibiotic, so this was re-ordered. 1/31: Partner found him dead at 8:18AM on his bed. Death certificate issued by state says		No prior vaccinations for this event.

cause of death: COVID. Autopsy was not performed. Buried on 2/9/21.

	CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On December 17, 2020, my husband, received his first BioNTech BNT162b2 COVID-19 vaccination. On Thursday January 7, 2021, he received this second COVID-19 vaccination. The following three days after his second vaccination, he felt fine. The fourth day, on Sunday January 10, my husband felt extremely fatigued. On Monday the 11th and Tuesday the 12th, he worked a full shift but complained of extreme fatigue and extreme chills to the point that his teeth were chattering while on the phone with me. He decided to work through it. When he got home on Monday night, he started vomiting. On Wednesday January 13, he woke up and had swollen eyes. Once again, he felt extremely fatigued, even after a full nights rest. He had the day off but had an early meeting. After his meeting, he was still tired so he went back to sleep. I left to get lunch, and drop off our kids, and upon my return, I found him on the walk in closet floor, face up, having passed away. He felt as cold as ice. The rapid test done after they called the paramedics resulted in a negative COVID-19 test for him.		No prior vaccinations for this event.

	CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
right arm swelling immediately after injection. followed by bilateral lower leg edema, chills and body aches that continued daily at 2 weeks post immunization admin 2/4/21 treated with dexamethasone 6mg PO x 7 days- this resolved his s/s 2/13/21 patient passed away at facility		No prior vaccinations for this event.

	CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.	No prior vaccinations for this event.
CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
As per patient daughter - patient had some minor chills on the day of the vaccination - Friday 1/15/21; felt well next day -Saturday, than she was found slumped and lifeless on the couch on Sunday 1/17. Cause of death on death certificate was reportedly put as COPD, Lung Ca and ASHD.	No prior vaccinations for this event.
CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No symptoms or signs on the day 1st dose of vaccine was received (2/11/2021). 3 days later, (2/14/2021) patient experienced chills for approximately 6 hours, followed by severe (visible) chest spasms, and then cardiac arrest. 911 was called upon witnessing chest spasms, but cardiac arrest/death occurred before patient could be transported to the hospital.	No prior vaccinations for this event.

	CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received the 2nd dose of the Covid vaccine approximately around 1105 by pharmacy through the pharmacy LTC partnership vaccination program. Resident had no adverse effects until around 8:00 pm she began complaining of body aches, and chills, Tylenol was given at this time. Around 9:30pm resident was sleeping in bed. Around 12:00 am the CNA called nurse into room to assess resident as the resident stated she did not feel good. Temperature at that time was 102.2, and vomiting. RN came to assess @ 1220 am She was noted to be vomiting, diaphoretic, pale and having trouble breathing. Temp was 97.3 after vomting, Pulse 53, Resp 20, o2 sats were 40-45%, unable to obtain Blood pressure, Applied 5 L of oxygen at this time and had LPN call 911 immediately. Resident was repsonsive and able to follow staff members instructions but was only answering yes or no simple questions at the time time of assessment. Paramedics arrived at 0040 and resident was sent to Hospital. @ 0130 ER nurse called to nursing facility to notify resident had coded in the ER and passed away @ 0110.		No prior vaccinations for this event.

	CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1. Fatigue ? day 1 - Tuesday 2. Loss of appetite ? day 1 Tuesday 3. Fever 102.0 ? day 2 - Wednesday 4. Chills ? day 2 - - Wednesday 5. Weak ? day 2 - - Wednesday 6. Non-ambulatory (unusual) ? day 2 - - Wednesday 7. Two emergency service ambulance assessment ? day 2 - - Wednesday 8. Symptoms improved ? day 3 - Thursday 9. Ambulatory - day 3 - Thursday 10. Symptoms worsened ? day 4 - Friday 11. Chills ? day 4 - Friday 12. Non-ambulatory again ? day 4 - Friday 13. Fever 102.0 ? day 4 - Friday 14. Left side flank pain ? day 4 - Friday 15. CPR and declared decease at home by paramedics - day 5 - Saturday morning @ 1:32am		No prior vaccinations for this event.

	CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
within 24 hours after her second injection she developed chills, had a syncopal episode and had, difficulty breathing. this progressed over the next day when she had a second syncopal episode and her dyspnea and confusion worsened EMT was called and she was brought to the hospital. she was in flash pulmonary edema and with her history of severe aortic stenosis she was admitted to the cardiac icu. she had no prior history up to that time of pulmonary edema and was functioning without distress in her home. she had a history of covid in early april, manifesting primarily as severe confusion, from which she recovered.		No prior vaccinations for this event.
	CHILLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Pt he reports he developed chills SOB body aches the same night as receiving the COVID vaccine on 1.26.2021-pt is currently reporting CheSt tightness and SOB Admitted to hosp: ICU with Bilateral Pulmonary Emboli, LLE DVT, NSTEMI, Arrhythmia.		No prior vaccinations for this event.
	CHILLS	**COVID19 (COVID19 (UNKNOWN)) (1202)**
Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2 diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated) then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and		No prior vaccinations for this event.

was intubated. Transported to hospital. SARS CoV-2 and influenza negative.		
	CHILLS	**COVID19 (COVID19 (UNKNOWN)) (1202)**
Received first SARS-CoV2 vaccination yesterday at local store Experienced new symptoms of chills, nausea as well as worsening from baseline dyspnea at night. Wife states he had rough morning breathing and had sudden loss of consciousness and unresponsiveness and failed to respond to bystander CPR. He expired at his home.		No prior vaccinations for this event.
	CHLAMYDIA TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.		No prior vaccinations for this event.
	CHOKING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of		No prior vaccinations for

consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.		this event.
	CHOLANGIOCARCINOMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death ""cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its components or a severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed. MDs recommending hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative status. 1/29 Pt passed away."		No prior vaccinations for this event.
	CHOLECYSTITIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient passed su hospital on 23Jan2021 stopped breathing; complained of not feeling well; had an inflamed gall bladder; This is a spontaneous report from a contactable consumer. A 98-year-old female patient received bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL8982 and expiry date unknown), via an unspecified route of administration on 16Jan2021 at single dose for covid-19 immunisation. The patient medical history was not reported. The patient concomitant medication reported as has received other medications (unspecified) within 2 weeks. The patient passed in hospital on 23Jan2021 with stopped breathing. Day after vaccine on 17Jan2021, the patient complained of not feeling well, went to hospital where was told she had an inflamed gall bladder. The events caused patient hospitalization for 4 days. The cause of death reported as stopped breathing. It was unknown if autopsy done. Prior to vaccination, the patient not diagnosed with COVID-19. The outcome of the event breathing arrested was fatal, outcome of the other events was unknown.; Reported Cause(s) of Death: Stopped breathing

No prior vaccinations for this event.

CHOLELITHIASIS

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

CHROMATURIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report

No prior vaccinations for this event.

she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

CHROMATURIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L	No prior vaccinations for this event.

of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

CHRONIC KIDNEY DISEASE		**COVID19 (COVID19 (MODERNA)) (1201)**
Death on 1/17/21. Death certificate reports: Septic Shock, UTI, Pneumonia, Chronic Renal Failure	No prior vaccinations for this event.	
CHRONIC OBSTRUCTIVE PULMONARY DISEASE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
As per patient daughter - patient had some minor chills on the day of the vaccination - Friday 1/15/21; felt well next day -Saturday, than she was found slumped and lifeless on the couch on Sunday 1/17. Cause of death on death certificate was reportedly put as COPD, Lung Ca and ASHD.	No prior vaccinations for this event.	
CHRONIC RESPIRATORY FAILURE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
We do not believe that the patient's death was an adverse event from the vaccine. Patient received COVID vaccine from Pfizer Dose #1 12/19/2020 (lot # EK5730) and Dose #2 1/7/2021 (lot # EL1284). No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Patient died 1/10/2021 from chronic respiratory failure and congestive heart failure after recent aspiration pneumonia requiring hospitalization. Death was anticipated and not sudden. We were told to report his death to VAERS even though his death was anticipated and not related to his vaccination.	No prior vaccinations for this event.	
CHRONIC RESPIRATORY FAILURE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient passed away from chronic respiratory failure with cardiogenic shock 24 hours from 2nd dose of	No prior vaccinations for	

vaccine. Patient with longstanding history of pulmonary HTN and heart failure with desire for comfort care only. Entering into VAERS out of abundance of caution.		this event.
	CIRCULATORY COLLAPSE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
reported causes of death :circulatory collapse; asystole; reported causes of death :circulatory collapse; asystole; This is a spontaneous report from a Pfizer-sponsored program received from the Regulatory Authority-WEB GB-MHRA-WEBCOVID-20201214111558, satety Report unique Identifier GB-MHRA-ADR 24542972 and EU-EC-10007191566 received via Regulatory Authority 908245. A contactable pharmacist and three consumers reported that an adult female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 13Dec2020 at a single dose for COVID-19 vaccination. The patient's medical history was not reported. Concomitant medications included acetylsalicylic acid, amiloride HCl, allopurinol, desogestrel, furosemide, levothyroxine, sildenafil, and spironolactone. The patient experienced circulatory collapse and asystole on 13Dec2020. The patient died due to asystole and circulatory collapse on 13Dec2020. It was unknown if an autopsy was performed. No follow-up attempts are possible, information about lot/batch number cannot be obtained. No further information Is expected.; Sender's Comments: The information available is limited and does not allow a meaningful case evaluation. However, based solely on a close chronological association (same day) a causal relationship between events circulatory collapse and cardiac arrest and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: reported causes of death :circulatory collapse;		No prior vaccinations for this event.

asystole; reported causes of death :circulatory collapse; asystole

CIRCULATORY COLLAPSE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
73-year-old man s/p first dose of Pfizer at 10:20 AM Ambulated comfortably to exit after 20 minutes in observation but 10:45 collapsed while exiting the building 10:47 CPR initiated 10:49 medical team/EMS found no pulse, agonal respirations, ventricular fibrillation Paramedics and team performed ACLS; of note patient was intubated 7.5 ETT with bilateral breath sounds on ventilation; paramedic reported easy intubation with no apparent throat swelling; 11:02 transported to Emergency Department 11:30 Pronounced dead at Emergency Department	No prior vaccinations for this event.
CLOSTRIDIUM DIFFICILE COLITIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.	No prior vaccinations for this event.
CLOSTRIDIUM DIFFICILE INFECTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My dad received the Pfizer vaccination on 2/5/21. He was admitted into the hospital the next day for C-Diff bacterial infection. He had been on dialysis treatments for kidney failure treatment since 2017 and had recently been diagnosed with stage 3 colon cancer in June 2020. He had completed his final treatment of	No prior vaccinations for this event.

chemotherapy on 2/4/21 and several weeks prior had been determined cancer free. On Tuesday 2/9/21 he was released from the hospital and went home. Early Thursday morning 2/11/21 @ approximately 1:30 am CST his eyes rolled back in head and he stopped breathing and was non responsive. My mother called 911 and attempted CPR. Paramedics arrived and were able to successfully get a pulse then transferred him to the hospital. He was put on a ventilator @ the hospital and then transferred to a different hospital a few hours later. He lost pulse/heartbeat several times @ the 2nd hospital he was transferred to. We were not allowed to travel with him or see him b/c of all of the COVID restrictions. We were communicating with the ICU doctor by phone who ultimately communicated to us that there was nothing further that could be done to save his life. He subsequently passed away @ approximately 8:55 am CST on 2/11/21.

COAGULATION TEST	**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.	No prior vaccinations for this event.

COAGULOPATHY	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received vaccination on 1/15/2021. Hemorrhagic Stroke on 1/20 , then diagnosed with complicated idiopathic coagulopathy	No prior vaccinations for this event.

COGNITIVE DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
unresponsive Narrative: 74yo patient with pacemaker, type 2 DM, parkinson's and history of syncopal epsisodes presented to emergency dept on Jan 24th. He was observed and discharged on Jan 26th back to the home where he continued to have cognitive decline and later passed away on 2/2/2021	No prior vaccinations for this event.
COGNITIVE DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
Narrative: 89yo with type 2 DM, HT, pacemaker and prior COVID+ in Nov 2020. Shortly after administration of 2nd Covid vaccine, patient began to have increased cognitive decline and 2 days after he expired at the facility	No prior vaccinations for this event.
COGNITIVE DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.	No prior vaccinations for this event.
COLD SWEAT	**COVID19 (COVID19 (MODERNA)) (1201)**

Pt received second dose of COVID vaccine on 01/20/2021 at 1430. At 1600 Pt developed a wet productive cough with coarse crackles. Pt ate dinner at 5 pm cough persisted. At 18:30 the nurse went to Pt's room to give him his medications. Pt still had a cough, denied shortness of breath. Pt was in a good mood and joking with staff. Pt asked to be shaved. At 19:45 Pt was sitting in the lounge and a CNA noticed that Pt was pale/white in color and clammy. 02 Sat was 85%. Respirations were labored. Pt was placed on 4 L of 02. Increased to 5 L via face mask and 02 sat was 89-90%. Ambulance was called at unknown time. Pt arrived at Medical Center at 2120 and was pronounced dead at 2127.		No prior vaccinations for this event.
COLD SWEAT		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to the Emergency Department complaining of chest pain, pale, cool diaphoretic, and hypotensive. The patient was discovered to have a large saddle pulmonary embolism, went into cardiac arrest and expired. Of note, the patient received her second Moderna COVID vaccine on 1/23, which would place her first one approximately 12/25 if she received them at the appropriate interval. This information is from the patient's daughter and the ED record, the information is not available in CAIR. Per the daughter, the patient started feeling ill on 1/21, improved on 1/25, and then acutely worsened on 1/27, resulting in the ED visit.		No prior vaccinations for this event.
COLD SWEAT		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident c/o nausea evening of 1/29 (nausea common for her post dialysis), had a large emesis at approx 2220, 0030 (unusual for resident to vomit)- received Zofran per order. Skin cool and damp, Blood sugar 147 (checked due to h/o diabetes and poor intake). At approx 230am Blood pressured checked and noted to be 52/29. Resident transferred to ER, intubated and transferred to higher level of care where she passed away on 1/30 at 736pm. Resident's medical notes indicated likely shock, cardiogenic in nature, sepsis (source unknown) along with a multitude of other co-morbidities that resident has.		No prior vaccinations for this event.

COLD SWEAT		**COVID19 (COVID19 (MODERNA)) (1201)**
"Possible heart attack on 2/5/21. Complaint: "" On Feb 5th I believe I experienced a mild hear attack"" (Comment: He said he felt ""clammy, sweaty, excruciating pain on my left side - including his left arm, and left leg, dizzy, exhausted."" This happened after work, and after taking a shower. He said that was the first time he's experienced it, and that it has not happened since then. He said he has constant headaches, ""It just went away yesterday.""""		No prior vaccinations for this event.
COLITIS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.		No prior vaccinations for this event.
COLITIS ISCHAEMIC		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer Covid Vaccine in the AM on 2/9/21. Arrived to emergency department later the same day complaining of nausea, weakness, fatigue, Vomiting, Diarrhea. Post operative diagnosis, Ischemic colon/toxic megacolon.		No prior vaccinations for this event.
COLONOSCOPY NORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**

Received Moderna #1 on 1/12/2021. 1/15/2021 developed worsening shortness of breath. Went to hospital and diagnosed with anemia, 4 negative fecal tests, neg EGD and colonoscopy. Discharged and readmitted (circumstances unknown for this episode) then readmitted a third time 1/20/2021 for shortness of breath. Diagnosed covid + at third hospitalization and continued to get worse. He died 1/23/2021.

No prior vaccinations for this event.

COMA

COVID19 (COVID19 (MODERNA)) (1201)

Passed away; Found unconscious; Coma; Lack of oxygen to the brain; A spontaneous report was received from a consumer, concerning his mother, a 71-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and passed away, prior to death, patient experienced lack of oxygen to the brain and was found unconscious and went to coma. The patient's medical history reported included seizures. Concomitant medications included phenobarbital, lamotrigine and levetiracetam. On 27 Jan 2021, approximately six days prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (lot number: 030L20A) intramuscularly for prophylaxis of COVID-19 infection. On 01 Feb 2021 at 4 am, the patient was found to be unconscious on the couch, hence she was rushed to the hospital with lack of oxygen to the brain. Later, she went into a coma, hence she was in hospital for 30 hours and then was transferred to a different hospital for a second opinion on 06-Feb-2021, where she was passed away at 02:20 PM. Treatment information was not provided Action taken with mRNA-1273 in response to the events were not applicable. The outcome of events, lack of oxygen to the brain, found unconscious and coma were considered unknown. The outcome of event passed away was fatal as she died on 06 Feb 2021 at 2:20 pm. The cause of death was not provided. Plans for an autopsy were unknown.; Reporter's Comments: This is a case of 71-year-old female subject with a history of seizures who died 6 days after receiving first dose of vaccine. Very limited information has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Passed away

No prior vaccinations for this event.

COMA

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - anuerism lead to death approximately 14 hours after initial symptoms.	No prior vaccinations for this event.
COMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The	No prior vaccinations for this event.

patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

	COMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"He collapsed due to a cardiac arrest on Friday 15Jan and passed away on 19Jan; He collapsed due to a cardiac arrest on Friday 15Jan and passed away on 19Jan; his cardiac arrest was caused by an arrhythmia; This is a spontaneous report from contactable pharmacist via Pfizer Sales Representative. A 45-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not reported), via an unspecified route of administration on 11Jan2021 at single dose for covid-19 immunisation. Patient had a long history of congenital heart issues. He had been stable and closely monitored for the past 20 years. He had no history of arrhythmia. The patient's concomitant medications were not reported. Patient collapsed due to a cardiac arrest on Friday 15Jan2021 and passed away on 19Jan2021. The doctors feel that his cardiac arrest was caused by an arrhythmia. Reporter reported this through the v safe app. And received a message stating reporter would be contacted by the cdc. After patient passed away reporter replied stop to v safe. But still had not been contacted by anyone. This may or may not be related. Reporter have no way of knowing. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported ""collapsed due to a cardiac arrest"", ""cardiac arrest was caused by an arrhythmia"" and the administration of COVID-19 vaccine, BNT162B2, based on the reasonable temporal association. The patient's pre-existing long history of congenital heart issues might have provided alternative explanations. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: He collapsed due to a cardiac arrest on Friday 15Jan and passed away on 19Jan; his		No prior vaccinations for this event.

cardiac arrest was caused by an arrhythmia; He collapsed due to a cardiac arrest on Friday 15Jan and passed away on 19Jan"

	COMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"never woke up after arrival; Suffered with vascular dementia; Death cause: Covid/Tested positive to Covid 31Jan, tested due to increased lethargy; This is a spontaneous report from a contactable consumer. An 85-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Jan2021 at single dose for COVID-19 immunization. The patient received the vaccine at nursing home/senior living facility. Medical history included dementia, hypertension, past strokes. The patient was exposed to asymptotic staff member on or prior to 25Jan2021. The patient had no known allergy. No COVID prior vaccination. Concomitant medication included lisinopril. No other vaccine was received in four weeks. The patient was tested positive to COVID on 31Jan2021, tested due to increased lethargy started from 26Jan2021. The patient suffered with vascular dementia. She was ambulatory up to 31Jan2021. The patient was sent to hospice that evening on 31Jan2021 to quarantine, never woke up after arrival. Palliative Care started 02Feb2021, the patient expired 12Feb2021. Cause of death was COVID. The patient did not receive treatment for events. The autopsy was not performed. The outcome of events ""never woke up, vascular dementia"" was unknown. Information on Lot /Batch Number has been requested.; Reported Cause(s) of Death: Death cause: Covid"		No prior vaccinations for this event.

	COMA SCALE ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Rapid decline in health status, Elevated BP&P, posturing, loss of consciousness, Glasgow coma Scale 4 starting 2/1/2021, Deceased 2/3/21		No prior vaccinations for this event.

COMA SCALE ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."	No prior vaccinations for this event.	
COMMUNICATION DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**	
On the evening of 10JAN2021, patient experienced a low grade fever, decreased oxygen saturation of 38%, heart rate of 124, confusion. Patient received oxygen via face mask, morphine and ativan. By 11JAN2021,	No prior vaccinations for this event.	

patient was no longer verbal, able to eat or communicate and was kept on comfort measure only. On the morning of 17JAN2021, the patient passed away.

COMMUNICATION DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine administered 02/08/2021 , by Thursday 02/11/2021 patient almost nonverbal, by Monday 02/15/2021 patient went to the hospital with bruising, sores on her stomach and clots reported as thrombocytopenia, deceased by Friday 02/19/2021.	No prior vaccinations for this event.
COMMUNICATION DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/23 - Mild injection site discomfort. Appetite loss compared to previous day. Beginning loss of mental acuity compared to previous day. 1/24 - Continued loss of appetite. Near complete loss of ability to move. Continued decline of mental acuity. Very little speaking. 1/25 - Stopped speaking completely. Loss of bowel control in the evening and continued until death. Complete loss of appetite. 1/26 - Near complete loss of ability to swallow. Moved to hospice 4:00pm. 1/27 - Died 4:00am	No prior vaccinations for this event.
COMPLETED SUICIDE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the	No prior vaccinations for this event.

vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.

COMPLETED SUICIDE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death by suicide Narrative: death by suicide; 12/26/20, self inflicted gun shot wound; found deceased by family member	No prior vaccinations for this event.
COMPLICATION ASSOCIATED WITH DEVICE	**COVID19 (COVID19 (MODERNA)) (1201)**
hypoxia, secretions,cough, dyspnea Narrative: ALS patient on hospice with ongoing history of aspiration pna, receiving tube feeds. Developed incr in secretions, hypoxeia, temp and with recently noted clogged feeding tube.	No prior vaccinations for this event.
COMPLICATION ASSOCIATED WITH DEVICE	**COVID19 (COVID19 (MODERNA)) (1201)**
Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.	No prior vaccinations for this event.

COMPUTERISED TOMOGRAM **COVID19 (COVID19 (MODERNA)) (1201)**

Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21 No prior vaccinations for this event.

COMPUTERISED TOMOGRAM **COVID19 (COVID19 (MODERNA)) (1201)**

Hemorrhagic Stroke, Right Basal Ganglion No prior vaccinations for this event.

COMPUTERISED TOMOGRAM **COVID19 (COVID19 (MODERNA)) (1201)**

Death due to hemorrhagic stroke. No prior vaccinations for this event.

COMPUTERISED TOMOGRAM **COVID19 (COVID19 (MODERNA)) (1201)**

High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had

No prior vaccinations for this event.

profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

COMPUTERISED TOMOGRAM **COVID19 (COVID19 (MODERNA)) (1201)**

ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation

No prior vaccinations for this event.

COMPUTERISED TOMOGRAM **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Fatigue, muscle aches, vomiting, hematoma No prior vaccinations for this event.

COMPUTERISED TOMOGRAM **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble

No prior vaccinations for this event.

swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."

COMPUTERISED TOMOGRAM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was hospitalized for confusion, and hypotension and increased weakness; resident proceeded to have a NSTEMI and died on 5th day in hospital on 1/31/2021.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had one occurrence of thrombotic thrombocytopenic purpura in 1996 for which she had plasma exchange therapy in 1996. No other occurrence since 1996 until she received her first dose of the Pfizer covid vaccine.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient woke up on the morning of 2/6 with symptoms of a stroke. Rushed to hospital where clot found in brain. Recovered from initial stroke but then had another major stroke on 2/8 and never recovered.	No prior vaccinations for this event.

COMPUTERISED TOMOGRAM		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Minor arm pain on 2nd day of each vaccine Diarrhea 3 days after 2nd vaccine Massive heart attack (left ventricle) 8 days (2/24/21) after vaccine Home hospice 3:30pm 2/24/21 Stopped breathing 5:45 am, pronounced dead at 8:22 am on 2/25/21	No prior vaccinations for this event.	
COMPUTERISED TOMOGRAM		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
within 24 hours after her second injection she developed chills, had a syncopal episode and had, difficulty breathing. this progressed over the next day when she had a second syncopal episode and her dyspnea and confusion worsened EMT was called and she was brought to the hospital. she was in flash pulmonary edema and with her history of severe aortic stenosis she was admitted to the cardiac icu. she had no prior history up to that time of pulmonary edema and was functioning without distress in her home. she had a history of covid in early april, manifesting primarily as severe confusion, from which she recovered.	No prior vaccinations for this event.	
COMPUTERISED TOMOGRAM		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion; On 21Feb he went to the ER after vomiting and passing out; On 21Feb he went to the ER after vomiting and passing out; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; fever; headache; stomach upset; This is a spontaneous report from a contactable consumer reporting for the father: A 75-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EL3428) at single dose at left arm on 03Feb2021 for Covid-19 immunisation. Medical history included type 2 diabetes mellitus. No known allergies. The patient had not experienced Covid-19 prior vaccination.	No prior vaccinations for this event.	

Concomitant medication in 2 weeks included amitriptyline hydrochloride (manufacturer unknown) 10 mg, atorvastatin (manufacturer unknown) 20 mg, dutasteride (manufacturer unknown) 0.5 mg, linaclotide (LINZESS) 290 mcg, gabapentin (manufacturer unknown) 300 mg, montelukast (manufacturer unknown) 10 mg, ramipril (manufacturer unknown) 5 mg, insulin degludec (TRESIBA) 100 unit/ml, liraglutide (VICTOZA) 18 mg/3ml solution. No other vaccine in 4 weeks. The patient experienced cardiac arrest due to pericardial effusion on 21Feb2021 14:15, fever on 13Feb2021, headache on 13Feb2021, stomach upset on 13Feb2021, on 19feb, he began to feel ill again with a fever, he felt worse on 20feb on 19Feb2021, on 21feb he went to the ER after vomiting and passing out on 21Feb2021. Events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of cardiac arrest due to pericardial effusion. Course of events: In Feb2021, 10 days after his 1st injection, the patient developed fever, headache, and stomach upset. He went for a rapid Covid-19 test (nasal swab) and it was negative on 11Feb2021. The doctor told him he might be having a delayed reaction to the vaccination. After a couple of days, he improved. On 19Feb2021, he began to feel ill again with a fever. He felt worse on 20Feb2021. On 21Feb2021 he went to the ER after vomiting and passing out and received treatment: IV fluids, diagnostic testing at ER. Rapid Covid test (nasal swab) at ER came back negative again on 21Feb2021. His heart arrested suddenly and he could not be resuscitated. CT scan results, that came back after death, showed Covid like pneumonia and pericardial effusion. The patient died on 21Feb2021 14:15. Cause of death was cardiac arrest due to pericardial effusion. An autopsy was not performed. The outcome of cardiac arrest due to pericardial effusion was fatal, of fever, headache, stomach upset was recovering, of he began to feel ill again with a fever, he felt worse was not recovered, of he went to the ER after vomiting and passing out was unknown.; Reported Cause(s) of Death: cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion

COMPUTERISED TOMOGRAM ABDOMEN

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21

No prior vaccinations for this event.

COMPUTERISED TOMOGRAM ABDOMEN **COVID19 (COVID19 (MODERNA)) (1201)**

Patient developed Covid pneumonia dx 1/15/21, patient expired No prior vaccinations for this event.

COMPUTERISED TOMOGRAM ABDOMEN **COVID19 (COVID19 (MODERNA)) (1201)**

Do not know if patient informed her physician that she received vaccine on 1/29/2021. She had appt at 3:15 pm on 1/29 and afterwards stated she received the Moderna vaccine. Reporter is uncertain if this was at a health office or clinic. She drove herself to the ER at about 3am on 1/30/2021 with increased cramping and pain. No prior vaccinations for this event.

COMPUTERISED TOMOGRAM ABDOMEN **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm No prior vaccinations for this event.

COMPUTERISED TOMOGRAM ABDOMEN **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

emesis bright yellow in color, liquid BM, increased respirations No prior vaccinations for this event.

COMPUTERISED TOMOGRAM ABDOMEN **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored No prior vaccinations for this event.

respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

COMPUTERISED TOMOGRAM ABDOMEN ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting

No prior vaccinations for this event.

and dry heaving.

COMPUTERISED TOMOGRAM ABDOMEN ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was an 87 y/o female admitted for septic shock. She was started on and eventually maxed on 3 pressors. CT abd showed colonic obstruction with dilatation of large and small bowel. Patient was made DNR in the ED. Palliative care consulted on case. Family opted for comfort care. Patient was asystole on monitor. No spontaneous breath/cardiac sounds ausculted. Patient did not withdraw to pain. Pupils fixed and dilated. She was pronounced and 1230 on 1/28/21	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM ABDOMEN ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient reported to Emergency room on 01/23/2021 with complaint of nausea. According to ER record patient reported he received a COVID 19 vaccine Pfizer the day before. Work up in the ER (CT ABD PELVIS) reveal a clotted of SMA. CT CHEST REVEALED BILATERAL PULMONARY EMBOLUS. THE PATIENT WAS TRANSFERRED TO THE STATE HOSPITAL. HE WAS SCHEDULED FOR EMERGENT VASCULAR SURGERY WHICH WAS CANCELLED AS THE PATIENT DIED SHORTLY AFTER HIS ARRIVAL.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM ABDOMEN ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon	No prior vaccinations

after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.	for this event.
COMPUTERISED TOMOGRAM ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
At approximately, 1855, I was alerted by caregiver, resident was not responding. Per caregiver, she was doing her rounds and found resident in bed, unresponsive, mouth open, observed gurgling noises and tongue hanging out of mouth. This primary caregiver observed resident at baseline and ambulating after dinner at approximately, 1800 less than an hour prior to incident. This PCG called 911 for EMS and gave report of incident. Resident was taken to Medical Center Emergency Department. At ER, CT scan and X-ray was performed. Per report from ER RN, CT scan and x-ray revealed an intracranial aneurysm and fluid in the lungs. Per RN, resident was still unresponsive and was admitted to Medical Center for observation and comfort measures. This primary caregiver reported to RN, resident recently received the first dose of COVID-19 vaccine on 1/2/21. Primary caregiver received a call from Castle RN at 0700, resident expired at 0615.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
"85 year old patient with multiple medical problems. PEA/asystolic arrest 5 days after receiving vaccine, hospitalized. Patient died on 2/1/2021. It is not clear whether the vaccine administration led to the patient's death or not. ""...healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event)"""	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial	No prior vaccinations

NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of the MCA territory (TPA not recommended). CTA did show distal L M1/M2 occulsion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.	for this event.
COMPUTERISED TOMOGRAM ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene when EMS arrived. Autopsy showed a left temporal subdural hematoma.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received Covid Vaccine Moderna at 1145, multiple syncopal episodes at pharmacy, sent	No prior vaccinations for this event.

to ER. Outcome Death

COMPUTERISED TOMOGRAM ABNORMAL **COVID19 (COVID19 (MODERNA)) (1201)**

I am the patient's daughter as well as an RN-BSN. My mother was given the Moderna vaccine on Feb 11, 2021 and on Feb 15, 2021 she had a CVA and MI. She was found on her apt. floor unconscious. She was transferred to the Hospital by ambulance where a CT scan and other tests were done. It was determined she had a stroke and heart attack. My mother was in great health, took no medications, and lived alone in her apt. before this incident. The medical professionals determined she would not recover so she was admitted to hospice and died on Feb. 21, 2021. I believe there is a relationship between the vaccine and the CVA and MI.

No prior vaccinations for this event.

COMPUTERISED TOMOGRAM ABNORMAL **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

emesis bright yellow in color, liquid BM, increased respirations No prior vaccinations for this event.

COMPUTERISED TOMOGRAM ABNORMAL **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

bowel perforation; pain in her upper abdomen; This is a spontaneous report from a contactable consumer. An 86-year-old female patient received the 2nd dose of bnt162b2 (BNT162B2) at single dose on 13Jan2021 for Covid-19 immunisation, administerd at nursing home/senior living facility Medical history included dementia, arthritis. No known allergies. Patient was not pregnant. Patient had not COVID prior vaccination. Concomitant medication in 2 weeks included: memantine (manufacturer unknown) 10 mg BID, diclofenac (manufacturer unknown) BID, carbidopa, levodopa (manufacturer unknown) 25-100 mg TID, quetiapine (manufacturer unknown) 12.5 mg q HS, escitalopram oxalate (LEXAPRO) 10 mg q HS, paracetamol (TYLENOL) 650 mg BID, glucosamine (manufacturer unknown) drink. The patient received the 1st dose of

No prior vaccinations for this event.

bnt162b2 (BNT162B2) at single dose on 24Dec2020 for Covid-19 immunisation. No other vaccine received in 4 weeks. The patient experienced bowel perforation and pain in her upper abdomen on 18Jan2021 07:30. The events resulted in Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event), and death. On 18Jan2021 07:30 AM, less than a week after the second shot, she had pain in her upper abdomen and was taken to the ER on 18Jan2021. CT showed a bowel perforation in the small bowel. She had never had bowel surgery or diverticulitis. She had been healthy other than her dementia and arthritis. Patient received treatment for the events: hospice and pain management. COVID-19 was not tested post vaccination. The cause of death was bowel perforation. An autopsy was not performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: bowel perforation

COMPUTERISED TOMOGRAM ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death ""cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its components or a severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed. MDs recommending hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative

No prior vaccinations for this event.

status. 1/29 Pt passed away."

COMPUTERISED TOMOGRAM ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt fell within 24 hours after vaccine. was sent to hospital. pt was found to be hypoxic with multifocal opacities on CT scan	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM HEAD	**COVID19 (COVID19 (MODERNA)) (1201)**
VACCINATION WAS RECEVIED THE MORNING OF 1/5/2021- IN THE EVENING OF THAT DAY RESIDENT SUSTAINED A FALL AND WAS TRASNPORTED TO FACILITY FOR TREATMENT. IT IS NOT UNUSUAL THAT RESIDENT WAS SELF TRANSFERRING AND HAS A HISTORY OF FALLS.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM HEAD	**COVID19 (COVID19**

(MODERNA)) (1201)

On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of the MCA territory (TPA not recommended). CTA did show distal L M1/M2 occulsion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.

No prior vaccinations for this event.

COMPUTERISED TOMOGRAM HEAD

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm No prior vaccinations for this event.

COMPUTERISED TOMOGRAM HEAD **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was

No prior vaccinations for this event.

admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

COMPUTERISED TOMOGRAM HEAD ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.

No prior vaccinations for this event.

COMPUTERISED TOMOGRAM HEAD ABNORMAL

COVID19 (COVID19

(MODERNA)) (1201)

on 1/13/2021 at 3:40am Cliff called for assistance. He lost his balance and had fallen. Cliff refused vitals, refused emergency department, denied hitting his head. As the day progressed patient developed a headache, diarrhea, and vomiting. He again declined the offer for the emergency room. At supper time wife and staff found Cliff unresponsive, 911 was called and he was taken to the emergency department. The ER did a CT scan and found an acute subdural hematoma. Patient was placed on comfort cares and expired at 3pm on 01/14/2021. Cliff did not have a history of falls.

Influenza vaccine 10/06/2020, age 88, fever, chills, vomiting, malaise

COMPUTERISED TOMOGRAM HEAD ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021

No prior vaccinations for this event.

COMPUTERISED TOMOGRAM HEAD ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A

No prior vaccinations for this event.

STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.

COMPUTERISED TOMOGRAM HEAD ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21	No prior vaccinations for this event.

COMPUTERISED TOMOGRAM HEAD ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P	No prior vaccinations for this event.

67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

COMPUTERISED TOMOGRAM HEAD ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was found unresponsive on her kitchen floor about 9:45 AM on February 10, 2021 approximately 18 hours after receiving her first Covid-19 vaccination. Exact time of the event is unknown. She was known to get up between 6:30 and 7:30 AM. It appeared that she had not eaten breakfast nor taken any medication that morning. She was taken by ambulance to Medical Center where a CT scan showed an unrecoverable massive brain hemorrhage. She died at approximately 3:50 PM after the respirator was removed. She was sent to the local Medical Examiner afterwards.

No prior vaccinations for this event.

COMPUTERISED TOMOGRAM HEAD ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

No prior vaccinations for this event.

COMPUTERISED TOMOGRAM HEAD ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of

No prior vaccinations for

worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.	this event.
COMPUTERISED TOMOGRAM HEAD ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM HEAD ABNORMAL	**COVID19 (COVID19 (UNKNOWN)) (1202)**

5 days after receiving his COVID vaccination the patient had a spontaneous (nontraumatic) subarachnoid hemorrhage which was fatal. The patient had previously been stable on his coumadin dosing with therapeutic INRs for the past several months per his wife. At time of presentation his blood pressure in the ER was elevated to 223/94 and his INR was risen to 3.1	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM HEAD NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM HEAD NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal	No prior vaccinations for this event.

right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

COMPUTERISED TOMOGRAM HEAD NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM HEAD NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21	No prior vaccinations for this event.

and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

COMPUTERISED TOMOGRAM HEAD NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident returned to the memory support unit at 1500. Resident was than toileted and transferred in to bed per his request. At 1515 resident was observed face down beside bed, resident sustained a 1inX1in eccyhmotic/hematoma to the forehead. Neuro Checks with in normal limes Vital signs: 100/52, 100, 97.2, 28. Resident sent to ED for further medical evaluation via EMS.

No prior vaccinations for this event.

COMPUTERISED TOMOGRAM HEAD NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Symptoms of fever (Tmax 102.9), diarrhea, and altered mental status started ~ 24 hours after vaccination. No evidence of septicemia with negative blood cultures Minimal improvement over 3 days, transferred to tertiary care center for MRI brain after which LP was recommended. However family declined as intubation would have been required and was not consistent with patient's goals of care.		No prior vaccinations for this event.
	COMPUTERISED TOMOGRAM INTESTINE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
bowel perforation; pain in her upper abdomen; This is a spontaneous report from a contactable consumer. An 86-year-old female patient received the 2nd dose of bnt162b2 (BNT162B2) at single dose on 13Jan2021 for Covid-19 immunisation, administerd at nursing home/senior living facility Medical history included dementia, arthritis. No known allergies. Patient was not pregnant. Patient had not COVID prior vaccination. Concomitant medication in 2 weeks included: memantine (manufacturer unknown) 10 mg BID, diclofenac (manufacturer unknown) BID, carbidopa, levodopa (manufacturer unknown) 25-100 mg TID, quetiapine (manufacturer unknown) 12.5 mg q HS, escitalopram oxalate (LEXAPRO) 10 mg q HS, paracetamol (TYLENOL) 650 mg BID, glucosamine (manufacturer unknown) drink. The patient received the 1st dose of bnt162b2 (BNT162B2) at single dose on 24Dec2020 for Covid-19 immunisation. No other vaccine received in 4 weeks. The patient experienced bowel perforation and pain in her upper abdomen on 18Jan2021 07:30. The events resulted in Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event), and death. On 18Jan2021 07:30 AM, less than a week after the second shot, she had pain in her upper abdomen and was taken to the ER on 18Jan2021. CT showed a bowel perforation in the small bowel. She had never had bowel surgery or diverticulitis. She had been healthy other than her dementia and arthritis. Patient received treatment for the events: hospice and pain management. COVID-19 was not tested post vaccination. The cause of death was bowel perforation. An autopsy was not performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: bowel perforation		No prior vaccinations for this event.
	COMPUTERISED TOMOGRAM NORMAL	**COVID19 (COVID19**

	(MODERNA)) (1201)
Resident yelling for assistance in apartment. Nursing personnel found resident on floor at 6:10 AM on 2/18/2021. Resident was transported to Hospital on 2/18/2021. Status update on 2/18/2021 from son, resident CT & X-rays were done all normal. Labs done and WBC count was elevated and awaiting results. Resident stable and admitted to hospital for observation. Resident passed away on 2.21.2021.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM PELVIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm No prior vaccinations for this event.

COMPUTERISED TOMOGRAM PELVIS ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM PELVIS ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient reported to Emergency room on 01/23/2021 with complaint of nausea. According to ER record patient reported he received a COVID 19 vaccine Pfizer the day before. Work up in the ER (CT ABD PELVIS) reveal a clotted of SMA. CT CHEST REVEALED BILATERAL PULMONARY EMBOLUS. THE PATIENT WAS TRANSFERRED TO THE STATE HOSPITAL. HE WAS SCHEDULED FOR EMERGENT VASCULAR SURGERY WHICH WAS CANCELLED AS THE PATIENT DIED SHORTLY AFTER HIS ARRIVAL.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM SPINE	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene when EMS arrived. Autopsy showed a left temporal subdural hematoma.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM SPINE	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm No prior vaccinations for this event.

COMPUTERISED TOMOGRAM SPINE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021. Influenza Vaccine

COMPUTERISED TOMOGRAM THORAX **COVID19 (COVID19 (MODERNA)) (1201)**

Patient developed Covid pneumonia dx 1/15/21, patient expired No prior vaccinations for this event.

COMPUTERISED TOMOGRAM THORAX **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

on 1/8/2021 17:30 patient taken to ER, cerebellar hemorrhage, stroke, aneurysm No prior vaccinations for this event.

COMPUTERISED TOMOGRAM THORAX **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to No prior vaccinations

our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

for this event.

COMPUTERISED TOMOGRAM THORAX ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.	No prior vaccinations for this event.
COMPUTERISED TOMOGRAM THORAX ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall,	No prior vaccinations for this event.

our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned

positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

COMPUTERISED TOMOGRAM THORAX ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient reported to Emergency room on 01/23/2021 with complaint of nausea. According to ER record patient reported he received a COVID 19 vaccine Pfizer the day before. Work up in the ER (CT ABD PELVIS) reveal a clotted of SMA. CT CHEST REVEALED BILATERAL PULMONARY EMBOLUS. THE PATIENT WAS TRANSFERRED TO THE STATE HOSPITAL. HE WAS SCHEDULED FOR EMERGENT VASCULAR SURGERY WHICH WAS CANCELLED AS THE PATIENT DIED SHORTLY AFTER HIS ARRIVAL.	No prior vaccinations for this event.

COMPUTERISED TOMOGRAM THORAX ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt	No prior vaccinations for this event.

was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.

	COMPUTERISED TOMOGRAM THORAX ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.		No prior vaccinations for this event.

	COMPUTERISED TOMOGRAM THORAX ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.		No prior vaccinations for this event.

	COMPUTERISED TOMOGRAM THORAX NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up		No prior vaccinations for this event.

with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.

COMPUTERISED TOMOGRAM THORAX NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.	No prior vaccinations for this event.

COMPUTERISED TOMOGRAM THORAX NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen,	No prior vaccinations for this event.

but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21

COMPUTERISED TOMOGRAM THORAX NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.	No prior vaccinations for this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (MODERNA)) (1201)**
ON 1/14/2021 TYPICAL UTI SYMPTOMS FOR RESIDENT DEVELOPED INCLUDING FEVER AND RIGIDITY. RESIDENT IS NON-VERBAL. IV ANTIBIOTICS WERE STARTED. FREQUENT UTI'S ARE COMMON FOR THIS RESIDENT.	No prior vaccinations for this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has a history of advanced melanoma with brain metastasis. He developed seizure disorder as well and had some mild seizures at home over the prior month. He received the vaccine at 4pm and was monitored in the office for 15 minutes. He then went home with his daughter whom he lives with. He ate dinner with her and read until 8pm when he went to his room. She found him in his room at 9pm unresponsive with seizures. Hospice was alerted and recommend oral valium. He continued to be unresponsive and expired	No prior vaccinations for this event.

the following day at 7:30 pm.

CONDITION AGGRAVATED		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.		No prior vaccinations for this event.
CONDITION AGGRAVATED		**COVID19 (COVID19 (MODERNA)) (1201)**
I helped facilitate scheduling for his COVID vaccine and received notification from his wife that he passed away unexpectedly this morning. She reported he had been experiencing a rheumatoid arthritis flare and was on steroids. His diabetes was not well controlled as a result. He did not have any reactions in the days immediately after the vaccine.		No prior vaccinations for this event.
CONDITION AGGRAVATED		**COVID19 (COVID19 (MODERNA)) (1201)**
Fever 101.1, unresponsive episode. Transferred to Hospital on 1/28. Diagnosis there was anemia and CHF, aware that he had vaccine day prior. Transfused with 2 units pRBC's. Transferred back to Nursing Home on 1/30 and passed away 0140 1/31/2021		No prior vaccinations for this event.

CONDITION AGGRAVATED **COVID19 (COVID19 (MODERNA)) (1201)**

Patient's wife called the physician's office with increasing SOB. MD advised that the patient go to the ED. While dressing, the patient became unresponsive, 911 called. Patient expired in ED. No prior vaccinations for this event.

CONDITION AGGRAVATED **COVID19 (COVID19 (MODERNA)) (1201)**

Resident received the vaccine on 1-22-21 and she was diagnosed with COVID-19 during routine testing on 1-28-21. She didn't have any symptoms except feeling weak and she had a decrease in her appetite. She already had a poor appetite prior. She died on 2-2-21. No prior vaccinations for this event.

CONDITION AGGRAVATED **COVID19 (COVID19 (MODERNA)) (1201)**

Patient presented to emergency room on 2/1/2021 with a chief complaint of having a chronic headache and fatigue following receipt of the Moderna vaccine 10 days prior. Following examination by the physician, the patient was diagnosed with an acute subdural hematoma. The patient subsequently underwent decompressive surgery, however demonstrated worsening neurologic status over the next several days and ultimately expired on 2/4/2021. No prior vaccinations for this event.

CONDITION AGGRAVATED **COVID19 (COVID19 (MODERNA)) (1201)**

2/6/2021 stroke. 2/8/2021 he died No prior vaccinations for this event.

CONDITION AGGRAVATED **COVID19 (COVID19 (MODERNA)) (1201)**

Received Moderna #1 on 1/12/2021. 1/15/2021 developed worsening shortness of breath. Went to hospital and diagnosed with anemia, 4 negative fecal tests, neg EGD and colonoscopy. Discharged and readmitted (circumstances unknown for this episode) then readmitted a third time 1/20/2021 for shortness of breath. Diagnosed covid + at third hospitalization and continued to get worse. He died 1/23/2021.	No prior vaccinations for this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient sent to the ED or sudden onset of shortness of breath on 02/02/2021. Per documentation by the MD, the patient had COVID19 ""several weeks ago"" and the nursing facility felt like he had recovered. A rapid test done in the ED was negative. When the patient worsened and seemed to be following the same path as other COVID patients, a send out PCR test was done, which was positive. The patient worsened and passed away that same day (02/05/2021) I was not made aware that the patient had the vaccine on 01/21/2021 until Monday 02/08/2021."	No prior vaccinations for this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (MODERNA)) (1201)**
No reported adverse reactions from 1st or 2nd vaccine doses Patient died on 2/6/2021 at Correctional facility- autopsy was performed at medical examiner's office. The COD was artherosclerotic cardiovascular disease	No prior vaccinations for this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (MODERNA)) (1201)**
On monitoring for declining in condition, loss of appetite and generalized body weakness on2/1/2021. Was confirmed COVID-19 positive 4/23/2020.	No prior vaccinations for this event.

CONDITION AGGRAVATED	**COVID19 (COVID19 (MODERNA)) (1201)**

Patient died at home in hospice care from complications of stage 4 bladder cancer No prior vaccinations for this event.

CONDITION AGGRAVATED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient previously had dizzy spills, but about a week after receiving the vaccine her dizzy spills began to get worse. The whole prior she kept saying I am just not right. On the 2/7/21 she a COVID test done, a nurse came to her house and preformed. On the morning of the 8th patient was on the phone with someone else and patient asked this person to call me and go check on her. Within 5 minutes I was over at her house, and I found her on the floor, she on her belly facedown. It looked like she was on the toilet, and it looked like she fall getting her off, she was still wet, she still felt warm. I called the ambulance and immediately began CPR. When EMS arrived they took over the CPR and transported her to the Hospital. The EMS was there for about 40 minutes and used an machine to preform the compressions. She was pronounced deceased at the hospital. No autopsy was done.	No prior vaccinations for this event.

CONDITION AGGRAVATED	**COVID19 (COVID19 (MODERNA)) (1201)**
Beginning in the evening 2/19/21, fever/chills/fatigue; worsening of symptoms 2/20/21 with lethargy/lack of appetite/weakness; unable to arouse on 2/21/21 then breathing stopped, patient's spouse called 911 performed CPR, EMS continued for 15 min then while in ambulance to hospital where he was pronounced dead. Official time of death 2:20pm	No prior vaccinations for this event.

CONDITION AGGRAVATED	**COVID19 (COVID19 (MODERNA)) (1201)**
Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with	No prior vaccinations for

recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.	this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
coughing up blood, significant hemoptysis -- > cardiac arrest. started day after vaccine but likely related to ongoing progression of lung cancer	No prior vaccinations for this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient did not have any adverse reaction to the COVID vaccine, but we were asked by our health dept to submit a VAERS report since the patient died between his first and second dose. Received Pfizer Dose #1 12/17/2020. No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Date of death 12/23/2020 from aspiration pneumonia complicated by end-stage heart failure and ischemic cardiomyopathy. Death was anticipated and not sudden.	No prior vaccinations for this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
respiratory distress; fever; anxiety developed requiring oxygen; Passed away; This is a spontaneous report via a Pfizer-sponsored program from a non-contactable consumer. A 63-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot and expiry not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. Medical history	No prior vaccinations for this event.

included anaphylactic reaction (broad), neuroleptic malignant syndrome (broad), anticholinergic syndrome (broad), acute central respiratory depression (broad), hypersensitivity (broad), respiratory failure (narrow), drug reaction with eosinophilia and systemic symptoms (broad), hypoglycaemia (broad), COVID-19 (broad) and chronic obstructive pulmonary disease (COPD); all from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine sodium and lorazepam (ATIVAN). Within 24 hours of receiving the vaccine, the patient experienced fever, respiratory distress, and anxiety developed requiring oxygen, morphine and lorazepam (ATIVAN). The patient passed away on the evening of 26Dec2020. The patient underwent lab tests and procedures which included SARS-COV-2 antibody test: negative on an unspecified date. The outcome of the event death was fatal, while of the other events was unknown. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Passed a

CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client was being treated with antibiotics by her PCP for diverticulitis flare up. It had not been resolved on the date of her death which occurred 01/27/21, She was found unresponsive by staff, 911 contacted, and paramedics pronounced her deceased at 7:48 AM. After consultation with PCP manner of death was noted as cardiac arrest. PCP was to sign off on death certificate.	No prior vaccinations for this event.

CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was hospitalized for confusion, and hypotension and increased weakness; resident proceeded to have a NSTEMI and died on 5th day in hospital on 1/31/2021.	No prior vaccinations for this event.

CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient with past medical history of CAD, CKD, sCHF, LGL Leukemia admitted to Hospital on 1/19 with pleural effusion. Pt expired on 2/1/2021. Hs of essential HTN, complete heart block, T2Diabetes,thyroid issues, stroke, papillary CA of thyroid, dyslipidemia, anemia, hypercalcemia, pulmonary nodule, hypoparathyroidism, pacemaker, bilat carotid stenosis, afib, pleural effusion, pancytopenia, cardiomyopathy, severe aortic stenosis, sick sinus syndrome, Dressler syndrome, empyema, ESRD	No prior vaccinations for this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began with vomiting and diarrhea. C/O chest pain. Bradycardia. Hypotension. 2 seizures in 45 minutes after not having one in years. We gave fluids. Gave Zofran. Comfort measures. Pt passed at midnight. Was completely fine one day before. Had minimal issues with COVID though did have a pneumonia that was treated w ATB early on and resolved.	No prior vaccinations for this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had one occurrence of thrombotic thrombocytopenic purpura in 1996 for which she had plasma exchange therapy in 1996. No other occurrence since 1996 until she received her first dose of the Pfizer covid vaccine.	No prior vaccinations for this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Ongoing decline overall. Remained on Hospice with increased lethargy documented on 1/20/21 and progressively worsening thereafter.

No prior vaccinations for this event.

CONDITION AGGRAVATED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

No prior vaccinations for this event.

CONDITION AGGRAVATED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client was administered the vaccine while symptomatic (01/25/21) although client did not know he was symptomatic for COVID-19. He had been exposed to a family member who had tested positive and should have been in quarantine but wasn't either because it was not felt he was considered a close contact by his family opinion or his family member never notified public health of this close contact...?. Clinet had presented to the ED following day after vaccination for shortness of breath and fatigue and an antigen test showed he was positive for COVID-19. He was sent home that same day 01/26/21. He was back in ED on 01/28/21 for worsening symptoms and admitted to hospital and later placed on ventilator. He passed away on 02/09/2021 (date of death was per his wife).	No prior vaccinations for this event.	
CONDITION AGGRAVATED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
COVID 19 symptoms and a positive test was confirmed on 1/6, employee noted previous exposure to positive family members Narrative: Employee noted exposure to COVID prior to presenting for 1st dose of vaccine on 1/5/21. On 1/6/21 employee reported the onset of symptoms and was tested and was confirmed COVID positive that day. Positive result was reported to employee health on 1/8/21. Employee Health continued to track employees progress and was informed of the need for hospitalization on 1/14/21. Course of hospitalization noted the need for intubation and significant issue with comorbid condition (rheumatoid arthritis). Employee died on 2/9/2021. Unable to confirm a direct connection to Vaccine vs. COVID infection, but felt it should be reported.	No prior vaccinations for this event.	
CONDITION AGGRAVATED		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

"Patient and her husband are elderly, but healthy and live independently. Patient took blood pressure medicine 'off and on' according to family. She was 5'2"", 120 pounds and slim and healthy and active, so was her husband, though he had pulmonary fibrosis so they had been staying home and not attending church etc, and masking when they did go out to protect against covid disease. They were both vaccinated with covid Pfizer vaccine (dose #1) on Thursday Feb 11. (02/11/2021) Thursday night as they went to bed they checked in with each other on how they each felt. Patient said she felt totally fine, and her husband said his arm was a bit sore. Patient woke before her husband on Friday Feb 12, went downstairs and, from what the family can tell, fixed herself a snack, then sat on the sofa. Patient's husband found her deceased on the sofa. He called 911 and they asked him to do CPR until the paramedics arrived. Because of proximity to covid vaccine, the ME wanted to examine the body in the home and also ordered an autopsy. Autopsy was completed on the same day as death, Feb 12, 2021"

No prior vaccinations for this event.

CONDITION AGGRAVATED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Received Pfizer 1/22/2021. RNA+ 2/4/2021. S/S SOB, cough, confusion. COVID assoc. resp. failure, stage 4 lung cancer, COPD, HTN, former smoker. patient in hospice and died 2/10/2021.

No prior vaccinations for this event.

CONDITION AGGRAVATED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

symptoms of ongoing congestive heart disease just progressed No prior vaccinations for this event.

CONDITION AGGRAVATED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center.

No prior vaccinations for

Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received her vaccine on 2/2/2021 in the morning. She was observed for over 15 minutes and had no history of any anaphylactic reaction of any sort. She felt fine and went home. 2/15/2021 we were notified by her family that she had passed away on 2/7/2021 at home. The cause of death was stated as myocardial infarct secondary to coronary artery disease. We do not think it had to do with the vaccine administration. The patient had many comorbidities.	No prior vaccinations for this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning	No prior vaccinations for this event.

and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.	No prior vaccinations for this event.

CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was found with no pulse no heart rate by a staff member around 11 pm. Earlier that day seen by myself for fatigue, sorethroat, nausea.	No prior vaccinations for this event.

CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient passed away from chronic respiratory failure with cardiogenic shock 24 hours from 2nd dose of vaccine. Patient with longstanding history of pulmonary HTN and heart failure with desire for comfort care	No prior vaccinations for this event.

only. Entering into VAERS out of abundance of caution.

CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.	No prior vaccinations for this event.

CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice,	No prior vaccinations for this event.

memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200 mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation: tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed, metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous

bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral patchy opacities

CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt	No prior vaccinations for this event.

was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.

CONDITION AGGRAVATED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient passed away on 2/1/21 at the Health System. She was there for congestive heart failure (CHF) which had been a problem for her since contracting COVID-19 (symptoms began 10/29/20 and tested positive 10/30/20). She had been to see her medical provider several times after her isolation period as well as a few trips to the hospital for, what they called ""CHF flare-ups"". Her last hospitalization began on January 30, 2021. Her social worker reported on t1/31/21 that ""she would likely be returning in another day or two""."		No prior vaccinations for this event.
CONDITION AGGRAVATED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.		No prior vaccinations for this event.
CONDITION AGGRAVATED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

within 24 hours after her second injection she developed chills, had a syncopal episode and had, difficulty breathing. this progressed over the next day when she had a second syncopal episode and her dyspnea and confusion worsened EMT was called and she was brought to the hospital. she was in flash pulmonary edema and with her history of severe aortic stenosis she was admitted to the cardiac icu. she had no prior history up to that time of pulmonary edema and was functioning without distress in her home. she had a history of covid in early april, manifesting primarily as severe confusion, from which she recovered.	No prior vaccinations for this event.
CONDITION AGGRAVATED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion; On 21Feb he went to the ER after vomiting and passing out; On 21Feb he went to the ER after vomiting and passing out; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; fever; headache; stomach upset; This is a spontaneous report from a contactable consumer reporting for the father: A 75-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EL3428) at single dose at left arm on 03Feb2021 for Covid-19 immunisation. Medical history included type 2 diabetes mellitus. No known allergies. The patient had not experienced Covid-19 prior vaccination. Concomitant medication in 2 weeks included amitriptyline hydrochloride (manufacturer unknown) 10 mg, atorvastatin (manufacturer unknown) 20 mg, dutasteride (manufacturer unknown) 0.5 mg, linaclotide (LINZESS) 290 mcg, gabapentin (manufacturer unknown) 300 mg, montelukast (manufacturer unknown) 10 mg, ramipril (manufacturer unknown) 5 mg, insulin degludec (TRESIBA) 100 unit/ml, liraglutide (VICTOZA) 18 mg/3ml solution. No other vaccine in 4 weeks. The patient experienced cardiac arrest due to pericardial effusion on 21Feb2021 14:15, fever on 13Feb2021, headache on 13Feb2021, stomach upset on 13Feb2021, on 19feb, he began to feel ill again with a fever, he felt worse on 20feb on 19Feb2021, on 21feb he went to the ER after vomiting and passing out on 21Feb2021. Events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of cardiac arrest due to pericardial effusion. Course of events: In Feb2021, 10 days after his 1st injection, the patient	No prior vaccinations for this event.

developed fever, headache, and stomach upset. He went for a rapid Covid-19 test (nasal swab) and it was negative on 11Feb2021. The doctor told him he might be having a delayed reaction to the vaccination. After a couple of days, he improved. On 19Feb2021, he began to feel ill again with a fever. He felt worse on 20Feb2021. On 21Feb2021 he went to the ER after vomiting and passing out and received treatment: IV fluids, diagnostic testing at ER. Rapid Covid test (nasal swab) at ER came back negative again on 21Feb2021. His heart arrested suddenly and he could not be resuscitated. CT scan results, that came back after death, showed Covid like pneumonia and pericardial effusion. The patient died on 21Feb2021 14:15. Cause of death was cardiac arrest due to pericardial effusion. An autopsy was not performed. The outcome of cardiac arrest due to pericardial effusion was fatal, of fever, headache, stomach upset was recovering, of he began to feel ill again with a fever, he felt worse was not recovered, of he went to the ER after vomiting and passing out was unknown.; Reported Cause(s) of Death: cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion

CONDUCTION DISORDER

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at

No prior vaccinations for this event.

01:53 on 1/19/21.

CONFUSIONAL STATE		**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21	No prior vaccinations for this event.	

CONFUSIONAL STATE		**COVID19 (COVID19 (MODERNA)) (1201)**
Presented to Urgent Care for weakness and confusion, transferred to ED, patient had a cardiac arrest and was unable to be resuscitated	No prior vaccinations for this event.	

CONFUSIONAL STATE		**COVID19 (COVID19 (MODERNA)) (1201)**
On the evening of 10JAN2021, patient experienced a low grade fever, decreased oxygen saturation of 38%, heart rate of 124, confusion. Patient received oxygen via face mask, morphine and ativan. By 11JAN2021, patient was no longer verbal, able to eat or communicate and was kept on comfort measure only. On the morning of 17JAN2021, the patient passed away.	No prior vaccinations for this event.	

CONFUSIONAL STATE		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient family had been noticing onset confusion for a few weeks prior to vaccine and event. Patient was taken to ED when found unconscious and died of a subdural hemorrhage a few days after vaccine clinic at retirement home.	No prior vaccinations for this event.	

CONFUSIONAL STATE		**COVID19 (COVID19 (MODERNA)) (1201)**
1/31/2021 12:50 Nursing Note Note Text: Res had low BP, low O2 sats, 30 breaths per minute, eyes open wide, making confused utterances. Started supplemental oxygen via NC, 2L, then 3L. Sats went up to 93% for a while, Sprvsr called. Unable to auscultate Left lung sounds. Called to update Res daughter. Called to page NP, writer went back to assess Res and O2 sats were 88%, turned O2 to 4LPM, called 911 for transport to Hospital ED. Left around 1030. NP called back afterwards, was updated. Family updated that Res was sent to Hospital ED. Note Text: Received phone call from daughter as well as information from hospital. Resident has pneumonia with septic shock. She is on abx and had thoracentesis performed for large pleural effusion. [linked]		No prior vaccinations for this event.
CONFUSIONAL STATE		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.
CONFUSIONAL STATE		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident had severe CAD, DM type 2, and hx of RBKA and left 5 digits on foot amputation. Hx of osteomyelitis post surgical. After last surgery, resident did not have a good appetite, more restless, increased confusion with dementia. Significant other passed away on 12/30/20, resident began refusing meals, decreased eating. Vaccinated on 1/13/21. On 1/25/21 Resident labs showed kidney failure. Dr. spoke with family and transitioned to Comfort care, on 2/5/21 went hospice. Patient passed away on 2/13/2021.		No prior vaccinations for this event.

	CONFUSIONAL STATE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.		No prior vaccinations for this event.
	CONFUSIONAL STATE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
71 year old woman at rehabilitation center for physical therapy with history of cirrhosis of the liver, asthma, and heart condition was tested for COVID-19 on 01/07/21, received 1st dose of Pfizer COVID-19 vaccine on 01/08/21, positive test result for COVID-19 received on 01/09/21. She was sent to the hospital and admitted on 01/12/21 after O2 was 70% and was in a confused state. Patient passed away on 01/17/21.		No prior vaccinations for this event.
	CONFUSIONAL STATE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and		No prior vaccinations for

a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."		this event.
	CONFUSIONAL STATE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1-12-21 Resident is complaining of heart pain. Resident blood pressure is 228/105. 1-22-21 Dx UTI 1-13-21 His nurse called MD at approximately 0645, reported to him that it was reported to this nurse that resident has not slept in 2 days and night, has an increased blood pressure, reports severe pain in lower back, and appears to be uncomfortable Resident is able to verbalize his pain and where it is at, but is unable to explain the quality of the pain or give a number on the 0/10 pain scale.		No prior vaccinations for this event.
	CONFUSIONAL STATE	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Resident was hospitalized for confusion, and hypotension and increased weakness; resident proceeded to have a NSTEMI and died on 5th day in hospital on 1/31/2021.

No prior vaccinations for this event.

CONFUSIONAL STATE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 1/29/21 patient began not feeling well and saw her provider. The doctor gave her fluids and tramadol for pain. They noticed increased confusion, but thought that could have been due to the tramadol. They also increased her gabapentin as she was experiencing nerve pain. Patient also developed a rash and was diagnosed with shingles on 2/1/21. Patient died on 2/3/21

No prior vaccinations for this event.

CONFUSIONAL STATE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.

No prior vaccinations for this event.

CONFUSIONAL STATE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Received Pfizer 1/22/2021. RNA+ 2/4/2021. S/S SOB, cough, confusion. COVID assoc. resp. failure, stage 4 lung cancer, COPD, HTN, former smoker. patient in hospice and died 2/10/2021.

No prior vaccinations for this event.

CONFUSIONAL STATE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On the 25th he was home alone, he called 911 and let them know he thought he was having a stroke. EMS arrived and transported him to Hospital. It was massive stroke, he was not able to comprehend anything, he was put into Hospice the following day and passed away on the 27th. There was no autopsy preformed.		No prior vaccinations for this event.
	CONFUSIONAL STATE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
within 24 hours after her second injection she developed chills, had a syncopal episode and had, difficulty breathing. this progressed over the next day when she had a second syncopal episode and her dyspnea and confusion worsened EMT was called and she was brought to the hospital. she was in flash pulmonary edema and with her history of severe aortic stenosis she was admitted to the cardiac icu. she had no prior history up to that time of pulmonary edema and was functioning without distress in her home. she had a history of covid in early april, manifesting primarily as severe confusion, from which she recovered.		No prior vaccinations for this event.
	CONFUSIONAL STATE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Day After - severe headache, 2 days after headache continues, itchy scalp, day 3 rash visible at hair line headache continues, more confusion than normal, day 4 on site nurses check rash and think it is dermatitis, day 5 continues to get work nurse practitioner was to visit next day, day 6 NP thinks that she has UTI and sends her to hospital (2/11/21). Hospital determines - Rash is Shingles, UTI present, - MRSA is now present in shingles which is on right back of head and right neck and face. Next Sepsis is diagnosed. Since 2/11/21 patient was not conscious. 2/20/21 famiy is notified that she should be moved to Hospice. Moved to hospice on 2/20/21. The patient, my mother, died on 2/23/21 official cause of death is UTI.		No prior vaccinations for this event.
	CONSTIPATION	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Patient stated he wasn't feeling well on January 25, 2021, wasn't eating and complained of abdominal pain. Patient noted to have indigestion and was constipated. Meds provided and labs ordered. On morning of January 26, 2021, patient became weak, lethargic and hypoxic and was sent to emergency department around 0700 hours on January 26, 2021. At approximately 1100 hours, emergency physician notified this writer that patient was not going to overcome his illness and would be placed on comfort care. At approximately 1130 hours, this writer was notified that patient had passed away from multi-organ failure.

No prior vaccinations for this event.

CONSTIPATION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were

No prior vaccinations for this event.

no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the

ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

CONTUSION

COVID19 (COVID19 (MODERNA)) (1201)

Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented

No prior vaccinations for this event.

Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

CONTUSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine administered 02/08/2021 , by Thursday 02/11/2021 patient almost nonverbal, by Monday 02/15/2021 patient went to the hospital with bruising, sores on her stomach and clots reported as thrombocytopenia, deceased by Friday 02/19/2021.	No prior vaccinations for this event.
CONTUSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM	No prior vaccinations for this event.

of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."		
	CONTUSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.		No prior vaccinations for this event.
	CONTUSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.		No prior vaccinations for this event.
	CONVERSION DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
approximately 24 hours post vaccine Patient developed a low grade fever of 99.5 and had increased fatigue. 48 hours later she had decreased neurological functioning. 02/23 she had difficulty swallowing. 02/23 She was admitted to hospice services. 02/26 she passed just before 10 am.		No prior vaccinations for this event.

COORDINATION ABNORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.		No prior vaccinations for this event.
CORONARY ARTERY DISEASE		**COVID19 (COVID19 (MODERNA)) (1201)**
"The patient came to the Emergency Room at approx 3:30 am on 02/03/2021 with pain in right arm (same arm the COVID vaccine had been administered in approx 12 hours earlier) and feeling generally unwell. Patient was concerned about possibility of gout flare or that something was wrong with her arm. Elevated blood pressure was noted; this was attributed to anxiety. She was evaluated, given 500 mg Tylenol, and discharged since the pain was decreasing and blood pressure was stabilized. Patient instructed to follow-up with physician. The next day, on 02/04/2021, the patient arrived at the Emergency Room by ambulance; cardiac arrest was the chief complaint. The patient's daughter stated the patient had been ""feeling generally poor and then suddenly collapsed."" Daughter described ""gurgling respirations"" and being unresponsive. 911 was called, police arrived within 5 minutes and initiated CPR. Epinephrine, atropine, lidocaine and bicarb administered after arrival to Emergency Room. Shockable rhythm never demonstrated. Patient never recovered spontaneous respiration or movement. The death was called at 23:04. Coronary artery disease with cardiac arrest is the cause from the ER records; the coroner is putting COVID-19 vaccination in Part 1 of the death certificate."		No prior vaccinations for this event.

CORONARY ARTERY DISEASE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	No prior vaccinations for this event.	
CORONARY ARTERY DISEASE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received her vaccine on 2/2/2021 in the morning. She was observed for over 15 minutes and had no history of any anaphylactic reaction of any sort. She felt fine and went home. 2/15/2021 we were notified by her family that she had passed away on 2/7/2021 at home. The cause of death was stated as myocardial infarct secondary to coronary artery disease. We do not think it had to do with the vaccine administration. The patient had many comorbidities.	No prior vaccinations for this event.	
CORONARY ARTERY DISEASE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient had swelling around her jaw after her second shot of the covid , Pfizer vaccine (.5 ml IM) on the Friday morning, January 29th, I took her to a follow up appointment with the cardiologist at 3:00 pm, as a follow up to a small heart attack event with hospitalization two weeks previously, at the cardiologist she was given the ok/all is well. That next morning early, she had a 911 event at her assisted living apartment and was sent back to the hospital, having had another heart attack. Patient died on the following Thursday, February 4, 2021. I do not know if the vaccination had any cause for my mothers death; but I feel it is necessary to report this series of heart attacks after she received the pfizer vaccine. Her Certificate of	No prior vaccinations for this event.	

Death records the cause of death as ""Coronary Artery Disease""."

CORONARY ARTERY DISEASE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of covid vaccine on 1/22/2021. Patient had no immediate reaction. Patient presented to the Emergency Department on 1/26/2021 c/o shortness of breath and chest pain. ECG showed a ST elevation myocardial infarction. Patient was treated and transferred to a cath lab where he died. Patient had significant coronary artery disease.	No prior vaccinations for this event.
CORONARY ARTERY OCCLUSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient and her husband are elderly, but healthy and live independently. Patient took blood pressure medicine 'off and on' according to family. She was 5'2"", 120 pounds and slim and healthy and active, so was her husband, though he had pulmonary fibrosis so they had been staying home and not attending church etc, and masking when they did go out to protect against covid disease. They were both vaccinated with covid Pfizer vaccine (dose #1) on Thursday Feb 11. (02/11/2021) Thursday night as they went to bed they checked in with each other on how they each felt. Patient said she felt totally fine, and her husband said his arm was a bit sore. Patient woke before her husband on Friday Feb 12, went downstairs and, from what the family can tell, fixed herself a snack, then sat on the sofa. Patient's husband found her deceased on the sofa. He called 911 and they asked him to do CPR until the paramedics arrived. Because of proximity to covid vaccine, the ME wanted to examine the body in the home and also ordered an autopsy. Autopsy was completed on the same day as death, Feb 12, 2021"	No prior vaccinations for this event.
CORONARY ARTERY THROMBOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Sudden cardiac death. Autopsy report: right coronary artery thrombosis. No prior vaccinations for this event.

CORONAVIRUS INFECTION **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21

No prior vaccinations for this event.

COUGH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient vaccinated on 12/28. Approximately one day later, develops cough and on azithromycin x 1 week. On 1/3, patient develops left-sided weakness and aphasia. Taken to the hospital, tested COVID+, required intubation -- acute hypoxic respiratory failure secondary to COVID - on H&P. Patient died on 1/4/21 at 7:20am.

No prior vaccinations for this event.

COUGH **COVID19 (COVID19 (MODERNA)) (1201)**

hypoxia, secretions,cough, dyspnea Narrative: ALS patient on hospice with ongoing history of aspiration pna, receiving tube feeds. Developed incr in secretions, hypoxeia, temp and with recently noted clogged feeding tube.

No prior vaccinations for this event.

COUGH

COVID19 (COVID19 (MODERNA)) (1201)

Started with cough, mild shortness of breath and feeling terrible in evening of 1/19. No prior vaccinations for this event.

COUGH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient obtained initial dose of Moderna vaccine on Thurday, Jan 14. No adverse effects reported during initial 15 minute post vaccine waiting period. Saturday morning (Jan 16), patient developed severe cough, labored breathing, and fever. Additionally patient mental status changed suddenly, became non-communicative (unable to speak, but would scream if she was touched). O2 status was irregular, dropping to 78. Sunday morning, EMT and then hospice was hospice called. Monday morning, after hospice emergency kit was initiated, patient passed away.

No prior vaccinations for this event.

COUGH

COVID19 (COVID19 (MODERNA)) (1201)

cough congestive heart failure death No prior vaccinations for this event.

COUGH **COVID19 (COVID19 (MODERNA)) (1201)**

started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level.

No prior vaccinations for this event.

Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.

	COUGH	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident expired on 2/5/21 at 03:35pm, about 25 hours after second dose of vaccine. At breakfast, resident was spitting a lot of secretions, coughing up liquids from nose and phlegm, facial swelling, which were all symptoms that he was struggling with prior to both doses of COVID vaccine, but had increased more than prior incidences on 2/5/21. Gurgling noted in upper airways, hyscolamine given, bath given to loosen secretions, morphine given. Family notified and came into facility for compassionate care visit around 1300. 1400 HR was 3 and RR was 2, but increased back to 60 and 12 within 20 minutes. Then resident expired at 1535.		No prior vaccinations for this event.
	COUGH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received his second dose of Moderna COVID vaccine on 2/6 at 12:40PM. Patient was observed for 15 minutes post-vaccination with no adverse events. On the evening of 2/6 (time unknown) the patient began to develop dry cough and fatigue. He was checked by a physician at that time (who was a family member). Patient continued to feel unwell into Sunday. His lungs were clear when checked Sunday afternoon (time unknown). At approximately 5:30pm on 2/7 the patient began experiencing sudden onset shortness of breath. A pulse ox was conducted at that time and it was 92%, and again shortly thereafter and it was 90% (as reported by family member). 9-1-1 was contacted at this time. CPR was initiated when he arrived at the emergency department, pulse ox was 60% (as reported by family member). The patient passed away shortly thereafter on 2/8/2021.		No prior vaccinations for this event.
	COUGH	**COVID19 (COVID19 (MODERNA)) (1201)**

Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.

No prior vaccinations for this event.

COUGH

COVID19 (COVID19 (MODERNA)) (1201)

Received Moderna covid vaccination 1/14/2021. 1/16/2021 received report of cough and difficulty breathing. Proceeded to hospital and was diagnosed Covid+ on testing. Continued to decline, died 1/31/2021.

No prior vaccinations for this event.

COUGH

COVID19 (COVID19 (MODERNA)) (1201)

covid shot 2/2; feel bad 2/5; covid positive diagnosis - 2/8 s/s cough, fever, shortness of breath , hypertension, afib (in er) - admitted went into DIC per intensivist 2/11 patient died

No prior vaccinations for this event.

COUGH

COVID19 (COVID19 (MODERNA)) (1201)

Patient passed away on 2/2/21 after being admitted on 1/31/21 after receiving COVID19 Moderna Vaccine on 1/26/21. On initial report to the hospital patient reported having a cough for over 2 weeks (starting approx. 1/17/21). He had a postive COVID19 PCR on 1/31/21. Intubated on 1/31/21 and passed away on 2/2/21

No prior vaccinations for this event.

	COUGH	**COVID19 (COVID19 (MODERNA)) (1201)**
death; hemiparesis; respiratory failure; Aphasia; SARS-COV-2 test positive; cough; A spontaneous report was received from other health care professional concerning a 32- year -female patient who received Modena's COVID-19 vaccine (mRNA-1273) and experienced aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive. The patient's medical history was not provided. No relevant concomitant medications were reported. On 28-Dec-2020, the patient received their first of two planned doses of mRNA-1273 (lot/batch 039k20A) intramuscularly on left arm for prophylaxis of COVID-19 infection. Approximately, one day later, patient developed cough and on treatment with azithromycin for one week. On 03-jan-2021, she experienced left sided weakness and aphasia and was shifted to hospital. Patient was confirmed COVID-19 positive which required intubation for acute hypoxic respiratory failure secondary to COVID-19. No laboratory data was provided. Action taken with mRNA-1273 in response to the events aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive not applicable. On an unknown date, the outcome of the events aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive was fatal. On 04 Jan 2021, the patient passed away due to the unknown cause. Autopsy results were unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the event of COVID-19 is assessed as unlikely related. The cause of death was not reported. Autopsy results were unknown.; Reported Cause(s) of Death: Unknown cause of death		No prior vaccinations for this event.
	COUGH	**COVID19 (COVID19 (MODERNA)) (1201)**
2-24-21 patient with development of cough, fatigue, increasing on chronic disability worsening debility and falls. scheduled for office visit 2-25.21 0900 call from spouse 0210 am patient was not breathing and lvad alarming low flow alarm on arrival of ems confirm asystolic not breathing and dead		No prior vaccinations for this event.

	COUGH	**COVID19 (COVID19 (MODERNA)) (1201)**
1-25-2021- Phone call: pt had cold and cough prior to vaccine. cough worsened 1-28-2021 Phone call: pt requesting provider visit, cough is same and taking tessalon pearls 1-29-2021 Provider in office visit: pt complain of cough and SOB for 6 days. Getting worse. Temp 101.2, pulse ox 87%, BP 128/70. level of distress- leaning forward to breath. appeared ill. diffuse rales throughout both lung fields, more at bases. Diagnosis Pneumonia due to COVID 19 virus. Sent to ER		No prior vaccinations for this event.
	COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
At approximately 10:30pm on 1/14/2021, resident was noted to have a rash on her face, hands, arms, and chest. VS:100.2, 113, 20,108/59, 84% room air. applied nasal cannula at 4-L, telephoned Physician orders 6mg Decadron one time order, a second set of Vitals , reads 99.3, 110, 20, 106/60, 90% on 4-L N/C. On coming shift advised. At approximately 2:00am on 1/15/2021, resident congested and coughing. BP 151/70, pulse 124, temp 98.1 forehead, resp 20 and pulse oc 79% on 3L. At approximately 2:30am PRN cough syrup and breathing tx. Resident's condition began to worsen with breathing tx. This LPN updated at 0248 doctor on resident's condition. Doctor gave permission for resident to go to hospital. At 4:19am the Er called to say resident passed away.		No prior vaccinations for this event.
	COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was		No prior vaccinations for this event.

extubated and put on comfort measures and passed away

	COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.		No prior vaccinations for this event.
	COUGH	**COVID19 (COVID19**

	(PFIZER-BIONTECH)) (1200)
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel	No prior vaccinations for this event.

can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the

steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

	COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Client tested positive for COVID-19 by rapid test on 1/8/21. On 1/9/21 at 1405 his oxygen saturation dropped to 86% and oxygen was initiated at 2L per nasal cannula. A non-productive cough was noted on 1/10/21 and oxygen was increased to 3L. On 1/12/21 Client became non-responsive with 30 second periods of apnea. Dexamethasone was initiated on 1/13/21. Lung sounds were noted with crackles on 1/15/21 at 1158 and at 2120 Client was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.	No prior vaccinations for this event.

	COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Patient tested positive for COVID-19 by rapid test on 1/6/21. She began to demonstrate a dry cough on 1/11/21. On 1/12/21 at 1723 her oxygen saturation dropped to 79% and oxygen was applied at 4L per nasal cannula. On 1/19/21 at 2130 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.	No prior vaccinations for this event.

	COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Patient began to demonstrate a cough the evening of 1/5/2021, after receiving the COVID-19 vaccine	No prior vaccinations for

earlier in the afternoon. A rapid COVID-19 test was performed and was positive. She began to demonstrate shortness of breath with exertion on 1/7/21, and lethargy on 1/12/21. Appetite and oral intake began to decline on 1/12/21, and Oxygen saturation dropped on 1/16/21 to 82%, and oxygen was initiated at 3L per nasal cannula. On 1/19/21 at 0414 patient was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.	this event.	
COUGH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient tested Covid positive, cough, low oxygen levels, COVID Pneumonia, patient is now deceased	No prior vaccinations for this event.	
COUGH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
passed away; cough; This is a spontaneous report from a contactable consumer, the patient's daughter. A 92-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration in the left arm on 13Jan2021 at 11:00 (at the age of 92-years-old) as a single dose for COVID-19 immunization. Ongoing medical history included nursing home resident, admitted to hospice on 13Jan2021 (prior to vaccination), and oxygen supplementation (due to low oxygen levels) from a few days prior to the vaccine (Jan2021). Other relevant medical history included congestive heart failure from Dec2020 and sulfa allergy. Prior to the vaccination, the patient was tested numerous times (as reported) for COVID-19 and was negative. There were no concomitant medications. The patient did not receive any other vaccines within four weeks prior to the vaccination. A few days before the vaccination, her oxygen level had gone down, and she had been placed on oxygen. Prior to receiving the vaccine, the patient was reported as being 'fine'. On 13Jan2021, the patient received the vaccine at 11:00. The patient coughed maybe 5 or 6 times and then dropped her	No prior vaccinations for this event.	

head. Resuscitation was not performed as patient had a do not resuscitate (DNR) order. The patient passed away on 13Jan2021 at 13:05. The cause of death was not reported. An autopsy was not performed. The clinical outcome of the cough was unknown at the time of death. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Reported Cause(s) of Death: passed away		
	COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021.		No prior vaccinations for this event.
	COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21		No prior vaccinations for this event.

COUGH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021		No prior vaccinations for this event.
COUGH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident on Hospice. 1/18 Hand Shaky. 1/19- Covid +19. 1/20 Desat 85% on RA, provided 2L O2 supplement= 97% 1/20 congestive cough, 1/28- RR-28;1/29- Hypoglycemia 1/30-NPO. 1/30-resident passed away.		No prior vaccinations for this event.
COUGH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.		No prior vaccinations for this event.
COUGH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident coughing in dining room, staff suctioned, physician stated to transfer via 911 to hospital, 6:33 PM. Hospital notified Nursing Home staff resident passed away at 8:25 PM. No adverse reaction noted to the Covid vaccine 24 hours after each dose at Nursing Home. There was no airway obstruction, cardiorespiratory arrest, death was natural at hospital.		No prior vaccinations for this event.

	COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
7 days after receiving the vaccine, patient suffered excessive diarrhea and slight coughing. 9 days after vaccine, patient was tested for Covid 19, and received positive results. Patient was transported to hospital via ambulance but hospital returned her to the nursing home since chest was clear, no respiratory issues, and no fever. 10 days after receiving the vaccine, patient was turned over to hospice care but still in the nursing home. Hospice was called in to provide better physician advice and access 24/7. 14 days after receiving vaccine, patient began experiencing excruciating body aches, coughing, low oxygen levels, and no appetite. 18 days after vaccine, patient died.		No prior vaccinations for this event.
	COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer 1/22/2021. RNA+ 2/4/2021. S/S SOB, cough, confusion. COVID assoc. resp. failure, stage 4 lung cancer, COPD, HTN, former smoker. patient in hospice and died 2/10/2021.		No prior vaccinations for this event.
	COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on		No prior vaccinations for this event.

2/11/21.

COUGH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

No prior vaccinations for this event.

COUGH

COVID19 (COVID19

(PFIZER-BIONTECH))
(1200)

Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called

No prior vaccinations for this event.

her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse

events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

COUGH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

A few days after the vaccination my father had a sore throat and slight cough. This progressed into pneumonia like symptoms and he died on 2/11/21.

No prior vaccinations for this event.

COUGH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.

No prior vaccinations for this event.

COUGH

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.

No prior vaccinations for this event.

COUGH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Pfizer-BioNTech COVID- 19 Vaccine EUA Patient received COVID-19 Vaccine dose #2 on February 24, 2021. On February 25th at 10:36 AM,Patient's son called physician to report some side effects to second dose of Covid vaccine. She had diarrhea when she came home yesterday. Son has been up all night with her as patient has had a ""hacking cough,feels terrible, and now has had diarrhea x2"". Patient has taken Advil and will be taking tylenol periodically through out the day for her side effects. Patients son notified physician at 09:55 AM on February 26 that the patient has expired."

No prior vaccinations for this event.

COUGH

COVID19 (COVID19 (UNKNOWN)) (1202)

Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2 diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated)

No prior vaccinations for this event.

then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and was intubated. Transported to hospital. SARS CoV-2 and influenza negative.

	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
After vaccination, patient tested positive for COVID-19. Patient was very ill and had numerous chronic health issues prior to vaccination. Facility had a number of patients who had already tested positive for COVID-19. Vaccination continued in an effort to prevent this patient from contracting the virus or to mitigate his risk. This was unsuccessful and patient died.		No prior vaccinations for this event.
	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
At the time of vaccination, there was an outbreak of residents who had already tested positive for COVID 19 at the nursing home where patient was a resident. About a week later, patient tested positive for COVID 19. She had a number of chronic, underlying health conditions. The vaccine did not have enough time to prevent COVID 19. There is no evidence that the vaccination caused patient's death. It simply didn't have time to save her life.		No prior vaccinations for this event.
	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
Prior to the administration of the COVID 19 vaccine, the nursing home had an outbreak of COVID-19. Patient was vaccinated and about a week later she tested positive for COVID-19. She had underlying thyroid and diabetes disease. She died as a result of COVID-19 and her underlying health conditions and not as a result of the vaccine.		No prior vaccinations for this event.

COVID-19		**COVID19 (COVID19 (MODERNA)) (1201)**
"Called to schedule second vaccine and daughter reports that he died on01/19/2021 with ""COVID"""	No prior vaccinations for this event.	
COVID-19		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient diagnosed with COVID on January 9, 2021 after being exposed to family member that was under quarantine in the same household. Admitted to the hospital and was discharged on January 14, 2021 with home hospice. Patient passed away on January 18, 2021	No prior vaccinations for this event.	
COVID-19		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt developed COVID-19 infection, symptoms starting 7 days after first dose was given. Patient was admitted to hospital on 1/21 after falling (secondary to weakness) and striking head on toilet. Patient expired due to respiratory complications of COVID on 1/25.	No prior vaccinations for this event.	
COVID-19		**COVID19 (COVID19 (MODERNA)) (1201)**
Narrative: Symptoms: & DEATH DUE TO COVID 01/13/21 Treatment: No prior vaccinations for this event.		
COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**	
Resident vaccinated on 01/06/21 she acquired COVID 19 on 01/10/2021. Resident had multiple co	No prior vaccinations for this	

morbidities and was declining prior to the vaccine. Resident expired on 01/20/2021	event.
COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
VACCINE ADMINISTERED 01/06/21 ACQUIRED COVID 19 01/10/21 RESIDENT HAD MULTIPLE CO MORBIDITIES AND WAS DECLINING PRIOR TO VACCINE. RESIDENT EXPIRED ON 01/25/2021	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt likely presented to vaccine appt with asymptomatic/early infection of COVID-19, as he presented 2 days post-vaccination and tested positive for COVID-19 on rapid and PCR test. He was hospitalized where he eventually died of complications from COVID-19 while in ICU. Date of death was 1/15/2021.	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
weakness and fallsNarrative: 95 yo male w/ a PMH significant for Afib, legal blindness, Hx of CVA, cognitive impairment, GERD, HTN, pseudogout, BPH, chronic knee infection, and DJD who received his first dose of the Moderna COVID-19 vaccine on 01/08/21. The pt's COVID-19 screening questionnaire prior to receiving the vaccine was negative. The pt presented to the ED on 01/13/21 for weakness and m PCR test on ultiple recent falls (since receiving his first dose of the COVID-19 vaccine). The pt's COVID-19 01/13/20 was positive and he was admitted. He was started on treatment with remdesivir + dexamethasone on 1/14. The pt initially required supplemental oxygen via low-flow NC, however his oxygen requirements increased to 100% NRB. On 01/16/21 his MPOA elected for hospice care. The pt passed on 01/17/21. Unclear if the COVID-19 vaccine attributed to the patient's hospitalization and eventual death, or whether these events occurred from COVID-19 itself, however this case is being reported the FDA since this vaccine is under an emergency use	No prior vaccinations for this event.

authorization (EUA).

	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
	My Mother was given the Covid Vaccine (1st Dose) on 12/28/2020. Later that night we received a call from the nursing facility that my Mother was having uncontrollable seizures and had to be transported to the nearby hospital. The ER doctor confirmed that my Mother had tested positive to Covid. She was treated for Covid and was on life support. A few days later we received a call that my Mother had a major stroke. She passed away on January 4, 2021	No prior vaccinations for this event.
	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
	Resident received the vaccine on 1-22-21 and she was diagnosed with COVID-19 during routine testing on 1-28-21. She didn't have any symptoms except feeling weak and she had a decrease in her appetite. She already had a poor appetite prior. She died on 2-2-21.	No prior vaccinations for this event.
	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
	Received Moderna covid vaccination 1/14/2021. 1/16/2021 received report of cough and difficulty breathing. Proceeded to hospital and was diagnosed Covid+ on testing. Continued to decline, died 1/31/2021.	No prior vaccinations for this event.
	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
	Received Moderna #1 on 1/12/2021. 1/15/2021 developed worsening shortness of breath. Went to hospital	No prior vaccinations

and diagnosed with anemia, 4 negative fecal tests, neg EGD and colonoscopy. Discharged and readmitted (circumstances unknown for this episode) then readmitted a third time 1/20/2021 for shortness of breath. Diagnosed covid + at third hospitalization and continued to get worse. He died 1/23/2021.	for this event.
COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient sent to the ED or sudden onset of shortness of breath on 02/02/2021. Per documentation by the MD, the patient had COVID19 ""several weeks ago"" and the nursing facility felt like he had recovered. A rapid test done in the ED was negative. When the patient worsened and seemed to be following the same path as other COVID patients, a send out PCR test was done, which was positive. The patient worsened and passed away that same day (02/05/2021) I was not made aware that the patient had the vaccine on 01/21/2021 until Monday 02/08/2021."	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away; Positive result; A spontaneous report was received from a consumer concerning a female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed COVID-19 and passed away. The patient's medical history was not provided. Concomitant product use was not reported. On 05 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 08 Jan 2021, the patient had a positive COVID-19 test. On 18 Jan 2021, the patient passed away. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 18 Jan 2021. The cause of death was not reported.; Reporter's Comments: This spontaneous report concerns a female patient who experienced COVID-19 and passed away. The event of COVID-19 occurred 4 days after the first and only dose of the mRNA-1273 vaccine administered and death occurred 14 days after administration of the mRNA-1273 vaccine. Based on the information provided and the known etiology of COVID-19, it is unlikely to be	No prior vaccinations for this event.

associated with mRNA-1273 vaccine administration. With no definite information on the clinical details of the death, it is difficult to adequately assess a causal association with mRNA vaccine. Main field defaults to æpossibly related'; Reported Cause(s) of Death: unknown cause of death

	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
patient tested positive for covid on 1/29/21. was hospitalized on 2/8/21 for shortness of breath, generalized weakness, nausea.		No prior vaccinations for this event.

	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
covid shot 2/2; feel bad 2/5; covid positive diagnosis - 2/8 s/s cough, fever, shortness of breath , hypertension, afib (in er) - admitted went into DIC per intensivist 2/11 patient died		No prior vaccinations for this event.

	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was given vaccine the following day he died , No prior vaccinations for this event.		

	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident tested COVID-19 confirmed positive a few days after covid vaccination. No prior vaccinations for this event.		

	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient passed away on 2/2/21 after being admitted on 1/31/21 after receiving COVID19 Moderna Vaccine on 1/26/21. On initial report to the hospital patient reported having a cough for over 2 weeks (starting approx.		No prior vaccinations for this event.

1/17/21). He had a postive COVID19 PCR on 1/31/21. Intubated on 1/31/21 and passed away on 2/2/21

	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient described feeling nervous, anxious the next morning (Wednesday) after the vaccine. He later fell in the bathroom after using the restroom, his legs gave out (his words) and consequently was on the ground for 23 hours before being transported to the hospital. That was Thursday afternoon. He was diagnosed with COVID-19 on Saturday night and died the following Friday morning.		No prior vaccinations for this event.
	COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am		No prior vaccinations for this event.

unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

COVID-19	COVID19 (COVID19 (MODERNA)) (1201)
Moderna COVID 19 Vaccine: Patient started with symptoms of covid 5 days after first vaccine. She was hospitalized and passed due to COVID 19 on 2/6/21. Patients family informed us when she was due for the second dose.	No prior vaccinations for this event.

COVID-19	COVID19 (COVID19 (MODERNA)) (1201)
death; hemiparesis; respiratory failure; Aphasia; SARS-COV-2 test positive; cough; A spontaneous report was received from other health care professional concerning a 32- year -female patient who received Modena's COVID-19 vaccine (mRNA-1273) and experienced aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive. The patient's medical history was not provided. No relevant concomitant medications were reported. On 28-Dec-2020, the patient received their first of two planned doses of mRNA-1273 (lot/batch 039k20A) intramuscularly on left arm for prophylaxis of COVID-19 infection. Approximately, one day later, patient developed cough and on treatment with azithromycin for one week. On 03-jan-2021, she experienced left sided weakness and aphasia and was shifted to hospital. Patient was confirmed COVID-19 positive which required intubation for acute hypoxic respiratory failure secondary to COVID-19. No laboratory data was provided. Action taken with mRNA-1273 in response to the events aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive not applicable. On an unknown date, the outcome of the events aphasia, cough,	No prior vaccinations for this event.

death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive was fatal. On 04 Jan 2021, the patient passed away due to the unknown cause. Autopsy results were unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the event of COVID-19 is assessed as unlikely related. The cause of death was not reported. Autopsy results were unknown.; Reported Cause(s) of Death: Unknown cause of death

COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**

COVID infection, death No prior vaccinations for this event.

COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was admitted to hospital on 2-9-21 for urinary tract infection and tested positive for Covid. Developed pneumonia and expired on 2-12-21.	No prior vaccinations for this event.

COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient rcvd 1st covid 19 vaccine on 1/26/2021. Patient had house guests on 1/30/21. Those house guests tested positive for covid on 2/1/2021. Patient started getting symptoms on 02/2/2021. Patient tested postivie on 2/4/2021. Patient was hospitalized 2/7/2021. Patient passed away on 2/21/21.	No prior vaccinations for this event.

COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
Found lying face down without respiration or pulse, believed to be within 5 minutes of event. ACLS procedures unsuccessful. Unable to get autopsy. Believed to be heart attack secondary to COVID infection,	No prior vaccinations

but unconfirmed. Relative contribution of recent vaccination unknown.		for this event.
COVID-19		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt tested positive for COVID-19 on 2/10/2021 and died from illness related to COVID-19 on hospice at home on 2/18/2021, per care facility.		No prior vaccinations for this event.
COVID-19		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt tested positive for COVID-19 on 2/10/2021 and was hospitalized on 2/15/2021 and deceased on 2/18/2021 at the hospital of admission, per caregiver.		No prior vaccinations for this event.
COVID-19		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt tested positive for COVID-19 on 2/10/2021 and was deceased on 2/16/2021 per the caregiver.		No prior vaccinations for this event.
COVID-19		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt tested positive for COVID-19 on 2/10/2021, and was deceased on 2/16/2021 at.		No prior vaccinations for this event.
COVID-19		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt tested positive for COVID-19 on 2/10/2021, and deceased on 2/12/2021, per caregiver at.		No prior vaccinations for this event.

COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
NO SPECIFIC ADVERSE EVENT DUE TO THE VACCINE BUT THE PATIENT PASSED AWAY 02/10/2021 DUE TO COVID	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
1-25-2021- Phone call: pt had cold and cough prior to vaccine. cough worsened 1-28-2021 Phone call: pt requesting provider visit, cough is same and taking tessalon pearls 1-29-2021 Provider in office visit: pt complain of cough and SOB for 6 days. Getting worse. Temp 101.2, pulse ox 87%, BP 128/70. level of distress- leaning forward to breath. appeared ill. diffuse rales throughout both lung fields, more at bases. Diagnosis Pneumonia due to COVID 19 virus. Sent to ER	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (MODERNA)) (1201)**
Death Narrative: Family was able to be present at bedside shortly after patient was extubated. Fentanyl bolus given 10-15 minutes prior. Patient passed away soon after endotracheal tube removed. Time of death 10:14am.	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine 12/30/2020 Screening PCR done 12/31/2020 Symptoms 1/1/2021 COVID test result came back positive 1/2/2021 Deceased 1/4/2021	No prior vaccinations for this event.

COVID-19	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
COVID-19; COVID-19; Pneumonia; respiratory failure; This is a spontaneous report from a contactable consumer. An 80-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 02Jan2021 for COVID-19 immunization. Medical history included Alzheimer's and others. No known allergies. Concomitant medications included unspecified medications. The reporter's mother in law was tested for COVID-19 at a nursing facility on 25Dec2020 and she was negative. On 02Jan2021, she received the first dose of Pfizer vaccine. On 04Jan2020, she developed a high fever, needed oxygen and was positive for COVID-19. Date of death was 04Jan2021. The cause of her death was listed as pneumonia, respiratory failure and COVID-19. No autopsy performed. No treatment received. No one knew if the vaccination contributed to her death. It was hard to know if her death was due to the administration of the vaccine or it exacerbated the COVID19 symptoms which led to her death. Since this was unknown, it could have been a possibility. The reporter wanted to give us this information because we might want to consider having high risk population, patients with underlying conditions, older population tested for COVID-19 prior to the vaccination, as this is not currently a recommendation or a requirement. All is very new and they are all learning so the reporter wanted to share this information with us. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There are medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. The outcome of the events was fatal. Information about Lot/Batch has been requested.; Sender's Comments: The association between the fatal event lack of effect (pneumonia, respiratory failure and COVID-19) with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19;	No prior vaccinations for this event.

Pneumonia, respiratory failure and COVID-19

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient expired 1/15/2021; had been treated as outpatient for pneumonia, likely COVID-19 but no positive test result in December 2020. PMH diabetes	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient sent to hospital 1/2 and 1/5. Returned both times to nursing home covid unit without a hospital admission. Resident had been diagnosed with COVID later in the day on 12/30, when routine testing PCR results returned to facility, after resident had already had her first covid vaccination on 12/30/20 in the morning. Resident continued decline, was again sent to hospital on 1/24/21, and expired in hospital 1/25/21.	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic #1. Patient tested positive for COVID-19 by rapid testing on 1/6/21. She demonstrated poor appetite and fluid/food intake and an IV of Normal Saline was initiated on 1/7/21. Oxygen saturation was initiated on 1/12/21 at 4L per nasal cannula. for shortness of breath. On 1/22/21 at 0310 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.	No prior vaccinations for this event.

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
TESTED POSITIVE FOR COVID-19 1-7-2021, TRANFERRED TO HOSPITAL ON 1-18-2021. HE READMITTED TO THE FACILITY ON 1-21-2021 WITH HOSPICE SERVICES AND EXPIRED ON 1-25-2021.	No prior vaccinations for this event.

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was vaccinated on 12/31/20. Then on 1/14/21 he tested positive for SARS-CoV-2 on routine surveillance PCR testing. Another resident on the same hall was COVID positive on 1/11/21. Results of the PCR test were obtained on 1/16/21. He appeared asymptomatic at that time. Given his COVID positive status, all aerosol generating procedures had to be stopped. Overnight on 1/16/21 into 1/17/21, he had the onset of acute respiratory failure and was transported to the hospital. Per notes, he was put on BiPAP for several hours, but his CO2 level did not improve. Per prior advance directives completed with the resident and his two brothers, he had DNR/DNI orders. The hospital physician spoke with his brother and the decision was made to move to comfort care. He was discharged to inpatient hospice and died around 4pm on 1/18/21. This outcome does not appear to be vaccine-related, but death from COVID-19 infection is listed as a reportable event following COVID-19 vaccination.	No prior vaccinations for this event.

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Tested positive for COVID19 on 12-30-2020, Admitted to Hospital on 1/5/2021 with active COVID, Patient died 1/29/2021.	No prior vaccinations for this event.

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident vaccinated-1/7/21 Resident covid positive 1/11/21 Resident covid PNA-1/12/21 Resident hospitalized 1/16/21 Resident deceased 1/20/21	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite.	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Ongoing decline overall. Remained on Hospice with increased lethargy documented on 1/20/21 and progressively worsening thereafter.	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-**

	BIONTECH)) (1200)
Resident on Hospice. 1/18 Hand Shaky. 1/19- Covid +19. 1/20 Desat 85% on RA, provided 2L O2 supplement= 97% 1/20 congestive cough, 1/28- RR-28;1/29- Hypoglycemia 1/30-NPO. 1/30-resident passed away.	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Xrays showed covid Poss pockets all in her lungs on 15Jan; Xrays showed covid Poss pockets all in her lungs on 15Jan; This is a spontaneous report from a contactable consumer. An 85-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for covid-19 immunisation. Medical history included dementia. Concomitant medications were not reported. Patient popped hot 02Jan2021 along with 4 others on the hall she lived. Within 9 days 50+ patients were positive. All had the vaccine the same day. Patient was test positive on 02Jan2021. She was on day 12 of her quarantine when she started to get worse. She was unresponsive by 16Jan2021 and passed 18Jan2021. We were with her from 14Jan2021 to 18Jan2021. But had not been allowed to visit with her since Mar2020. And what post treatment pairs well with it? Publicly we hear Remdesivir and Bamlanivimab but these patients only received a general antibiotic and some vitamins. Death cause was Xrays showed covid Poss pockets all in her lungs on 15Jan2021. No autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based	No prior vaccinations for this event.

on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information; Reported Cause(s) of Death: Xrays showed covid Poss pockets all in her lungs on 15Jan		
	COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client was administered the vaccine while symptomatic (01/25/21) although client did not know he was symptomatic for COVID-19. He had been exposed to a family member who had tested positive and should have been in quarantine but wasn't either because it was not felt he was considered a close contact by his family opinion or his family member never notified public health of this close contact...?. Clinet had presented to the ED following day after vaccination for shortness of breath and fatigue and an antigen test showed he was positive for COVID-19. He was sent home that same day 01/26/21. He was back in ED on 01/28/21 for worsening symptoms and admitted to hospital and later placed on ventilator. He passed away on 02/09/2021 (date of death was per his wife).		No prior vaccinations for this event.
	COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was		No prior vaccinations for this event.

found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/15: Pfizer vaccine dose 1 administered 1/16: Fever, chills 1/22: Sore throat, coughing w/white phlegm, taking Tylenol and Mucinex. Fever and chills from 1/16 subsided. Had telehealth consultation with PA. Per her notes, patient said he gets these symptoms annually, requested for an antibiotic. PA referred him for a COVID test. Ordered hydrocodone/chlorphen ER suspension for his cough and an antibiotic. Antibiotic was recommended if symptoms do not subside. 1/23: COVID test administered 1/25: Reported positive for COVID 1/26: Telehealth session w/PA: she informed patient of his positive test, advised to quarantine and seek medical help at hospital if symptoms worsen. Patient reported that his sore throat mostly subsided but is still coughing at night. Said that the pharmacy didn't receive the prescription order for the antibiotic, so this was re-ordered. 1/31: Partner found him dead at 8:18AM on his bed. Death certificate issued by state says cause of death: COVID. Autopsy was not performed. Buried on 2/9/21.	No prior vaccinations for this event.

	COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
7 days after receiving the vaccine, patient suffered excessive diarrhea and slight coughing. 9 days after vaccine, patient was tested for Covid 19, and received positive results. Patient was transported to hospital via ambulance but hospital returned her to the nursing home since chest was clear, no respiratory issues, and no fever. 10 days after receiving the vaccine, patient was turned over to hospice care but still in the nursing home. Hospice was called in to provide better physician advice and access 24/7. 14 days after receiving vaccine, patient began experiencing excruciating body aches, coughing, low oxygen levels, and no appetite. 18 days after vaccine, patient died.		No prior vaccinations for this event.
	COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death 2/12/21 No prior vaccinations for this event.		
COVID-19 COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)		
COVID 19 symptoms and a positive test was confirmed on 1/6, employee noted previous exposure to positive family members Narrative: Employee noted exposure to COVID prior to presenting for 1st dose of vaccine on 1/5/21. On 1/6/21 employee reported the onset of symptoms and was tested and was confirmed COVID positive that day. Positive result was reported to employee health on 1/8/21. Employee Health continued to track employees progress and was informed of the need for hospitalization on 1/14/21. Course of hospitalization noted the need for intubation and significant issue with comorbid condition (rheumatoid arthritis). Employee died on 2/9/2021. Unable to confirm a direct connection to Vaccine vs. COVID infection, but felt it should be reported.		No prior vaccinations for this event.

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Unresponsive, Increase BP and H. Hospital Dx Renal Failure No prior vaccinations for this event.	
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer 1/22/2021. RNA+ 2/4/2021. S/S SOB, cough, confusion. COVID assoc. resp. failure, stage 4 lung cancer, COPD, HTN, former smoker. patient in hospice and died 2/10/2021.	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed/died on 09Feb2021 from respiratory failure from COVID19; presented to the ER with COVID symptoms and was	No prior vaccinations for

diagnosed/died on 09Feb2021 from respiratory failure from COVID19; This is a spontaneous report from a contactable physician. An 89-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in 10Jan2021 at 12:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had no COVID prior to vaccination. The patient received one dose of Pfizer vaccine on 10Jan2021. The patient was presented to the ER with COVID symptoms and was diagnosed on 27Jan2021. Patient subsequently died on 09Feb2021 from respiratory failure from COVID19. It was unknown if autopsy was done. The patient was tested for COVID post vaccination via nasal swab: covid-19 virus test positive on 27Jan2021. The events resulted in emergency room/department or urgent care, hospitalization, and patient died. No follow-up attempts are possible, information about batch number cannot be obtained. No further information is expected.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported COVID post vaccination and respiratory failure with fatal outcome, and the administration of COVID 19 vaccine, BNT162B2, based on the reasonable temporal association. More information on the underlying medical condition in this 89-year-old male patient is required for the Company to make a more meaningful causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: presented to the ER with COVID symptoms and was diagnosed on 27Jan. Patient subsequently died on 09Feb from respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed on 27Jan. Patient subsequently died on 09Feb from	this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o	No prior vaccinations for

of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.	this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
THE RESIDENT WAS ROUTINELY TESTED FOR COVID ON 1/29/21 AND POSITIVE RESULTS RETURNED ON 1/30/21; WAS ASYMPTOMATIC AT FIRST, BUT DEVELOPED SYMPTOMS ON 1/31/21 THAT PROGRESSED AND THE RESIDENT DIED ON 2/7/21	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197,	No prior vaccinations for this event.

creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on	No prior vaccinations for this event.

2/19/21.

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

death 2/25/21 No prior vaccinations for this event.

COVID-19 COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/14/21 - Resident complained of SOB. SPO2 66% on RA, vs 105/66-96-20 T98.2 O2 administered Pox 97% Binax test revealed (+) COVID results. Resident transferred to COVID wing. Family (HCP) updated and declined transfer to hospital Resident continued with fever, hypoxia and lethargy. Family elected CMO and Hospice notified. Resident died on 1/16/2021 @ 930AM.	No prior vaccinations for this event.

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
contracted covid after first dose Narrative: First covid vaccine dose 12/31/2020, tested positive for covid 1/7/2021, died from complications 1/25/2021	No prior vaccinations for this event.

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"never woke up after arrival; Suffered with vascular dementia; Death cause: Covid/Tested positive to Covid 31Jan, tested due to increased lethargy; This is a spontaneous report from a contactable consumer. An 85-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Jan2021 at single dose for COVID-19 immunization. The patient received the	No prior vaccinations for this event.

vaccine at nursing home/senior living facility. Medical history included dementia, hypertension, past strokes. The patient was exposed to asymptotic staff member on or prior to 25Jan2021. The patient had no known allergy. No COVID prior vaccination. Concomitant medication included lisinopril. No other vaccine was received in four weeks. The patient was tested positive to COVID on 31Jan2021, tested due to increased lethargy started from 26Jan2021. The patient suffered with vascular dementia. She was ambulatory up to 31Jan2021. The patient was sent to hospice that evening on 31Jan2021 to quarantine, never woke up after arrival. Palliative Care started 02Feb2021, the patient expired 12Feb2021. Cause of death was COVID. The patient did not receive treatment for events. The autopsy was not performed. The outcome of events ""never woke up, vascular dementia"" was unknown. Information on Lot /Batch Number has been requested.; Reported Cause(s) of Death: Death cause: Covid"

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Caller is nephew of patient. Patient was admitted to Hospital on 2/15/21 with Covid like symptoms and decreased O2 sat. He tested positive for Covid 2/15/21. Treated with Remdesivir. Patient status continued to decline and he passed away in hospital 2/22/21 0612.	No prior vaccinations for this event.

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine	Influenza Vaccine

without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.

COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/13/21 Patient had covid like symptoms 2/15/21 Patient admitted to Hospital with covid like sx and decreased O2 sat; tested positive for Covid on 2/15/21; treated with Remdesivir and convalesent Plasma. Sx worsened and patient died 2/26/21..	No prior vaccinations for this event.
COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up	No prior vaccinations for this event.

revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and

underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

	COVID-19	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The same day that the person was vaccinated he started feeling dizzy and had difficulty breathing. He was hospitalized from February 5 to February 23. Patient died in the hospital on February 23, 2021		No prior vaccinations for this event.
	COVID-19 PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient developed Covid pneumonia dx 1/15/21, patient expired No prior vaccinations for this event.		
COVID-19 PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**	
Patient was hospitalized on 31 Jan for COVID pneumonia after 3 days of increasing baseline supplemental O2 requirements and dyspnea and ultimately died on comfort care on 3 Feb 2021.		No prior vaccinations for this event.
	COVID-19 PNEUMONIA	**COVID19 (COVID19**

	(MODERNA)) (1201)
Patient was vaccinated on 1/14/2021. On 1/22/2021, patient tested positive for COVID-19 and admitted to the hospital for acute hypoxemic respiratory failure, COVID-19 pneumonia, and severe ARDS. Patient was intubated on 1/23/2021 and later died on 2/10/2021 after being extubated and placed on comfort measures.	No prior vaccinations for this event.
COVID-19 PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due	No prior vaccinations for this event.

to Covid 19 pneumonia.

	COVID-19 PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Per family, patient has been feeling sick since he was vaccinated, patient went to ER on 02/15/2021, and after few hours at ER patient passed away.		No prior vaccinations for this event.

	COVID-19 PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Started feeling unwell; Headaches; Body aches; Chest pain; Didn't had wishes to eat; Diarrhea; COVID-19 pneumonia; A spontaneous report was received from a consumer concerning a 69-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced COVID-19 pneumonia, feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea The patient's medical history high blood pressure which was controlled with medication. Concomitant product use included nifedipine and fenofibrate. On 20-JAN-2021, approximately a week and a half or two prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number 030L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. A week and a half or two later the patient stated feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea for which patient was hospitalized on 06-FEB-2021. Since everything seemed to be fine the patient was discharged on an unknown date in FEB-2021 however, patient's family was not notified that it was a late reaction to the vaccine's first dose. Later, due to shortness of breath he was hospitalized again on 08-FEB-2021 and was diagnosed for pneumonia and was intubated on the same day. Due to COVID-19 situation patient's family could not be in the facilities and that there wasn't any follow up of the patient given to the family, so family did not have much information. During the first hospitalization(06-FEB-2021) the patient had a blood test which showed a normal result and was tested for COVID-19 and Influenza, both were negative. During second hospitalization (08-FEB-2021) the hospital said that the patient was stable. The patient's family did not know the results of the tests conducted at		No prior vaccinations for this event.

the time. The action taken with the vaccine in response to the events is not applicable. The outcome of COVID-19 pneumonia was fatal. The patient died on 14 Feb 2021 The cause of death was reported as COVID-19 related pneumonia. The autopsy was not done.; Reporter's Comments: Very limited information regarding this event has been provided at this time. The cause of death was reported as COVID-19 related pneumonia. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the events are assessed as unlikely related. Further information has been requested.; Reported Cause(s) of Death: COVID-19 pneumonia		
COVID-19 PNEUMONIA		**COVID19 (COVID19 (MODERNA)) (1201)**
1-25-2021- Phone call: pt had cold and cough prior to vaccine. cough worsened 1-28-2021 Phone call: pt requesting provider visit, cough is same and taking tessalon pearls 1-29-2021 Provider in office visit: pt complain of cough and SOB for 6 days. Getting worse. Temp 101.2, pulse ox 87%, BP 128/70. level of distress- leaning forward to breath. appeared ill. diffuse rales throughout both lung fields, more at bases. Diagnosis Pneumonia due to COVID 19 virus. Sent to ER		No prior vaccinations for this event.
COVID-19 PNEUMONIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away		No prior vaccinations for this event.
COVID-19 PNEUMONIA		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

No prior vaccinations for this event.

COVID-19 PNEUMONIA

COVID19 (COVID19 (PFIZER-BIONTECH))
(1200)

Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I

No prior vaccinations for

(person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.	this event.
COVID-19 PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient tested Covid positive, cough, low oxygen levels, COVID Pneumonia, patient is now deceased	No prior vaccinations for this event.
COVID-19 PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021.	No prior vaccinations for this event.

COVID-19 PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident vaccinated-1/7/21 Resident covid positive 1/11/21 Resident covid PNA-1/12/21 Resident hospitalized 1/16/21 Resident deceased 1/20/21	No prior vaccinations for this event.
COVID-19 PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
According to medical report, Pt presented to the ED on 1/14/21 w/ cc of SOB for 1 day. She received her COVID-19 vaccine on 1/9/21. Pt stated that she developed a dry hacking cough 2 days prior to the vaccine on 1/7/21. Over the last few days prior to admission, she developed generalized weakness, SOB, loss of sense of taste and smell w/ associated decreased appetite and nausea ultimately SOB in the24 hours prior to admission. Final Diagnosis- acute hypoxic respiratory failure secondary to COVID-19 pneumonia. Pt died on 2/3/21. See Medical report for more information.	No prior vaccinations for this event.
COVID-19 PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt with acute resp failure, COVID PNA, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior toa admit, then shortly after progressed with other covid symptoms and was admitted. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. Pt passed soon after(2/2).	No prior vaccinations for this event.

COVID-19 PNEUMONIA	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Pt passed soon after; shortly after progressed with other covid symptoms and was admitted / acute resp failure, COVID pneumonia; acute resp failure, COVID pneumonia; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; This is a spontaneous report from a non-contactable Pharmacist. A 76-years-old non-pregnant female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE lot number EL3247), intramuscular on 19Jan2021 at single dose for COVID-19 immunisation. The patient medical history included COVID symptoms from 16Jan2021 and ongoing. Concomitant medications were not reported. The patient with acute resp failure, COVID pneumonia, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior to a admit, then shortly after progressed with other covid symptoms and was admitted on 25Jan2021. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. The patient died on 02Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events death, COVID-19 pneumonia, acute respiratory failure, hypotension, abdominal wall haematoma and abdominal wall haemorrhage cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators,	No prior vaccinations for this event.

as appropriate.; Reported Cause(s) of Death: Pt passed soon after

COVID-19 PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO WITHDRAWL EXTRME MEASURES	No prior vaccinations for this event.

COVID-19 PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she	No prior vaccinations for this event.

contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased		
CRANIOCEREBRAL INJURY		**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine given in clinic per protocol - patient monitored for 15 minutes, no adverse reactions noted at the time. Patient stated he felt fine following 15 minute monitoring time. Patient left facility- it was later reported that pt had a fall at home. Upon review of pt's medical record - Pt's wife had to initiate CPR and call EMS for transportation and life saving measures enroute to the Emergency Room. Pt was intubated as pt was in asystole upon arrival to the ER, ACLS was continued, pt was noted to have a traumatic brain injury from his fall at home, and pt was pronounced dead at 1620.		No prior vaccinations for this event.
CRANIOCEREBRAL INJURY		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the		No prior vaccinations for this event.

same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."

CRANIOTOMY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - anuerism lead to death approximately 14 hours after initial symptoms.	No prior vaccinations for this event.
CREATINE URINE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right

No prior vaccinations for this event.

middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

CREPITATIONS	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second dose of COVID vaccine on 01/20/2021 at 1430. At 1600 Pt developed a wet productive cough with coarse crackles. Pt ate dinner at 5 pm cough persisted. At 18:30 the nurse went to Pt's room to give him his medications. Pt still had a cough, denied shortness of breath. Pt was in a good mood and joking with staff. Pt asked to be shaved. At 19:45 Pt was sitting in the lounge and a CNA noticed that Pt was pale/white in color and clammy. 02 Sat was 85%. Respirations were labored. Pt was placed on 4 L of 02. Increased to 5 L via face mask and 02 sat was 89-90%. Ambulance was called at unknown time. Pt arrived at Medical Center at 2120 and was pronounced dead at 2127.	No prior vaccinations for this event.

CREPITATIONS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9.	Influenza Virus Vaccines - Unknown date/type or brand

Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.

CREPITATIONS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
He started vomiting 2 days later. we suspect he was having stool issues as well. he vomited blood at some point over the weekend. there was black vomit right before he passed. from 2am-6am he was wheezing and rattling and then he passed at approximately 6am 3/1/2021 at home. EMS did come and try to revive him and were unsuccessful.	No prior vaccinations for this event.
CRYSTAL URINE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency	No prior vaccinations for this event.

room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

CRYSTAL URINE PRESENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to

No prior vaccinations for this event.

make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

CSF GLUCOSE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration

No prior vaccinations for this event.

CSF PROTEIN INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration		No prior vaccinations for this event.
CULTURE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM		No prior vaccinations for this event.
CULTURE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic		No prior vaccinations for this event.

steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice, memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200 mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation: tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed, metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not

detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral patchy opacities

CULTURE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
resident expired; This is a spontaneous report from a contactable healthcare professional. An 82-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot	No prior vaccinations for

number: EL0140), intramuscular in the left arm on 05Jan2021 15:00 at a single dose for COVID-19 immunization. Medical history included metabolic encephalopathy from, failure to thrive (FTT), diabetes mellitus (DM) 2 , chronic obstructive pulmonary disease (COPD), arthritis, weakness, hyperlipidemia, chronic kidney disease (CKD), dementia. Known allergies was none. The patient took unspecified concomitant medication. On 11Jan2021, the resident expired. The patient underwent lab tests and procedures which included nasal swab: negative on 09Jan2021. There was no treatment given for the event. The patient died on 11Jan2021. An autopsy was not performed.; Sender's Comments: Lacking information on the cause of patient's demise, the Company cannot completely exclude a causal relationship between COVID 19 vaccine, BNT162B2, and patient's death of unknown cause, as a cautionary measure and for reporting purposes. The patient's pre-existing medical condition of metabolic encephalopathy from, failure to thrive (FTT), diabetes mellitus (DM) 2 , chronic obstructive pulmonary disease (COPD), arthritis, weakness, hyperlipidemia, chronic kidney disease (CKD), dementia may have provided the contribution to the event in this 82-year-old male patient. The impacts of this report on the benefit/risk profile of the product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: resident expired

this event.

CULTURE NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

emesis bright yellow in color, liquid BM, increased respirations No prior vaccinations for this event.

CULTURE NEGATIVE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-

No prior vaccinations for this event.

19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

CULTURE THROAT NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
CULTURE TISSUE SPECIMEN	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received COVID-19 (Moderna) vaccine from the Health Department on afternoon of January 8, 2021	No prior vaccinations for

and went to sleep approximately 2300 that night. Was found unresponsive in bed the following morning and pronounced dead at 1336 on January 9, 2021

this event.

CULTURE URINE

COVID19 (COVID19 (MODERNA)) (1201)

ON 1/14/2021 TYPICAL UTI SYMPTOMS FOR RESIDENT DEVELOPED INCLUDING FEVER AND RIGIDITY. RESIDENT IS NON-VERBAL. IV ANTIBIOTICS WERE STARTED. FREQUENT UTI'S ARE COMMON FOR THIS RESIDENT.

No prior vaccinations for this event.

CULTURE URINE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Fever, Malaise No prior vaccinations for this event.

CULTURE URINE COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency

No prior vaccinations for this event.

room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

CULTURE URINE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.	No prior vaccinations for this event.

CULTURE URINE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored	No prior vaccinations for this event.

respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

CULTURE URINE NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi

No prior vaccinations for this event.

and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse	
CULTURE URINE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.	No prior vaccinations for this event.
CULTURE URINE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on	No prior vaccinations for this event.

vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

CULTURE URINE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21	No prior vaccinations for this event.

CULTURE URINE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was noted on 1/25 with an increased functional decline as she would not feed herself with utensils, but would eat finger foods if placed in her hand. She was started on Rocephin IM for possible infections. Labs had been obtained on 1/21/21, unremarkable for CBC and CMP. 75,000 colony count on	No prior vaccinations for this event.

urine. On 1/26/21 she was noted with right sided weakness and further decline. She was sent to Hospital for further evaluation. We were notified that she expired on 1/28/2021. Resident had been noted with a decline in function about 2 weeks earlier when she would not stand or transfer any longer. She was still responsive, taking meds, and feeding herself until 1/26/21. Further information on admitting diagnoses and progress notes from hospital have not been available to date.

CULTURE URINE NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19	No prior vaccinations for this event.

vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

CULTURE URINE POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1 fall after first dose on 1/8/2021 at 1930; no injuries; 4 falls after second dose on 1/14/21 at 1545, 1/15/21 at 1700, 1/21/21/at 1220 and 1/21/21 at 1330 all falls with no injuries. Started Ceftriaxone 1 GM IM daily for 5 dyas on 1/21/21 for UTI: E. Coli	No prior vaccinations for this event.

CULTURE URINE POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.

CULTURE WOUND NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21-	No prior vaccinations for this event.

WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse

	CYANOSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless and breathless and was pronounced. Autopsy currently pending.		No prior vaccinations for this event.

	CYANOSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient went home around 11 am on 1-31-21 after her vaccine and 15 minute observation period. She was eating breakfast after at home and complained to a neighbor that her teeth hurt and she was nauseated after eating. In the afternoon, she felt dizzy and had diarrhea accompanied with blood. Close to 9 PM, her son went to check on her. The patient was found on the floor--she was unresponsive and had purple lips. Her son called an ambulance and started chest compressions. The patient passed away at the hospital. The doctor has ordered an autopsy, and the results are pending.		No prior vaccinations for this event.

CYANOSIS		**COVID19 (COVID19 (MODERNA)) (1201)**
Admitted to hospital with sob upon exertion that started prior to vaccine. Hx COPD, HTN, CKD, hyperlipidemia, bladder cancer in remission. Stated he has been taking Eliquis and Xarelto between renal doctor and cardiologist Dr. Anticipating going home 2/5/21 but then turned blue and stopped breathing under a DNR. COVID test negative. Labs show acute on chronic renal failure with an elevated troponin likely from demand ischemia.		No prior vaccinations for this event.
CYANOSIS		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had no reaction at the clinic. Patient is a medical doctor whose partner called in this death. States patient had no complaint on 1/13 nor 1/14 while at work. States patient died at home on 1/15 a.m. Physician who stated she was called to the patient's home @ 0157 1/15/2021 and found cyanotic from head to toe. State girlfriend found him sitting in the chair a few minutes before they called her. The Coroner did not order autopsy. Did not sent patient to the hospital. Sent him directly Funeral Home. Death Certificate Number 123-2021-002593 list cause of death as pending. I spoke with the patient's primary doctor who gave me the history of HTN, Diabetes, & High Cholesterol. States he had not seen this patient since April 2020. They were also friends and he was not aware of any medical problems. The Coroner state she thinks patient has a heart attack. Neither the Coroner nor PMD think death was related to COVID Vaccine. Informed both that MSDH would have to complete VAERS. Both voiced understanding.		No prior vaccinations for this event.
CYANOSIS		**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair		No prior vaccinations for this event.

with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.

CYANOSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient discovered unresponsive in cell, blue coloration to skin, vital signs, undetectable. CPR initiated, Ambulance summoned. Following EMS arrival with additional unsuccessful attempts to revive patient, patient was determined to have expired.	No prior vaccinations for this event.
CYANOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Had no immediate issues with the vaccine. He had returned from the hospital on 12/21 and had some concerns about his weight which were shared with his physician on 1/4/21. On 1/5/21 had a visit with his cardiologist for a pacemaker check. On 1/8/21 staff were called to his room, he was on the floor, bluish skin color. No vital signs found, no heart rhythm heard at 2200.	No prior vaccinations for this event.
CYANOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any	No prior vaccinations for this event.

symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.

CYANOSIS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER

No prior vaccinations for this event.

trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

CYANOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2	No prior vaccinations for this event.

high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good

recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

CYSTATIN C INCREASED	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"	No prior vaccinations for this event.

CYTOKINE RELEASE SYNDROME	COVID19 (COVID19 (MODERNA)) (1201)
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.	No prior vaccinations for this event.

DEATH	COVID19 (COVID19 (MODERNA)) (1201)
Patient had mild hypotension, decreased oral intake, somnolence starting 3 days after vaccination and	No prior vaccinations for

death 5 days after administration. He did have advanced dementia and was hospice eligible based on history of aspiration pneumonia. this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

My grandmother died a few hours after receiving the moderna covid vaccine booster 1. While I don?t expect that the events are related, the treating hospital did not acknowledge this and I wanted to be sure a report was made. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident in our long term care facility who received first dose of Moderna COVID-19 Vaccine on 12/22/2020, only documented side effect was mild fatigue after receiving. She passed away on 12/27/2020 of natural causes per report. Has previously been in & out of hospice care, resided in nursing home for 9+ years, elderly with dementia. Due to proximity of vaccination we felt we should report the death, even though it is not believed to be related. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient died within 12 hours of receiving the vaccine. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

After vaccination, patient tested positive for COVID-19. Patient was very ill and had numerous chronic health issues prior to vaccination. Facility had a number of patients who had already tested positive for COVID-19. Vaccination continued in an effort to prevent this patient from contracting the virus or to mitigate his risk. This No prior vaccinations for this event.

was unsuccessful and patient died.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

At the time of vaccination, there was an outbreak of residents who had already tested positive for COVID 19 at the nursing home where patient was a resident. About a week later, patient tested positive for COVID 19. She had a number of chronic, underlying health conditions. The vaccine did not have enough time to prevent COVID 19. There is no evidence that the vaccination caused patient's death. It simply didn't have time to save her life. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Prior to the administration of the COVID 19 vaccine, the nursing home had an outbreak of COVID-19. Patient was vaccinated and about a week later she tested positive for COVID-19. She had underlying thyroid and diabetes disease. She died as a result of COVID-19 and her underlying health conditions and not as a result of the vaccine. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

1/1/2020: Residents was found unresponsive. Pronounced deceased at 6:02pm No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Two days post vaccine patient went into cardiac arrest and passed away. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

syncopal episode - arrested - CPR - death No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Redness and warmth with edema to right side of neck and under chin. Resident was on Hospice services and expired on 1.1.21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Found deceased in her home, unknown cause, 6 days after vaccine. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

DEATH ON 1/4/2021, RESIDENT RECIEVED VACCINE ON 1/2/20 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident had body aches, a low O2 sat and had chills starting on 12/30/20. He had stated that they had slightly improved. On 1/1/21 he sustained a fall with a diagnosis of a displaced hip fracture. On 1/2/21 during the NOC shift his O2 sat dropped again. He later went unresponsive and passed away. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient was vaccinated Dec 30, 2020. Prime dose of Moderna vaccine. Observed for full 15 minutes post-injection. No complaints when asked during observation. Released. Subsequently, vaccine clinic staff learned No prior vaccinations for this event.

from the patient's supervisor that on Jan 4, 2021 that the patient had expired on Jan 2, 2021. By report from the supervisor, the patient was found dead at his home. The patient's primary care provider was unaware of his death when contacted by this reporter today (Jan 6, 2021). Electronic Medical Record without any information since the vaccination.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

resident expired 1/1/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident expired 1/3/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

At approximately, 1855, I was alerted by caregiver, resident was not responding. Per caregiver, she was doing her rounds and found resident in bed, unresponsive, mouth open, observed gurgling noises and tongue hanging out of mouth. This primary caregiver observed resident at baseline and ambulating after dinner at approximately, 1800 less than an hour prior to incident. This PCG called 911 for EMS and gave report of incident. Resident was taken to Medical Center Emergency Department. At ER, CT scan and X-ray was performed. Per report from ER RN, CT scan and x-ray revealed an intracranial aneurysm and fluid in the lungs. Per RN, resident was still unresponsive and was admitted to Medical Center for observation and comfort measures. This primary caregiver reported to RN, resident recently received the first dose of COVID-19 vaccine on 1/2/21. Primary caregiver received a call from Castle RN at 0700, resident expired at 0615.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Deceased No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

Patient did not report any signs or symptoms of adverse reaction to vaccine. Patient suffered from several comorbidities (diabetes and renal insufficiency). Patient reported not feeling well 01/06/2021 and passed away that day.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Resident passed away in her sleep No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

Patient had been diagnosed with COVID-19 on Dec. 11th, 2020. Symptoms were thought to have started on 12/5/2020. Received Moderna vaccine on 12/23. Unexpected death on 1/8/2021. Resuscitation attempts unsuccessful

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

The patient was found deceased at home about 24 hours after immunization. Date of Death:: 12/29/2020; estimated time of death 6:00pm

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient received vaccine on 1/4/2021. He was in Hospice for CHF and renal failure, but was able to get up in his wheelchair and eat and take medications and talk. On 1/5/2021 am, he was noted to be very lethargic an could only mumble, could not swallow. No localizing neurologic findings. He was too lethargic to get up in chair.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Notified today that he passed away. No other details known at this time. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

Patient received COVID vaccination around 12:15pm. Patient was monitored for the appropriate amount of time by nursing staff. Patient passed away at 2:15pm.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19

	(MODERNA)) (1201)
"1-2-2021 10:30 PM Complained Right arm/back hurt - took Tylenol 1-3-2021 Complained Right arm hurt, dizzy 1-4-2021 Felt better - did laundry, daughter found her deceased at 3:30 pm. Dr. at hospital said it was ""cardiac event"" according to death certificate."	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Staff reported that patient was found Friday morning (Jan 8) sitting at a table with his head tilted forward and unresponsive to verbal or physical stimuli. Staff lowered patient to floor and started CPR. EMS was called and continued CPR at scene, however they were not able to revive patient. Patient was pronounced dead at the scene. Staff written statements following the death of patient show that he had a fall about 1 hr. prior. It is unknown if this fall contributed to patient's death. An autopsy has been requested.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
The resident resides in an independent living facility/apartment. The reporter at the center was informed by his daughter he was not feeling well on 1/1/2021 (specific symptoms could not be ascertained). He reportedly went to be COVID tested on 1/1/2020 and observed to be deceased in his apartment on 1/2/2020. I do not have confirmation of his COVID results, although the reporter indicates his daughter reports his test was positive.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received COVID-19 (Moderna) vaccine from the Health Department on afternoon of January 8, 2021 and went to sleep approximately 2300 that night. Was found unresponsive in bed the following morning and	No prior vaccinations for

pronounced dead at 1336 on January 9, 2021		this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was reported to be deceased at home by law enforcement on 1/7/21 No prior vaccinations for this event.		
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the 1st dose of Moderna and was found deceased in her home the next day.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the vaccine on 12/22/20 without complication. It was reported today that the patient was found unresponsive and subsequently expired at home on 1/11/21.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
The facility had positive cases of COVID when we were able to begin vaccinating residents. Within about a week of vaccination, patient was tested positive for COVID. He was 91 years old and his immune system did not have the time to allow the vaccine to begin working before exposure. His age was a major contributing factor to his death.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**

Pt expired due to possible cardiac arrest. Unsure if this was vaccine related. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient reported expired 1/7/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient vaccinated on 12/28. Approximately one day later, develops cough and on azithromycin x 1 week. On 1/3, patient develops left-sided weakness and aphasia. Taken to the hospital, tested COVID+, required intubation -- acute hypoxic respiratory failure secondary to COVID - on H&P. Patient died on 1/4/21 at 7:20am. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient received her vaccination on 1/12/21 administered by pharmacy*+. She expired on 1/12/21 an approximately 7:30pm. Resident did not have any adverse reactions and was a hospice patient. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

"Patient was found ""acting abnormal"" on 1/9/2021 at 1215. VS HR 20-30's. EMS activated. EMS arrived and patient was found pulseless in PEA/ asystole, CPR and ACLS initiated and then transported to the MC. Unsuccessful resuscitation and expired on 1/09/2021 at 1348. Clinical impression Cardiopulmonary arrest." No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Staff walked into resident's room around 10:00am and noted resident's left side of his face was flaccid. Nurse was called and upon assessment resident noted to have an unequal hand grasp with left worse. He was able to talk but was mumbled and hard to understand. Physician, hospice, and family were notified. Resident had a stroke at 10:06 am on 1/8/2020. He lost all ability to use his left side. Resident passed away on 1/11/2020. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

The patient passed away today, 1/13/2021. She was a hospice patient. She showed no adverse effects after receiving the vaccine on 1/12/2021. This morning she woke up as normal and during her morning shower she had a bowel movement, went limp and was non-responsive. The patient passed away at 7:45 am. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

This person was found to be deceased on routine rounds during the night, 3am. No symptoms of reaction noted post vaccine. No injection site reaction. No reports of any allergic reaction. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt collapsed at home approx 5:30 pm and died No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient died on 1/21-2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

51 year old M with h/o O2 dependent COPD, Severe pulmonary fibrosis became increasingly hypoxic around 1800hours 1/7/2021. He was transported to hospital for acute on chronic hypoxia respiratory failure. On 1/12/2021 he decompensated further, and after discussing with family and palliative care, He was changed to comfort care. He expired on 1/12/2021@2325 at medical center.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Resident received Moderna vaccine on 12/23/2020 around 5 pm. At approximately 3:35 am on 12/25/2020, resident had a CVA and died on 1/1/2021 at 3:00 am.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Accelerated decline in condition with decreased input, decreased responsiveness, somnolence, and death

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient had no immediate effects from the vaccine, but died approximately 8 hours after receiving first dose of vaccine.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Resident had lunch on 01/14/21 and after lunch around 2:00pm, he vomited and stopped breathing. We coded the resident and 911 paramedics came. They pronounced him dead at 2:18pm.

No prior vaccinations for this event.

DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Around 00:50am on 01/15/21, C.N.A. reported that the resident looked different and not responding. Initiated Code Blue and started CPR. 911 arrived and pronounced resident dead at 1:01 am.		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
This patient has been under hospice care for over 2 years at the nursing home. She has had a steady decline with gradual weight loss. She was totally dependent in her care needs. She received the vaccine on 1/2/2021 as part of the facility vaccination campaign. No adverse events noted initially. On 1/3/2021 at 6:06 pm, she was noted on vital sign checks (done every 4 hours for first 72 hours after vaccination) with BP 64/52 but otherwise asymptomatic. Subsequent BP improved. On 1/4/2021 at 4:45 am, pt found with respiratory rate of 30 with otherwise normal vital signs. Tachypnea persisted, so she received liquid morphine 2.5 mg without improvement. Supplemental oxygen was applied. Tachypnea persisted. She had poor oral intake after that point had persistent tachypnea and worsening hypoxemia despite clear lungs on exam. She remained under hospice care and comfort measures were continued. No blood testing or imaging tests were done. She required increasing amounts of oxygen, became hypotensive, and died peacefully on 1/8/2021 at 7:45 pm.		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
"On 1/15/2021 at 1800, resident noted to be lethargic and shaking, stating ""I don't care."" repeatedly. C/O head and neck pain. T100.6. Given Tylenol with no relief of pain. Order received for Aleve and administered.. Assisted to bed as usual in evening. Monitored during night shift and noted to be resting comfortably/sleeping.. Noted agonal breathing at 4:10 AM 1/16/2021 , T 99.4, Absence of vital signs at 4:15AM 1/16/21 and death pronounced at 4:40AM 1/16/21."		No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

""""Moderna COVID-19 Vaccine EUA"" It has been reported to me that pt. had gone into hospital for a heart catheterization on 1/12/2021. It was found during this procedure that pt. had suffered a MI. She was release to home the following day and passed away at her residence on 1/15/2021."

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Headache after dose was given at 10:00 a.m Died at after 7:30 pm the same night the dose was given.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

"Narrative: Patient with severe aphasia and only able to say ""hey, hey, hey"" or ""uh huh"" or shake his head no as a way to communicate. Patient previously able to ambulate with significant limp and hyperextension of right knee, but mostly wheelchair bound over last several years as he had had a slow and steady decline in overall health and mobility. Patient developed aggressive behavior of shouting ""hey"" and grabbing of groin in 2016. This was worked up with CT scans, labs, referral to urology, neurology, and referrals to psychiatry. The exact etiology of this action was never able to be affirmed, but thought to be more psychiatrically related. It improved significantly with addition of antipsychotics, worsened when antipsychotics were reduced, and improved again with addition of injectable antipsychotic on 12-10-2020.Patient suffered from falls on occasion given his significantly impaired physical mobility. His last documented fall was 8-31-2019. Patient began utilizing wheelchair most of time following that fall. No significant injuries noted in documentation of the falls. In the last 3 months, patient would often refuse medications. He would sometimes indicate that they would cause dizziness, and other times he would simply refuse. We attempted to hide medications in his food/fluid (with wife's blessing) and when he detected this he would occasionally refuse to eat. Patient previously on

No prior vaccinations for this event.

DOAC. After pharmacy review in 12/2020 it was recommended to discontinue this as no clear indication to continue use. He was high fall risk and would often refuse this medication as well since 10/2020. Noted to be in NSR on EKGs and decision made to discontinue the DOAC. Patient had no evidence of adverse effects noted after vaccination on December 28th. Patient seen by provider on the morning of his death (1/4/2021) with no noticeable significant change in health condition. Temperature 36.8Con January 4th at 19:45. During routine bedtime cares, patient suddenly collapsed and death was pronounced January 4, 2021 at 20:05. Autopsy was requested from next of kin and no autopsy was granted. Symptoms: & DEATH Treatment:"

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident expired 1/17/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Weakness, Low O2, death. Positive for COVID on 1/12/21, dies on 1/16/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient presented to our Emergency Department via EMS in full code status; asystole. Patient expired. Per No prior vaccinations

nursing, husband stated patient awoke this AM and reported pain in back between shoulders and in bilateral shoulders. Patient then went unresponsive and husband called EMS.	**DEATH**	**COVID19 (COVID19 (MODERNA)) (1201)** for this event.
Patient was living in a nursing home with positive cases when administered. His age and chronic condition was such that he did not have time after the vaccination to avoid exposure or develop immunity.	**DEATH**	**COVID19 (COVID19 (MODERNA)) (1201)** No prior vaccinations for this event.
Death	Hypersensitivity/ anaphylaxis to standard flu vaccine (egg containing) ~ 20 years ago. Of note, did tolerate FluBlok this past	
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**	
patient started to decline 1/10/2021, patient seen at facility by medical professional - patient deceased 1/13/2021		No prior vaccinations for this event.
On 1/13/2021, resident had sudden emesis. Immediately following emesis he was noted without a pulse and pronounced deceased. No acute symptoms noted prior to this episode. Resident does have a significant cardiac history.	**DEATH**	**COVID19 (COVID19 (MODERNA)) (1201)** No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19**

		(MODERNA)) (1201)
resident had a pressure ulcer to RT hip, was getting treatment on. Was scheduled to have wound debrided and wound vac applied on 1-19-2021. Appetite was poor, not wanting to get out of bed, and decline in alertness. Passed away on 1-16-2021		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient died 1 week after vaccination. According to family was having very rapid decline in status in recent weeks and they did not think related to vaccination.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Presented to Urgent Care for weakness and confusion, transferred to ED, patient had a cardiac arrest and was unable to be resuscitated		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19**

(MODERNA)) (1201)

Clients wife reported on 1/18/2021, that her husband died unexpectedly the day after receiving the COVID 19 vaccine. I called and spoke with her. She stated that the client had started experienced some tightness in his chest the evening of 1/11/2021. She stated that it was normal for him to have the tightness in his chest if he got stressed. She stated that she found him on the garage floor on 1/12/2021 at 2120. He was taken by ambulance to the hospital. She stated that the hospital told her that his COPD had caused him to go into arrythmia.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient received COVID 19 vaccine 01/14/2021. Patient died in his sleep 01/16/2021. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient died 4 days after immunization. Probably unrelated to immunization, as patient has been in poor health and was receiving hospice services. I have no details related to his illness or symptoms. Daughter is the HIPAA/emergency contact and will have all the information needed.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt passed away the day after the vaccine was given. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient received her first dose of the Moderna COVID-19 Vaccination on Saturday January 16th 2021 at approximately 12pm. She completed all necessary screening forms and was deemed to be at low risk for

No prior vaccinations

serious allergic reactions. She tolerated the vaccination well, and no complications or immediate adverse events occurred. She was observed for a full 15 mins per CDPHE/CDC guidelines and left the Clinic in stable condition after her observation period was complete. On the morning of Tuesday, January 19th, 2021, the patient was found unconscious and unresponsive by her husband. She was transferred by Ambulance to Hospital shortly thereafter. She was diagnosed with a brain bleed that was determined to be inoperable. She was transferred to other Hospital for higher level care. She was seen by neurosurgery and diagnosed with a ruptured aneurysm. She was treated in the ICU for 24 hours, at which point her team determined that the severity of her brain bleed would not respond to treatment. Supportive cares were withdrawn on Wednesday Jan 20th, and she passed away shortly thereafter.

for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

possibly got it at clinic, possibly who administered shot. Pts. daughter said the pts boyfriend denied any symptoms the whole day but that in the middle of the night the pt passed away.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Narrative: No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

"Called to schedule second vaccine and daughter reports that he died on01/19/2021 with ""COVID"""

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Pt received second dose of COVID vaccine on 01/20/2021 at 1430. At 1600 Pt developed a wet productive cough with coarse crackles. Pt ate dinner at 5 pm cough persisted. At 18:30 the nurse went to Pt's room to give him his medications. Pt still had a cough, denied shortness of breath. Pt was in a good mood and joking with staff. Pt asked to be shaved. At 19:45 Pt was sitting in the lounge and a CNA noticed that Pt was pale/white in color and clammy. 02 Sat was 85%. Respirations were labored. Pt was placed on 4 L of 02. Increased to 5 L via face mask and 02 sat was 89-90%. Ambulance was called at unknown time. Pt arrived at Medical Center at 2120 and was pronounced dead at 2127.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

No immediate reaction. Patient-reported deceased four days later on Jan. 19, 2021. As of this date cause of death is unknown to our clinic.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

unknown. Event occurred after leaving vaccination site No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Narrative: No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Narrative: Symptoms: & Cardiac Arrest; Death Treatment: EPINEPHRINE No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient diagnosed with COVID on January 9, 2021 after being exposed to family member that was under quarantine in the same household. Admitted to the hospital and was discharged on January 14, 2021 with home hospice. Patient passed away on January 18, 2021

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient passed away on 01/18/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient died unexpectedly 5 days after receiving vaccine (1/10/2021). No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient deceased on 01/17/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt died 4 days after vaccine, no known reaction to the vaccination No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Found deceased, presumed while exercising No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

1/13/21 pt came into clinic for vaccine. Had difficulty remembering age. Called me Mon. 1/18/21 stating she was sick. When asked what her sx were, she stated fatigue. She was well the night of the shot, Thur. and Fri.

No prior vaccinations for this event.

but became tired on Sat. and Sun. I went through other sx with her such as h/a, fever, n/v, muscle aches, weakness and she said she experienced none of those. I questioned her about eating and drinking and she said she ate and drank water. She seemed fine so I told her to call her doctor if she was worse or the fatigue persisted or call 911. She agreed. Two staff from clinic called her Mon. and Tues, (1/18 and 1/19). On Tues. she may have had sl slurred speech. She was found deceased on

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

began itching within 24 hours, within 5 days couldn't move on her own, by 6th day was having respiratory issues, by day 7 unresponsive, by day 8 dead

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient received her first dose of vaccine on Monday, January 18th. Two days later on Wednesday, January 18th, she retired to bed early. Later that night when her husband went to bed, he found her in the bed deceased. No other details of the event are know.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

We were alerted that the patient died at home. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Headache, pain in the injection site, threw up. A few hours later she died. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

"Patient is reported to have died at home, the day after his COVID test. Family member states that he did good the afternoon and evening after his COVID-19 injection, but that he started not feeling good the next day. The patient ""was having palpitations"". The family tried to convince him to go to the Emergency Room, but he refused. Patient died at home."

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

At 04:30 on 1/22/2021, facility was notified of employee death at home. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Died within 5 days of receiving vaccine. Exact cause and day unknown. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt passed away evening of 1/13 - unknown reason currently Narrative: No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

My dad got the Moderna Vaccine on Tuesday, January 12, 2021 in his left arm at the Mall injection site for the Health Department. He was told that the side effects could mean his arm hurting, tiredness, headache, and even a low grade fever. Additionally, the site informed us both (as I was with him to get the injection) that this was all normal and not to seek medical attention unless these symptoms last longer than 72 hours. That evening, my dad was experiencing all of those symptoms, and went to bed at 7pm. A little after 10am on Wednesday, January 13, 2021, when he awoke, my dad went to the bathroom vomiting. This was where he collapsed and went into cardiac arrest. Fire/Rescue was dispatched about 10:30am after my mom started

No prior vaccinations for this event.

CPR. County Fire Rescue EMTs and Paramedics continued CPR and other attempts at reviving him all the way to Hospital Emergency Department. He was pronounced dead at 12:14pm on Wednesday, January 13, 2021. We have no doubt my dad, following the instructions of the injection facility, thought he was just experiencing the side effects of the vaccine. He had no chance. Had this injection been done in the RIGHT arm, perhaps he could have recognized the arm numbness being that of an impending heart attack. We really miss Dad. He served this country with distinction for over 50 years, and we believe his country failed him.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

My mother died 12 hours after the vaccine was administered No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient received the Moderna Covid 19 vaccine on 1/23/2021 around 5:45pm wife called management today and reported that he had collapsed and passed away today around noon

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient obtained initial dose of Moderna vaccine on Thurday, Jan 14. No adverse effects reported during initial 15 minute post vaccine waiting period. Saturday morning (Jan 16), patient developed severe cough, labored breathing, and fever. Additionally patient mental status changed suddenly, became non-communicative (unable to speak, but would scream if she was touched). O2 status was irregular, dropping to 78. Sunday morning, EMT and then hospice was hospice called. Monday morning, after hospice emergency kit was initiated, patient passed away.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19**

(MODERNA)) (1201)

Found dead at home slumped on the floor; Loss of appetite; Body aches; Feverish; A spontaneous report was received from a physician, concerning a 65-years-old male patient, who received Moderna's COVID-19 Vaccine and experienced feverish, body aches, loss of appetite, and death. The patient's medical history, as provided by the reporter, included diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia. Concomitant medications reported included metformin, glimepiride, lisinopril, atorvastatin, aspirin, methimazole, propranolol, and cilostazol. On 05 Jan 2021, prior to the onset of events, the patient received the first of two planned doses of mRNA-1273 (lot number 037k20a) for COVID-19 infection prophylaxis. On an unknown date in Jan 2021, some time after receiving the vaccine, the patient was feeling feverish with body aches and loss of appetite. On 09 Jan 2021 at approximately 21:30, the patient was found dead at home slumped on the floor. According to the paramedics, the patient was dead longer than when his wife found him, and no resuscitation was performed. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events, feverish, body aches, loss of appetite, was considered resolved. The patient died on 09 Jan 2021. The cause of death was not reported. The reporter assessed the event, death, as not related to Moderna's COVID-19 Vaccine. The reporter did not provide assessment for the events, feverish and body aches, in relation to Moderna's COVID-19 Vaccine.; Reporter's Comments: This case concerns a 65 year old male patient with medical history of diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia, who experienced the serious unexpected event of death, non-serious unexpected event of loss of appetite, and non-serious expected events of fever and body pain. The event of death occurred 5 days after the first dose of mRNA-1273. The events of fever, body pain and loss of appetite occurred an unspecified period of time after the first dose of mRNA-1273. Very limited information regarding these events has been provided at this time. Based on temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Definitive causal association is confounded by age and medical history of diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and

No prior vaccinations for this event.

hypertriglyceridemia.

DEATH	COVID19 (COVID19 (MODERNA)) (1201)
death of unknown cause; Swelling on Right side of the neck and under chin; Warmth on right side of neck and under chin; Redness on right side of neck and under chin; A spontaneous report was received from a healthcare professional concerning an 89-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events of redness, warmth and swelling on right side of neck and under chin, and death of unknown cause. The patient's medical history included Alzheimer's and chronic obstructive pulmonary disease (COPD). No concomitant medications were reported. On 29 Dec 2020, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: Unknown) intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient experienced the events of redness, warmth and swelling on right side of neck and under chin. There was no indication that the patient was transferred out to hospital, which was unlikely because she was under hospice care. On 01 Jan 2021, the patient died due to an unknown cause of death. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2020. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns a 89-year-old, female subject with a medical history of Alzheimer's and chronic obstructive pulmonary disease (COPD) who experienced redness, warmth and swelling on R side of neck and under chin and expired from an unknown cause. The events of redness, warmth and swelling on R side of neck and under chin occurred 2 days after administration of the first and only dose of the mRNA-1273 vaccine and patient expired 4 days after mRNA-1273 vaccine administration. Lot # of the vaccine was not provided. De-challenge and re-challenge are not applicable. The events of redness, warmth and swelling on R side of neck and under chin are temporarily associated with the administration of the mRNA-1273 and thus, a causal relationship cannot be excluded. Due to limited information, the fatal outcome was considered unrelated to mRNA-1273 administration pending additional information. Fatal outcome is confounded by the patient's underlying condition and advanced age.; Reported	No prior vaccinations for this event.

Cause(s) of Death: Unknown cause of death

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient died. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Fever Feeling tired short of breath all night and morning after the vaccine My grandma had to be intubated and then passed away to a heart distress we think it was the vaccine because she was fine even with dialysis. When she got the vaccine it took hours and her health conditions changed.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Pt developed COVID-19 infection, symptoms starting 7 days after first dose was given. Patient was admitted to hospital on 1/21 after falling (secondary to weakness) and striking head on toilet. Patient expired due to respiratory complications of COVID on 1/25.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

"Pt. woke up the next morning after vaccination and ""didn't feel well"", described by wife as fatigue, no energy. At approximately 2 PM, he vomited. His wife checked on him at 4:20 PM and he wasn't breathing sitting in his chair. EMS squad was called but when they arrived he was asystole and mottling present. Did not start CPR since he was already gone too long. Pronounced by coroner on scene."

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient received vaccine on 1/20/2121, later that night husband found her slumped in chair, called EMS and patient was taken to Hospital where she died on 1/21/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident became lethargic and reports of blood coming from resident's nose and mouth on the morning of 1/13/21. Resident went out to ER for eval, and came back to facility with dx of pneumonia and recommendations for resident to be placed on hospice. Resident deceased on 1/14/21. Unknown if vaccine related, but with timeline of events I was advised to report this per medical director of facility, as well as Pharmacy who administered the vaccine. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient received covid vaccine and had a heart attack the next day and died No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Died about 24 hours later No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

"Patient was tested positive for Covid-19 on 12/9/20. Patient received Covid Vaccine on 1/21/21. Patient was observing for 15 minutes in treatment room by Nursing staff. Patient denied any signs/symptoms adverse effect: headache, dizziness & weakness, difficulty breathing, muscle pain, chills, nausea and vomiting, and No prior vaccinations for this event.

fever . Patient seated on treatment table appeared to be relaxed, respiration even and unlabored. Health teaching provided. Patient educated to report any changes in condition to staff immediately. Patient verbalized understanding and able to verbalize signs and symptoms and adverse effects to be aware of related vaccine. On 1/22/21: patient was seen by medical provider for ""altered behavior"". Per medical provider's documentation: ""Patient was fallen on 1/2/21 and was sent out to outside hospital on 1/4/21. CT head: no intracranial abnormality, age-related changes. Patient had labs (B12, RPR, folate) were within normal limit"". We did MMSE today: 22/30 score ""mild dementia"" On 1/23/20: ""Patient was inside his cell. He was walking towards cell door to obtain his breakfast, when custody witnessed him collapse and activated the alarm. Nursing staff arrived at cell front at 06:34 am and found the patient pulseless and unresponsive, and CPR was immediately initiated. AED was attached at 06:35 am and no shock advised. AMR then arrived and patient did not have ROSC, and was pronounced dead at 06:54 am."""

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

On the evening of 10JAN2021, patient experienced a low grade fever, decreased oxygen saturation of 38%, heart rate of 124, confusion. Patient received oxygen via face mask, morphine and ativan. By 11JAN2021, patient was no longer verbal, able to eat or communicate and was kept on comfort measure only. On the morning of 17JAN2021, the patient passed away.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

DEATH Narrative: No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Narrative: Symptoms: & DEATH DUE TO COVID 01/13/21 Treatment: No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident deceased on 1/26 at 445am. No signs ahead of time. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient received Moderna COVID vaccine on 12/30/2020 at a Pharmacy clinic where he was a resident. Nurses at the facility reported that he was responsive and showed no signs of any adverse effects until 1/2/2021 when he was observed slightly unresponsive and staring at the ceiling and trembling. He had a fever of 101F at this time. The facility ordered labs and a rapid COVID test (all of which came back normal) and started IV antibiotics. A few hours later, patient began bleeding from his eyes, nose, and mouth and was sent to the local ER. The patient refused being admitted to the ICU for possible sepsis/hemorrhage and died the following day on 1/3/2021. All healthcare professionals involved agreed that this was not likely due to the vaccine, but needed to be reported nonetheless.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient passed away 23 days after receiving COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

ON 1/21/2020 RESIDENT WAS EXPERINCING CHILLS AND LOOSE STOOLS. FOLLOWING THIS EPISODE BECAME UNRESPONSIVE, PALE, DIAPHORETIC AND BRADYCARDIC. PALLIATIVE CARE WAS PROVIDED. RESIDENT PASSED AWAY APPROX. 10 HOURS LATER.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

on 1/13/2021 at 3:40am Cliff called for assistance. He lost his balance and had fallen. Cliff refused vitals, refused emergency department, denied hitting his head. As the day progressed patient developed a headache, diarrhea, and vomiting. He again declined the offer for the emergency room. At supper time wife and staff found Cliff unresponsive, 911 was called and he was taken to the emergency department. The ER did a CT scan and found an acute subdural hematoma. Patient was placed on comfort cares and expired at 3pm on 01/14/2021. Cliff did not have a history of falls.

Influenza vaccine 10/06/2020, age 88, fever, chills, vomiting, malaise

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

CARDIAC ARREST THAT LEAD TO DEATH - IT WAS REPORTED BY EMS THAT THE PT HAD RECEIVED THE VACCINE ABOUT 30 MINS PRIOR. HE ARRIVED HOME, BECAME SHORT OF BREATH & COLLAPSED. 911 WAS CALLED AND HE WAS TRANSPORTED VIA EMS TO HOSPITAL (16:17) WHERE HE LATER EXPIRED (23:01).

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Resident was discovered deceased in his apartment on 1/23/2021. Family had No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident vaccinated on 01/06/21 she acquired COVID 19 on 01/10/2021. Resident had multiple co morbidities and was declining prior to the vaccine. Resident expired on 01/20/2021

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

VACCINE ADMINISTERED 01/06/21 ACQUIRED COVID 19 01/10/21 RESIDENT HAD MULTIPLE CO MORBIDITIES AND WAS DECLINING PRIOR TO VACCINE. RESIDENT EXPIRED ON 01/25/2021

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Pt deceased No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

death Narrative: No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident expired on january 21, 2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

ASYMPTOMATIC No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Notified by patient's sister on 1/26/2021 that patient died in his sleep on 1/25/2021. She did not know cause of death. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

about 20+ hours after vaccination resident was having hard time breathing, 911 was called. Resident coded multiple times at the facility after CPR she was taken to ICU. She coded again and was placed on life support. Due to her choice to not be on life support she passed on 11/26/2021. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

cough congestive heart failure death No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient has a history of advanced melanoma with brain metastasis. He developed seizure disorder as well and had some mild seizures at home over the prior month. He received the vaccine at 4pm and was monitored in the office for 15 minutes. He then went home with his daughter whom he lives with. He ate dinner with her and read until 8pm when he went to his room. She found him in his room at 9pm unresponsive with seizures. Hospice was alerted and recommend oral valium. He continued to be unresponsive and expired the following day at 7:30 pm. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient developed Covid pneumonia dx 1/15/21, patient expired No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident received the first dose of Moderna Vaccine on 01/12/2021 and Tested for COVID-19 on 01/12/2021. Resident tested positive on 01/13/2021. Resident was transferred to acute hospital on 01/19/2021 due to desaturation. Resident expired at Hospital on 01/24/2021.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient found dead in home the next morning. May or may not be connected to vaccination. Instructed to report it from our medical director and director of nursing.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient developed SOB but reported good O2Sats. Instructed on going to ER if worsening symptoms. Patient eventually expired on 1/22/21

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient recieved vaccine 1 of covid 19 i 1/19/2021. She felt poorly on 1/20/2021. She felt dizzy and fell at 3 AM on 1/23/2021. She felt poorly and did not know her son's name which was not normal. She went to ER on 1/24. She was assessed as not having fractures. She was going to be transferred to a skilled nursing facility. She was not having respiratory complaints. She was awaiting transfer when her O2 levels started dropping substantially. She declined aggressive intervention and she died within a few hours.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19**

(MODERNA)) (1201)

Not sure if it has to do with the COVID vaccine but her caregiver reported to me today (1/27/20201) that she passed away on 01/16/2021 from a pulmonary embolism that was 18 days after vaccine

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient went to hospital with COVID symptoms on 01/10/2021 and passed away on 01/22/2021

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Pt likely presented to vaccine appt with asymptomatic/early infection of COVID-19, as he presented 2 days post-vaccination and tested positive for COVID-19 on rapid and PCR test. He was hospitalized where he eventually died of complications from COVID-19 while in ICU. Date of death was 1/15/2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient died 3 days post Moderna vaccine. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Stroke, death No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

died 01/16/2021 No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to the Emergency Department complaining of chest pain, pale, cool diaphoretic, and hypotensive. The patient was discovered to have a large saddle pulmonary embolism, went into cardiac arrest and expired. Of note, the patient received her second Moderna COVID vaccine on 1/23, which would place her first one approximately 12/25 if she received them at the appropriate interval. This information is from the patient's daughter and the ED record, the information is not available in CAIR. Per the daughter, the patient started feeling ill on 1/21, improved on 1/25, and then acutely worsened on 1/27, resulting in the ED visit.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless and breathless and was pronounced. Autopsy currently pending.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

weakness and fallsNarrative: 95 yo male w/ a PMH significant for Afib, legal blindness, Hx of CVA, cognitive impairment, GERD, HTN, pseudogout, BPH, chronic knee infection, and DJD who received his first dose of the Moderna COVID-19 vaccine on 01/08/21. The pt's COVID-19 screening questionnaire prior to receiving

No prior vaccinations for this event.

the vaccine was negative. The pt presented to the ED on 01/13/21 for weakness and m PCR test on ultiple recent falls (since receiving his first dose of the COVID-19 vaccine). The pt's COVID-19 01/13/20 was positive and he was admitted. He was started on treatment with remdesivir + dexamethasone on 1/14. The pt initially required supplemental oxygen via low-flow NC, however his oxygen requirements increased to 100% NRB. On 01/16/21 his MPOA elected for hospice care. The pt passed on 01/17/21. Unclear if the COVID-19 vaccine attributed to the patient's hospitalization and eventual death, or whether these events occurred from COVID-19 itself, however this case is being reported the FDA since this vaccine is under an emergency use authorization (EUA).

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

resident was on hospice, chronically ill w dementia, COPD, HTN, failure to thrive, passed away 1/13/21. Not certain injection related as he was declining already. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient received COVID vaccine on 12/29/2020 and passed away on 1/23/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient died at hospital on j/16/2021 approximately 48 after receiving vaccination. Believe death related to fall at home prior to vaccination. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Worsening respiratory failure 1/20/2021 death 1/27/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Client's sister called crying and said the family just found out yesterday that Client had died some time last week. The last time any family talked to him was on the 19th of January, missed calls show on the phone on the 21st. His last internet search was sternum pain. . She will also call the Agency and report this. The vaccine isn't in Registery at this time, do I don't know the lot number but she said he was due back in one month. She said he was very healthy and ran triathalons.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient received COVID vaccine on 1/11/2021 and passed away on 1/25/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt presented to ER via EMS at 1556 3 days after receiving vaccine. pt was breathing approximately 50 times a minutes and o2 sats in the 70's upon arrival. NP decided to intubate, Rocuronium and Versed given. Pt became bradycardic and 1 amp of Atropine was given without improvement. No pulse felt, CPR started per ACLS protocol. 7 Epi's given. Time of death- 1632. After TOD pt was swabbed for COVID-19 and the results were positive.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

per recipient spouse - vaccine recipient became ill during the night of 1/21/21 or early morning of 1/22/21 and was deceased in the morning of 1/22/21.

No prior vaccinations for this event.

DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.		No prior vaccinations for this event.

DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Death Narrative: Patient had Parkinson's and advanced Dementia. He was on a palliative care unit and a DNR.		No prior vaccinations for this event.

DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**

Death Narrative: Patient with Severe Dementia and on Hospice for end of life care. No prior vaccinations for this event.

DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt started complaining of chest heaviness and shortness of breath on the afternoon of 1/21/21. EMS was called to the patients home and she was found to have an O2 sat in the 70's. She was admitted to hospital and found to have a proBNP of 5000. She tested negative for Covid-19. She was determined to be in acute-on-chronic heart failure and was referred for hospice care. She passed away on the evening of 1/24/21.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was feeling dizzy and under the weather after the vaccination. The following day he died in his sleep during a nap.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the vaccine on 12/29/20 and presented at the ER at the Hospital on 12/30/20 stating that he wasn't feeling well. It is stated that his health had declined over the past few weeks and currently on hospice. Visit was unremarkable. Patient stated that wanted to stop dialysis. Patient passed away on 01/02/2021.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face, increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family		No prior vaccinations for this event.

request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Extreme bouts of nausea first few days after vaccine. Estimated that patient died at home within 3-4 days after receiving the vaccine. Last phone call to daughter expressed extreme nausea and seemed to have altered mental status. Found dead by daughter on 01/04/2021.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident passed away at 8:15 am on 1/28/21-found to be without pulse/respirations/DNR order in place.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
My Mother was given the Covid Vaccine (1st Dose) on 12/28/2020. Later that night we received a call from	No prior vaccinations

the nursing facility that my Mother was having uncontrollable seizures and had to be transported to the nearby hospital. The ER doctor confirmed that my Mother had tested positive to Covid. She was treated for Covid and was on life support. A few days later we received a call that my Mother had a major stroke. She passed away on January 4, 2021 for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

REC'D CALL FROM PT'S SON, PT HAS BEEN ON HOSPICE CARE AND PASSED 1/26/21. DOES NOT BELIEVE THIS IS RELATED TO VACCINE ADMINISTRATION, BUT WANTED TO REPORT TO US. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Narrative: Symptoms: & death Treatment: No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

aspiration pneumonia/death No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

I helped facilitate scheduling for his COVID vaccine and received notification from his wife that he passed away unexpectedly this morning. She reported he had been experiencing a rheumatoid arthritis flare and was on steroids. His diabetes was not well controlled as a result. He did not have any reactions in the days immediately after the vaccine. No prior vaccinations for this event.

DEATH **COVID19 (COVID19**

(MODERNA)) (1201)

patient passed No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

Fever 101.1, unresponsive episode. Transferred to Hospital on 1/28. Diagnosis there was anemia and CHF, aware that he had vaccine day prior. Transfused with 2 units pRBC's. Transferred back to Nursing Home on 1/30 and passed away 0140 1/31/2021

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Vaccine given on 01-25-2021. Wife reported on 01-29-2021 that patient had a ran a fever on 01-26-2021, Was better on 01-27-2021. She found him dead when she came home work on the evening of 01-28-2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

got up in the night and stated that she couldn't breath, ambulance was called, pt expired in route to hospital. *relayed to me by Facility staff RN.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Per granddaughter's report, pt became very weak within hours of receiving the first dose of the Moderna COVID-19 vaccine and could not get out of bed the next morning without assistance, reported difficulty seeing, and did not recognize some family members. By Sunday, 1/31, pt was unable to be awakened, would

No prior vaccinations for this event.

not eat, and had low urinary output. Granddaughter reports that the morning of 2/1 he was awake and ate a small amount and seemed to be improving although still weak and unable to get out of bed. Granddaughter reported he died 2/1 around 10am in the morning.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient was found deceased at Nursing Home in his room 01/12/2021 at 5:25 AM. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident c/o nausea evening of 1/29 (nausea common for her post dialysis), had a large emesis at approx 2220, 0030 (unusual for resident to vomit)- received Zofran per order. Skin cool and damp, Blood sugar 147 (checked due to h/o diabetes and poor intake). At approx 230am Blood pressured checked and noted to be 52/29. Resident transferred to ER, intubated and transferred to higher level of care where she passed away on 1/30 at 736pm. Resident's medical notes indicated likely shock, cardiogenic in nature, sepsis (source unknown) along with a multitude of other co-morbidities that resident has.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

6 days after vaccine developed bloody diarrhea. Thought to have ischemic colitis but negative evaluation. became hypotensive bradycardic placed on ventilator. Subsequently was poorly responsive and eventually coded once more and succumbed

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

No adverse events reported post vaccine. 1 st dose on 1/11/21 by public health. Death 1/31/21

No prior vaccinations for this

Patient was on hospice for gradual decline. event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient's wife called the physician's office with increasing SOB. MD advised that the patient go to the ED. While dressing, the patient became unresponsive, 911 called. Patient expired in ED.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient complained to wife of not feeling well in evening after the vaccination and expired at home during the night.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
spoke with patient husband on Saturday 1/23 and he said that she had been in the hospital. that she had had a stroke, the MD's at the hospital told him that it was not contributed to the vaccine and that they were unsure even if the stroke had occurred prior to the vaccine or after. spoke with him again on 1-29 and he stated that she had passed away on 1/25/21	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Got vaccine on 1/15/21. He was tired right away, bedridden the next 3 days. He couldn't breathe so he was taken by ambulance on 1/18/21. He was in hospital for several days. put on remdesivir cocktail for 10 days.	No prior vaccinations for this event.	

Slowly getting worse and died in hospital on 1/30/21.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient went home around 11 am on 1-31-21 after her vaccine and 15 minute observation period. She was eating breakfast after at home and complained to a neighbor that her teeth hurt and she was nauseated after eating. In the afternoon, she felt dizzy and had diarrhea accompanied with blood. Close to 9 PM, her son went to check on her. The patient was found on the floor--she was unresponsive and had purple lips. Her son called an ambulance and started chest compressions. The patient passed away at the hospital. The doctor has ordered an autopsy, and the results are pending.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident received the vaccine on 1-22-21 and she was diagnosed with COVID-19 during routine testing on 1-28-21. She didn't have any symptoms except feeling weak and she had a decrease in her appetite. She already had a poor appetite prior. She died on 2-2-21.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
patient passed away 2 days after vaccine. patient had temperature, nausea, and vomiting after vaccine.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Death Narrative: Patient received the first COVID-19 dose on 12/23. Afterwards, patient complained of		No prior vaccinations

localized pain on L deltoid area where the vaccine was administered; his temperature was 98.1 F. On 12/26-27, staff reported that patient appeared more fatigued than usual and was shivering on 12/27, which seized after blanket was given. On 12/28, patient presented with fever (Tmax 100.2 F) and acetaminophen was administered for alleviation of fever. ADR was reported for the fever on 12/29. Patient continued to decline and was placed back on hospice care on 12/29; on 12/30. the symptoms reported on nursing note include erythema and pain on whole L arm. Lidocaine was applied. Patient's family and provider mutually agreed not to administer the second dose of vaccine. He continued to decline and was started on end-of-life care around 1/4 and passed on 1/20 1417.	for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Cardiac arrest; Pain on her upper right chest; Lot of pain in lower abdomen; Pain underneath arm; Thought it was muscle aches; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed upper right chest pain and underneath the arm, severe abdominal pain, muscle aches and cardiac arrest. The patient's medical history was not provided Concomitant product use was not provided by the reporter. On 14 Jan 2021, approximately five days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the arm for prophylaxis of COVID-19 infection. On 19 Jan 2021, the patient developed upper right chest pain and pain underneath the arm. They thought it was muscle aches. Sometime later, the patient developed a lot of pain in the lower abdomen. The called emergency services and an ambulance arrived but the patient then suffered cardiac arrest. Treatment for the event included tramadol. Action taken with mRNA-1273 in response to the events was not applicable due to the patient was died. The patient died on 19 Jan 2021. The cause of death was reported as cardiac arrest. Autopsy were not provided.; Reporter's Comments: Company Comment: This case concerns a 92-year-old female patient who experienced unexpected serious events of cardiac arrest, upper right chest pain and underneath the arm, severe abdominal pain, muscle aches. The event occurred 5 days after the administration of the first dose of the vaccine mRNA-1273 vaccine (Lot #: unknown, expiration date-unknown). Although a temporal association	No prior vaccinations for this event.

exist between the events and the administration of the vaccine, in the absence of critical details such as the patient's medical history, any diagnostic test or autopsy result, adequate evaluation and assessment cannot be established. Main field defaults to æpossibly related' for all events.; Reported Cause(s) of Death: Cardiac arrest

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

"Client came to nursing station about 2pm to report she ""was not feeling well"". Nurses took vital signs, then referred her to the vaccination clinic that was onsite. She was observed by vaccination team for a period of time. She reported shoulder pain radiating into shoulder blade in arm vaccine was received. Vaccination team offered ice pack to her, observed for a period of time, and released back to work. About 10pm that evening, she sent a text to another coworker that her pain was ""off the charts"" and that she had pain covering her whole left side of her body. She did not come to work in the morning and did not contact work. Well being check was performed at approximately 9am on 2/2/2021 and she was found dead in her home. 911 was immediately called and authorities took over the scene."

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Unknown. Was informed that the patient went to E/R on 1/25/21 (6 days after receiving vaccine. Died 1/29/21 (10 days after receiving vaccine).

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

"85 year old patient with multiple medical problems. PEA/asystolic arrest 5 days after receiving vaccine, hospitalized. Patient died on 2/1/2021. It is not clear whether the vaccine administration led to the patient's death or not. ""...healthcare professionals are encouraged to report any clinically significant or unexpected

No prior vaccinations for this event.

events (even if not certain the vaccine caused the event)"""

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Death on 1/17/21. Death certificate reports: Septic Shock, UTI, Pneumonia, Chronic Renal Failure

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

We were notified 02/02/2021 of patient's death. Unknown cause at this time. No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Rapid decline in health status, Elevated BP&P, posturing, loss of consciousness, Glasgow coma Scale 4 starting 2/1/2021, Deceased 2/3/21

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Resident passed away unexpectedly on 1/27/21 from presumed sudden cardiac death. No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Resident passed away unexpectedly on 01/19/21 after developing acute hypoxic respiratory failure on morning of 01/19/21. She was transferred to hospital via EMS where she was intubated, coded, and ultimately expired with uncertain underlying cause, potentially ACS.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient had no symptoms or adverse events until the next evening after shot (1/29/21) where daughter reported her having heart palpitations. Family told her to rest and did not seek medical attention. Saturday afternoon (1/30/2021), patient started experiencing labored breathing. Daughter called 911 and before the ambulance arrived, the patient's breathing became more and more shallow. Patient was taken to the local hospital and passed away Saturday evening around 5:30 pm.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Passed away yesterday, found deceased in her apartment; This spontaneous report was received from a consumer which refers to a 91-year-old female patient who received the Moderna COVID-19 vaccine (mRNA-1273) and next day the patient passed away. The patient's medical history was not provided. Concomitant medications were not reported. On 19 Jan 2021, the patient received her first of two planned doses of mRNA-1273 intramuscularly (Lot number: not provided) for prophylaxis of COVID-19 infection. On 20 Jan 2021, the patient passed away and she was found deceased in her apartment. No treatment medication was provided. Action taken with mRNA-1273 in response to the events was not applicable as the patient passed away. On 20 Jan 2021, the patient died, cause of death was unknown. Autopsy result was unknown. The reporter assessed the causality as related between the event and Moderna COVID-19 vaccine.; Reporter's Comments: This case concerns a 91-year old female patient. The medical history and concomitant medication is not provided. The patient experienced Death. The event occurred approximately one day after receiving their first of two planned doses of mRNA-1273 (Lot unknown). Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the onset of the event, a causal relationship cannot be excluded and the event is considered possibly related to the vaccine.; Reported Cause(s) of Death: Unknown Cause of Death

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

PATIENT WAS IN CLINIC FOR 1ST CLINIC. WAS DISCHARGED BEFORE OUR 2ND CLINIC. HE CAME BACK TO OBTAIN HIS 2ND SHOT. WE WENT OUT TO THE CAR GAVE SHOT. THE NEXT DAY TO MY KNOWLEDGE, HE STARTED CODING AT HOME. AMBULANCE WAS CALLED AND HE CONTINUED TO CODE. THE AMBULANCE CREW TRIED CPR FOR 30 MINS WITH NO LUCK. PATIENT PASSED 2-3-21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

spontaneous death, found unresponsive in cell after normal morning activities No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of the MCA territory (TPA not recommended). CTA did show distal L M1/M2 occulsion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient was seen at 0710 he was sleeping but at normal cognitive behavior Patient was again assessed at 0720 where he was noted to be unresponsive, BP 180/100s, HR 230s, he was a DNR therefore not CPR was administered. EMS arrived at facility patient was noted to be in full cardiac and respiratory arrest. Time of

No prior vaccinations for this event.

death 0735

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Client lives alone and had dinner at his home with family members after the 4:40 appointment. Client stated that in general he did not feel well but did not give any specific symptom. Family states they asked the client to go to the ER and the client refused. Family states they helped the client to his chair in the living room and then left to go home. Family states that the client was found in his bedroom the next morning at 7:54 a.m. deceased.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
CARDIAC ARREST, DEATH Narrative: The patient presents to the emergency department in cardiopulmonary arrest. CPR was continued upon arrival. The Combi tube was removed and an endotracheal tube was placed without complications. ROSC was obtained multiple times but the patient continued to go into PEA. The patient was seen in the emergency department by both critical care and Cardiology. EKG shows ST elevations, but the patient was unstable to go to catheterization. The patient had 1 episode of asystole. Despite best efforts and multiple attempts we were unable to resuscitate the patient. Time of death 1253 on 1/24/21.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
On 2/1/2021, the patients daughter, who claims is a nurse, reported this incident to me. She stated that the evening after the patient received the vaccine, she felt some mild injection site pain. The morning after, the patient reported severe abdominal pain, diarrhea and vomiting. The patients daughter then called her physician to report these symptoms and attributed them as an adverse reaction to the vaccine at that time.	No prior vaccinations for this event.

These symptoms were intermittent for one week and no other adverse reactions were noted. In the early morning hours of 1/27/2021, the patient was toileting and had expired while doing so. An ambulance was called and cause of death was not found. An autopsy was not performed.

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awake at 0300. When going into the room to get him ready for dialysis he was cold to touch, unresponsive other than to sound, and nonverbal. O2 sat was 67 via finger probe. Oxygen immediately initiated and a venturi mask retrieved and initiated. When unable to arouse him via sternal rub this RN called 911. Send to ED. Febrile 39.2 and hypotensive 58/43. Admitted. unknown after that as patient expired in hospital.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
"Death; A spontaneous report was received from a nurse concerning a 91-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and died two days later. The patient's medical history included dementia. Concomitant medications reported included paracetamol. On 21 Jan 2021, approximately two days prior to her death, the patient received the first of two planned doses of mRNA-1273, intramuscularly for prophylaxis of COVID-19 infection. On 23 Jan 2021, the patient died. The nurse reporting the event stated that the patient's death was considered as due to ""natural causes"" and that she was not aware of any new-onset symptoms of illness prior to the patient's death. The patient was described as ""fragile"" and was under hospice care at the time of her death. An autopsy was not performed. Action taken with the drug in response to the event is not applicable. The patient died on 23 Jan 2021. The cause of death was natural cause of death related to dementia. Autopsy was not performed.; Reporter's Comments: This case concerns a 91-years-old female patient, with medical history of dementia, who experienced a serious unexpected event of death. This event occurred 2 days after first dose of mRNA-1273, lot # unknown. At the time of death, the	No prior vaccinations for this event.

subject was very fragile and was in hospice care. Concomitant medication included Tylenol. Treatment details were not provided. The doctor considered that the death was due to natural causes. However, autopsy was not performed. Very limited information regarding this event has been provided at this time. Based on the limited information available, it is difficult to assess a cause and effect relationship. The benefit-risk relationship of Moderna's COVID-19 vaccine is not affected by this report.; Reported Cause(s) of Death: Natural cause of death related to dementia"

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene when EMS arrived. Autopsy showed a left temporal subdural hematoma. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Wife reported patient expired on 2/3/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Report of patient expired on 2/3/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

unresponsive Narrative: 74yo patient with pacemaker, type 2 DM, parkinson's and history of syncopal epsisodes presented to emergency dept on Jan 24th. He was observed and discharged on Jan 26th back to No prior vaccinations

the home where he continued to have cognitive decline and later passed away on 2/2/2021	**DEATH**	for this event. **COVID19 (COVID19 (MODERNA)) (1201)**
Nursing home called 911 for decline in condition. Patient transported to ER where she was admitted to inpatient care and expired 1/30 at 16:13	**DEATH**	No prior vaccinations for this event. **COVID19 (COVID19 (MODERNA)) (1201)**
chills 1 day after vaccine administration; found dead by family 1/18/2021 Narrative: Per patient family report, patient said the next day after vaccination that he didn't feel well because of chills. Patient was found dead at home by his family on January 18th. He was a 74yo man with castrate resistant prostate cancer and liver and bone metastases with rising PSA, status post intravenous chemotherapy 1/7/21	**DEATH**	No prior vaccinations for this event. **COVID19 (COVID19 (MODERNA)) (1201)**
"Significant other reported patient expired ""a week before 2nd vaccine was due""." No prior vaccinations for this event.	**DEATH**	**COVID19 (COVID19 (MODERNA)) (1201)**
We don't know what happened. 25 hours after the shot, he started gagging and stopped breathing. He was pronounced at OSF at 8:07pm after we took him off life support.	**DEATH**	No prior vaccinations for this event. **COVID19 (COVID19 (MODERNA)) (1201)**

Narrative: 89yo with type 2 DM, HT, pacemaker and prior COVID+ in Nov 2020. Shortly after administration of 2nd Covid vaccine, patient began to have increased cognitive decline and 2 days after he expired at the facility	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**

Pt. deceased. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Notes of the checks/events with resident: 18:36 2/2/21 Resident had no complaint of pain, swelling, redness or warmth to vaccine site. No signs and symptoms of fever, chills, tiredness or headache. T 97.2 02:50 2/3/2021 Resident received 2nd COVID vaccine. No complaint of pain, swelling, redness or warmth to vaccine site. No signs and symptoms of fever, chills, tiredness or headache. T 98.1 07:15 2/3/2021 Resident was observed not breathing. 911 was contacted along with the doctor. Resident was confirmed having passed away.	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**

2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.	No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

death- 2/1/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

death- 2/1/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

death- 2/2/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient died of a heart attack on 1/31/21, 2.5 weeks after vaccination No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient passed away within 60 days of receiving a COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

EARLY SUNDAY MORNING THE PATIENT BEGAN VOMITTING AND SHORT OF BREATH AND CHEST AND BACK PAIN. SHE CODED WHEN SHE GOT IN THE ER AND LATER PASSED AWAY THE MONDAY. DIAGNOSIS WAS PNEUMONIA AND HEART FAILURE PER STEP DAUGHTER. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient presented to emergency room on 2/1/2021 with a chief complaint of having a chronic headache and fatigue following receipt of the Moderna vaccine 10 days prior. Following examination by the physician, the patient was diagnosed with an acute subdural hematoma. The patient subsequently underwent decompressive surgery, however demonstrated worsening neurologic status over the next several days and ultimately expired on 2/4/2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient became immobile on 1/25/21 (4 days after receiving Moderna COVID-19 vaccine). He died on 1/27/21

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

pt was given vaccine on the afternoon of 01-29-2021. Pt was administered the moderna covid-19 shot into the deltoid muscle of this pt. Pt was observed and left pharmacy. on 2-6, pts daughter calls pharmacy, and says the night of 1-29, after recieveing the vaccine, her mother had a hemmorhagic stroke and passed away

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient passed away (Dead on Arrival on presentation to ER) on 02/03/2021 No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Brain aneurysm; Anaphylactic reaction; Collapsed; BP sky rocketed; Shortness of breath; A spontaneous report was received from a consumer concerning a 69-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced blood pressure skyrocketed, shortness of breath, loss of

No prior vaccinations for this event.

consciousness, massive anaphylactic reaction, and brain aneurysm. The patient's medical history, as provided by the reporter, included high blood pressure and arthritis. Products known to have been used by the patient, within two weeks prior to the event, included an antihypertensive. On 04 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. Twenty-two minutes later she had a massive anaphylactic reaction. She experienced shortness of breath, blood pressure skyrocketed, and loss of consciousness. She was taken to the emergency room. The patient had a brain aneurysm and never recovered. No treatment information was provided. The patient died on 04 Jan 2021. The cause of death was reported as brain aneurysm. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns a 69-year-old, female patient with a medical history of hypertension, who experienced fatal, serious, unexpected events of Anaphylactic reaction, hypertension, dyspnea, loss of consciousness and brain aneurysm. The events occurred 22 minutes after the first dose of mRNA-1273 was administered. No treatment information was provided. The patient never recovered and died. The cause of death was reported as brain aneurysm. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Additional information has been requested.; Reported Cause(s) of Death: Brain aneurysm

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient's son came to the vaccine clinic today 2/8/2021, stated that his father 2/24/1948 passed away the same day as the vaccine.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Received Covid vaccine in am. Last seen by family at 17:30 pm and observed to be well. About an hour later he collapsed, unresponsive. A 911 call was initiated at 18:29. Paramedics arrived to find the patient in cardiac

No prior vaccinations for this event.

arrest. CPR/ACLS was initiated, but resuscitation was unsuccessful. Pt. was transported to MC where he was pronounced dead at 19:32. There was no sing of an injection site reaction, nor of allergic reaction..

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident expired on 2/5/21 at 03:35pm, about 25 hours after second dose of vaccine. At breakfast, resident was spitting a lot of secretions, coughing up liquids from nose and phlegm, facial swelling, which were all symptoms that he was struggling with prior to both doses of COVID vaccine, but had increased more than prior incidences on 2/5/21. Gurgling noted in upper airways, hyscolamine given, bath given to loosen secretions, morphine given. Family notified and came into facility for compassionate care visit around 1300. 1400 HR was 3 and RR was 2, but increased back to 60 and 12 within 20 minutes. Then resident expired at 1535.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient passed away with in 60 days of receiving COVID vaccine series No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Cardiac arrest resulting in death on the third day post vaccine administration, 0224. Reported syncopal event post toileting. Rescue measures attempted but not successful. Time of death 0358, 02/06/2021.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient passed away within 60 days of receiving COVID vaccine series No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient passed away within 60 days of receiving COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Within a few days, my mother started reporting profound fatigue and shortness of breath while conducting routine household activities. She no longer had to energy for her daily exercise walks and became increasingly lethargic. She died in her sleep while taking an afternoon nap on Thursday, February 4th. I am highly concerned this could be a vaccine related.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient received his second dose of Moderna COVID vaccine on 2/6 at 12:40PM. Patient was observed for 15 minutes post-vaccination with no adverse events. On the evening of 2/6 (time unknown) the patient began to develop dry cough and fatigue. He was checked by a physician at that time (who was a family member). Patient continued to feel unwell into Sunday. His lungs were clear when checked Sunday afternoon (time unknown). At approximately 5:30pm on 2/7 the patient began experiencing sudden onset shortness of breath. A pulse ox was conducted at that time and it was 92%, and again shortly thereafter and it was 90% (as reported by family member). 9-1-1 was contacted at this time. CPR was initiated when he arrived at the emergency department, pulse ox was 60% (as reported by family member). The patient passed away shortly thereafter on 2/8/2021.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

Patient was hospitalized on 31 Jan for COVID pneumonia after 3 days of increasing baseline supplemental O2 requirements and dyspnea and ultimately died on comfort care on 3 Feb 2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

1-2 days after vaccine, pt developed weakness, fatigue, body aches, nausea, headache and poor appetite. Pt was admitted to the hospital on 2/5/21 and death occured on 2/6/21

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Vaccine was administered on 1/15/2021 and death occurred on 1/31/2021. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient received vaccine on 1/23/2021 and death occurred on 1/30/2021. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Death within 8 hours. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient found down at home with agonal respirations and per EMS asystole, received 2 rounds of epi at her house with return of spontaneous pulses, lost pulse again in route to ER and another round of epi was given, CPR in progress when arrived at hospital. Prior to this patient's husband states he heard her fall in the

No prior vaccinations for this event.

bathroom but did not immediately check on her as he states that this has happened before. He checked on her 10 min later and that's when he found her unconscious. Daughter called 911 and she began CPR. No previous complaints of headache, chest pain, back pain, fever or chills. Husband states patient was drinking that evening which is not unusual for her. Patient died at hospital.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

We were informed the patient passed away 2 days after receiving the vaccine. We do not have any details about what happened, we were informed by one of his employees. We have no knowledge that this had anything to do with the vaccination in any way.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

He had not been feeling well after his second Covid vaccination (on 01/23/2021) and was found unresponsive in his room at the nursing home (late evening on 02/02/2021). He was taken to a hospital where they did tests and he had pneumonia and kidney failure, but he was being transferred to a larger hospital when he arrested and died (02/03/2021)

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to

No prior vaccinations for this event.

asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident passed away in her sleep. No s/s of adverse events leading up to the residents death. Resident was previously declining- MD stated the vaccine had nothing to do with the death. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Family reported patient expired 1/31/2021. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient died 02/08/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

2/7/2021 at 0630, resident found in recliner without pulse or respirations. Resident had not been found to have any adverse reactions to the vaccine between the time of the vaccine on 2/4 until found deceased on 2/7. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

ON 02/08/2021 AROUND 0600 RESIDENTCOMPLAINED OF MOUTH PAIN AND RECEIVED OXYCODONE. DURING THE COURSE OF THE MORNING, RESIDENT EXHIBITED A FEW EPISODES OF LABORED/SHALLOW BREATHING AND SOB AT RESTING. 0XYGEN SATURATION RATE WAS 93-98% No prior vaccinations for this event.

ON ROOM AIR, LUNG SOUNDS CLEAR IN ALL LOBES AND PULSE AND TEMPERATURE WITHIN NORMAL RANGE. AS THE DAY PROGRESSED, VITAL SIGNS REMAINED STABLE BUT RESIDENT CONTINUED TO HAVE PERIODS OF SOB/LABORED BREATHING.FAMILY AND NURSE PRACTIONER UPDATED AND THE ORDER WAS RECEIVED TO SEND PATIENT TO MEDICAL CENTER ER FOR EVALUATION PER AMBULANCE. RESIDENT TRANSPORTED AT 1425. RESIDENT RETURNED FROM THE ER AT 1830 ON HOSPICE CARE WITH THE DIAGNOSIS OF: ACURE RESPIRATORY FAILURE WITH HYPOXIA AND END OF LIFE DECISION MAKING. RESIDENT WAS MADE COMFORTABLE AND MONITORED DURING THE NIGHT AND EXPIRED AT 0630 ON 02/09/2021.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

pt received vaccine on 2/3. early on 2/4 developed chest pain, dyspnea, and was seen in ED and diagnosed with acute exacerbation of CHF and NSTEMI type 2, and anemia. on 2/5 transfusion was started and pt developed worsening dyspnea and then PEA arrest. Pt achieved ROSC and was transferred to the cardiac intensive care unit where he required vasopressor support. he subsequently declined and died on 2/7

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient had Covid-19 in October of 2020. He recovered. He received the vaccination on 12/30/2020 with no complaints. On 01-05-2021 it was noted to he was incontinent of urine and bilateral lower extremity edema. Lab work was completed showed acute kidney injury. He had decreased blood pressure and oxygen saturations on 01-06-2021 He was admitted to the hospital with rapid progression of symptoms and suggested multi-system failure. He had a long cardiac history. On 01-14-2021 he passed away with a diagnosis of Cardiomyopathic CHF, A.Fib contributory.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19

(MODERNA)) (1201)

Pt was deceased when we came for second dose. COD unknown to pharmacy. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt was deceased when we came for second dose. COD unknown to pharmacy No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt was deceased when we came for second dose. COD unknown to pharmacy No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt was deceased when we came for second dose. COD unknown to pharmacy No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient received vaccination on 2/4. Patient's wife reported that he felt a slight soreness in his arm the day following the shot, but had no other symptoms. On 2/8 he passed away. Wife reports that it was related to his heart and they never made it to a hospital. The wife also reported that the patient had been in poor health prior to the vaccination No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

2/6/2021 stroke. 2/8/2021 he died No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

the following morning the patient became unresponsive while taking a shower, became asystolic and died despite about an hour of ACLS and 8 rounds of epi	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
The resident received his COVID-19 Moderna vaccination on 2/6/2021 2:11 pm and expired on 2/7/2021 at 6:04 am. There were no signs or symptoms of vaccination reaction leading up to death.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the Moderna COVID vaccine 1/28/21. He was tested for COVID 19 on 1/29/31. Results were received 1/30/21, at which time he was evaluated and found to be hypoxic with tachycardia. He was sent to the local ER and returned this same day. On 2/2/21, he was evaluated by the provider, who sent him to the emergency room with acute respiratory distress and poor O2 sats	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Given First Moderna covid vacc 1/19/2021. Doing well on multiple contacts from health care providers, then 2/5/2021 was driving, pulled over to the side of the road into a yard, got out of the car and told an observer that he could not breathe, collapsed face down in the snow, EMS called, unable to revive him.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported to be unresponsive on the morning after receiving his second dose of Moderna	No prior vaccinations for this	

COVID-19 vaccine. Patient had expired during the night.		event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Received Moderna covid vaccination 1/14/2021. 1/16/2021 received report of cough and difficulty breathing. Proceeded to hospital and was diagnosed Covid+ on testing. Continued to decline, died 1/31/2021.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Received Moderna #1 on 1/12/2021. 1/15/2021 developed worsening shortness of breath. Went to hospital and diagnosed with anemia, 4 negative fecal tests, neg EGD and colonoscopy. Discharged and readmitted (circumstances unknown for this episode) then readmitted a third time 1/20/2021 for shortness of breath. Diagnosed covid + at third hospitalization and continued to get worse. He died 1/23/2021.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
This is the patient who passed away 2d after his second COVID vaccine. Of note, the 2/8 telephone note makes it sound like he was hospitalized at time of death - that is incorrect. His daugther listed as EM contact works in the eye clinic here. He had mild illness, completed 10d isolation but missed his scheduled booster dose on 2/2 due to isolation. He was called on 2/5 when there was a booster visit cancellation and received his booster dose on that day. His daugther reported that he was doing fine and looking well on 2/7 AM, ate breakfast, shortly after stood up and just collapsed.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19**

(MODERNA)) (1201)

Patient received vaccine at Public Health Clinic. Patient ended up having a seizure 3 days later and ended up in the hospital. Found to have right lobe pneumonia and low depakote level. Patient noted to have multiple seizures at hospital, issues with stabilizing HR and BP, and passed away on 1/20/21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Passed away the morning of 2/9/21. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

"Patient sent to the ED or sudden onset of shortness of breath on 02/02/2021. Per documentation by the MD, the patient had COVID19 ""several weeks ago"" and the nursing facility felt like he had recovered. A rapid test done in the ED was negative. When the patient worsened and seemed to be following the same path as other COVID patients, a send out PCR test was done, which was positive. The patient worsened and passed away that same day (02/05/2021) I was not made aware that the patient had the vaccine on 01/21/2021 until Monday 02/08/2021."

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient had no reaction at the clinic. Patient is a medical doctor whose partner called in this death. States patient had no complaint on 1/13 nor 1/14 while at work. States patient died at home on 1/15 a.m. Physician who stated she was called to the patient's home @ 0157 1/15/2021 and found cyanotic from head to toe. State girlfriend found him sitting in the chair a few minutes before they called her. The Coroner did not order autopsy. Did not sent patient to the hospital. Sent him directly Funeral Home. Death Certificate Number 123-2021-002593 list cause of death as pending. I spoke with the patient's primary doctor who gave me the

No prior vaccinations for this event.

history of HTN, Diabetes, & High Cholesterol. States he had not seen this patient since April 2020. They were also friends and he was not aware of any medical problems. The Coroner state she thinks patient has a heart attack. Neither the Coroner nor PMD think death was related to COVID Vaccine. Informed both that MSDH would have to complete VAERS. Both voiced understanding.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

This resident of the assisted living facility received his Covid-19 Moderna (1st) vaccination and he has a leaking Aortic Aneurysm which resulted in hospitalization and he entered into Hospice care on 1.30.2021 and passed away on 1.30.2021.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient had passed since the first dose was given. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient had passed since the first dose was given. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient had passed since the first dose was given. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient had passed since the first dose was given. No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**	
Patient received first dose of Moderna COVID-19 vaccine on 2/3/21. Primary Care physician received call from coroner's office 2/8/21 asking for information contributing to cause of death. Per Primary Care Physician notes, wife states she and patient took turns shoveling snow on 2/4/21. On one trip back into the house she found him unresponsive on the floor and called 911. Paramedics were unable to revive patient and he passed away (2/4/21).		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Death; kidney failure (unable to urinate); shortness of breath; required oxygen; A spontaneous report was received from consumer concerning an 87-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced shortness of breath, kidney failure and death. The patient's medical history included advanced kidney and heart disease. No relevant concomitant medications were reported. On 06 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 17 Jan 2021, the husband reported that the patient experienced adverse events. Symptoms included shortness of breath and kidney failure (unable to urinate). The patient was admitted to the hospital and discharged to hospice. Oxygen was administrated for shortness of breath. Action taken with mRNA-1273 in response to the events was not applicable. On 20 Jan 2021, the patient died. The cause of death was unknown. Autopsy details were unknown.; Reporter's Comments: This case concerns a 87-year-old, female patient with the medical history of advanced kidney and heart disease, who experienced fatal unexpected event of dyspnea, renal failure and death. The events of dyspnea and renal failure occurred 12 days and the event of death occurred 15 days after the first dose of mRNA-1273 (Lot: unknown). The patient was admitted to the hospital and discharged to hospice. Oxygen was administrated for shortness of breath. The cause of death was unknown. Autopsy details were unknown. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.		No prior vaccinations for this event.

However, the history of advanced kidney and heart disease may remain as confounder. Additional information has been requested.; Reported Cause(s) of Death: Unknown cause of death

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away; Positive result; A spontaneous report was received from a consumer concerning a female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed COVID-19 and passed away. The patient's medical history was not provided. Concomitant product use was not reported. On 05 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 08 Jan 2021, the patient had a positive COVID-19 test. On 18 Jan 2021, the patient passed away. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 18 Jan 2021. The cause of death was not reported.; Reporter's Comments: This spontaneous report concerns a female patient who experienced COVID-19 and passed away. The event of COVID-19 occurred 4 days after the first and only dose of the mRNA-1273 vaccine administered and death occurred 14 days after administration of the mRNA-1273 vaccine. Based on the information provided and the known etiology of COVID-19, it is unlikely to be associated with mRNA-1273 vaccine administration. With no definite information on the clinical details of the death, it is difficult to adequately assess a causal association with mRNA vaccine. Main field defaults to æpossibly related'; Reported Cause(s) of Death: unknown cause of death	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
"The decedent experienced severe chest pain and dyspnea approximately nine days following the first series of the vaccine. He reported to family members that he was having a ""severe reaction"" to the vaccine and believed it was acute pericarditis due to the same symptoms he experienced prior. He reported that on 2/1/21 around 0300 hours, the symptoms were the most severe and he was going to seek medical attention, but did	No prior vaccinations for this event.

not. He waited till the convenient store opened and purchased OTC Tylenol for relief of symptoms. He continued to have dyspnea and chest pain up until 2/9/21, when he called 911 complaining of chest pain and was found to have a STEMI; subsequently died at Hospital in the ER."

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient died of cardiac arrest on 01/21/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021" No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt received the vaccine on 1/30/21 Pt reported symptoms of left armpit pain to wife on 2/7/21, went to work 4 am 2/8/21 and found face down, dead at work later that morning. Pt worked at a pet store, per wife he did complete his tasks and generally comes home by 7:30 am. Wife called when pt did not come back home and he was found dead. No prior vaccinations for this event.

DEATH **COVID19 (COVID19**

	(MODERNA)) (1201)
Patient was vaccinated on 1/14/2021. On 1/22/2021, patient tested positive for COVID-19 and admitted to the hospital for acute hypoxemic respiratory failure, COVID-19 pneumonia, and severe ARDS. Patient was intubated on 1/23/2021 and later died on 2/10/2021 after being extubated and placed on comfort measures.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
DIED WITHIN 5 DAYS OF RECEIEVING THE 2ND DOSE, EXPERIENCED GENERALIZED WEAKNESS.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt was administered Moderna Covid-19 Vaccine on 2/4/2021. Pt exhbited no symptoms of an adverse reaction of any sort. Pt was ambulating alert and attentive. Pt was observed for the alloted 15 mins by pharmacist and case worker who had escorted pt to vaccination clinic. It was reported that Either on sunday 2/7/2021 or monday 2/8/2021 pt had passed away. Circumstances revolving patient death is still unknown.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."	No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Moderna administered 02/01/21. Patient expired 02/10/2020 unexpectedly No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient passed away on February 5, 2021. There was no reaction after the shot was given, the patient's son said the death was not related to the vaccine. The patient had a bad case of shingles about a month prior to receiving the vaccine which the son said had been hard on the patient, the patient was also 90 years old. Per the son, the patient's doctor had wanted the patient to get the vaccine. Due to the close proximity of the date the vaccine was given and the date Patient passed away we wanted to complete the VAERS form.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient had the first Moderna Covid vaccine on Thursday 1/21/2021. She had a bit of sore arm on that day and the day after. On Saturday 1/23/2021, she had a fever of 100.5 F (11AM), nausea, light headache and chills. The temperature went down after she took ibuprofen. Patient's husband enrolled her to V-Safe to report all the adverse effects she experienced. On Sunday 1/24/2021, her temperature was 98.3F. She still had nausea and no appetite. She and her husband watched a football game in their bedroom upstairs. Husband noticed that his wife was pacing around the room many times. At 7Pm, Husband went downstairs for dinner but she refused to come down to eat. He went upstairs around 8pm, TV was still on. He turned off TV and went down stairs again thinking his wife felt as sleep while watching TV. He went back upstairs for bed around 10:30 PM. Husband said his wife had a deviated septum so she would snore very loudly when asleep. He didn?t hear her snoring so he went to check on her and found her not responsive. Husband called emergency services. Paramedic came at 10:45 and said patient was passed. Husband sent many texts to V-safe after that to report the incident. No response was received from V-safe. Patient?s doctor told her

No prior vaccinations for this event.

husband that she died due to cardiac arrest.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

DEATH ON 5TH DAY OF 2ND DOSE. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

covid shot 2/2; feel bad 2/5; covid positive diagnosis - 2/8 s/s cough, fever, shortness of breath , hypertension, afib (in er) - admitted went into DIC per intensivist 2/11 patient died

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt had passed away before second dose given. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt had passed away before second dose given. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt had passed away before second dose given. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Feb 8 states she had a cold. Feb 9 added stomach ache and nausea. Feb 9 visited urgent care facility for exam and Covid-19 test. Rapid test results were negative. Appeared tired but fine. Told to go home and rest.

No prior vaccinations for this event.

Feb 10 at 9:00 am found dead on the floor in pool of blood and aspirated. Excessive blood in toilet, pooled on floor and hallway rug.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient found by family in his home deceased on the morning of 02/10/2021. No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

No reported adverse reactions from 1st or 2nd vaccine doses Patient died on 2/6/2021 at Correctional facility- autopsy was performed at medical examiner's office. The COD was artherosclerotic cardiovascular disease

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient received vaccine on 2/5. We were told on 2/9 that the patient visited another emergency department on 2/6 but no information was given as to what prompted that visit. She was sent home. Daughter found her on 2/6 or 2/ 7 unresponsive and she died.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient received COVID19 vaccine at clinic at 11:52 am, discharge post treatment stable. Got home around 2:30 pm went to bed. He usually got tired post dialysis. He did not wake up at 6 pm. His wife went check on him. found patient cold and unresponsive. 911 pulseless PEA. ER Medical hospital. Pronounced death at 7:40 pm

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient expired on the morning of 2/11/2021. No known adverse events prior to death. Patient was observed for 20 to 25 minutes after administration of vaccine and reported experiencing no signs or symptoms of adverse events at that time.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

patient 6 hours post vaccination No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient experienced loss of taste and lack of appetite. Passed away on 1/23/21. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Received first 1/15/2021 with no adverse reaction. Received 2nd dose 2/9 @ 0846 with no adverse reaction or report of feeling ill. Traveled to store and arrived approx. 2 hours after receiving vaccine. Daughter stated patient felt well and had to go to the restroom to have BM. Collapsed in bathroom. Transported by ambulance to Hospital @ 1439 in cardiac arrest. Was in PEA and went in v fib back to PEA. Resuscitation efforts initiated and patient expired with time noted at hospital records at 15:11.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Resident expired 2/2/2021 one day after the vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident reviewed for incident. Resident received the second dose of the Moderna Covid-19 vaccine lot# 016M20A Exp 5/2/2021 on 2/5/2021 from clinic through pharmacy. Resident had her temp/O2 taken on AM shift and was 98.6/93%, beginning PM shift 98.4/95%. A few hours later noted that resident to have chills and was shaking RN assessment completed and vitals taken resident noted to have temp of 102.2, oxygen 95%, pulse 110. Resident alert and oriented at that time and talking to staff. Reported findings to APNP with order to send to ER. 911 called, residents brother updated. Upon EMT arrival RN went down to residents room with EMT and resident had an emesis as resident was getting cleaned up resident went unresponsive. Pulse noted to still be present at that time, resident did briefly respond to sternal rub and then went unresponsive again. Resident full code and EMT transferred to gurney and said that if they lost a pulse in route that they would transfer to hospital B instead of hospital A being the closest facility. RN called brother and gave update. Facility notified from Hospital that resident had passed away.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

resident had a stroke, sent to the hospital and died 4 days later No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident passed away this morning. No signs or symptoms prior to his death of an issue with the vaccine. He was an end stage dementia resident at the nursing home.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

The patient reported feeling well. I discussed with him the Covid-19 vaccine and he was able to state that he wanted it and to sign his consent form. The facility reported they had discussed this with him and he had

No prior vaccinations for

agreed prior to my visit. this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

"death. Per son pt was not feeling well after the vaccination ""like her legs were weak."" Son found the mom in her bed 1am on 2/12/2021 unresponsive." No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

My dad received his first COVID vaccine on January 14, 2021. On January 16, 2021 he ate breakfast around 7:00 am and went back to his room. When the staff checked on him around 8:00 am they found my dad unresponsive. His blood pressure was over 220 and his pulse was 43. They began manual CPR until the paramedics arrived, but my dad died. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

extreme fatigue. could not awaken for more than few seconds. When briefly awake she was coherent and not confused. slept deeply from 4pm and could not wake to eat or drink. No fever, bp normal, blood oxygen ok. Blood sugar at 11pm was 230. Gave her 15u lantus at 11pm (normally 25u). Was sleeping at 2:30am but had died at next check at 3:30am. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

I video chatted with her Thursday after receiving the vaccine. My mom was in poor health but she was talking in complete sentences and responded appropriately. She was upright in bed and made eye contact. She smiled and denied pain. By Sunday, she was extremely weak and unable to sip water with a straw. Her health had changed dramatically and rapidly. She moaned in pain and was very fatigued. Her condition continued to deteriorate over the week and she stopped talking and was constantly sleeping. They started antibiotics for the oozing cancer lesion and then morphine for pain and end of life care. She passed away on January 22nd which was 15 days post vaccination. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient was given vaccine the following day he died , No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

patient deceased No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Death; A spontaneous report was received from a reporter concerning a patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and passed away. The patient's medical history was not provided. No relevant concomitant medications were reported. The patient received their first of two planned doses of No prior vaccinations for this event.

mRNA-1273 on 28 Dec 2020 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, 2am the patient passed away. Administrator marked as natural causes. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not applicable. The outcome of the event was fatal. The patient died on 30 Dec 2020. The cause of death was reported as unknown. The reporter did not provide an assessment for the event, passed away.; Reporter's Comments: This case concerns a patient of unknown age and gender. The medical history and concomitant medication is not provided. The patient experienced Death. The event occurred approximately one day after receiving their first of two planned doses of mRNA-1273 (Lot unknown). Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. The benefit-risk relationship of Moderna's COVID-19 vaccine is not affected by this report.; Reported Cause(s) of Death: Unknown cause of death		
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient had COVID vaccination on 2/3 with no adverse s/s before leaving unit. Upon coming to treatment Friday 2/5 he reported to the RN that he had fallen on thursday 2/4 due to ""getting up fast"" did not hit head or hurt anything per RN discussion. Began treatment without difficulty. About 3/4 way through treatment was talking with staff and became unresponsive - code was called and pt expired after 30 minute resuscitation efforts."		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presents to ER with increased weakness, hypoxia, history of COPD, but not oxygen dependent., hypotension. Acute Kidney failure noted in labs, not previously diagnosed , new hyperkalemia. BP 73/39, HR 67. dopamine initiated, and switched to Levophed. Oxygen Sat 86%, requiring 10 L O2. Transferred from this critical access hospital to another Hospital. Expires later 2-13-2021		No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

This individual's employer informed our facility that he passed away at his home on 2/14/2021. Since he was not brought into our hospital, we do not have information regarding other health conditions or active medications. Since this individual received his second covid vaccine three days prior, this was reported to Moderna in addition to this VAERS report being completed. The coroner for County can be contacted.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

unknown, husband reported hospitalization 02/12 and deceased 02/15 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

2/10: Fever, fatigue, tylenol 2/11 @ 1300: pt made DNR, hospice consulted 2/11 @ 1800 decreased LOC, increased RR, fever, chills - 1/5L NS bolus IV, rectal tylenol. Refusing to eat/drink, PO morphine 2/12 @ 16:30, deceased at facility **resident was not doing well prior to vaccination

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Death Narrative: Patient received Covid vaccine on 2/2/21, person reports his legs were more rigid with some sweating the day of the vaccination with leg rigidity that was slowly improving. No other adverse effects reported for following 7 days. Person states he had vomiting episode earlier this week, person states he had no other symptoms before or after the vomiting episodes. On morning of 2/12/21, person reports patient got up ready for breakfast with no issues. She says he asked for chorizo and oatmeal but she laughed and said don't you mean chorizo and eggs. He said yes. They got him into W/C and he was rolling himself into dining room got stuck in hallway. She says he took several breaths then 3 very deep breaths and passed away. She

No prior vaccinations for this event.

called 911 they took his VS but he has passed. She told them to leave him along no resuscitation.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient family had been noticing onset confusion for a few weeks prior to vaccine and event. Patient was taken to ED when found unconscious and died of a subdural hemorrhage a few days after vaccine clinic at retirement home.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
On February 11, 2021 around 10:15 am, patient was given the Moderna brand COVID-19 vaccination. After his vaccination, he was instructed to wait around for 15 minutes after the administration of the vaccine. During this time, there were no reported issues with the patient. On February 15, 2021 around 9:15am, patient's wife called the pharmacy and spoke with the pharmacist informing her that patient had passed away in his sleep on Saturday evening. Patient's wife inquired about whether death may have been caused by an adverse reaction to the vaccine. During the call patient's wife mentioned that patient slept a lot the day of the vaccine and the day after. patient's wife mentioned that patient woke up Saturday to eat breakfast and lunch. She states that later that evening, she found patient asleep and cold which she then realized that he'd passed away.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient became nauseated about 10 minutes after vaccine administered, this subsided but returned several hours after the vaccine was given. She continued with intractable nausea and vomiting for about 24 hours. This patient was enrolled in hospice and she continued to decline and refused to eat or drink. She was taking Ibuprofen due to intractable back pain. Her emesis was coffee ground color. After this her condition continued		No prior vaccinations for this event.

to decline until her death

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
1/31/2021 12:50 Nursing Note Note Text: Res had low BP, low O2 sats, 30 breaths per minute, eyes open wide, making confused utterances. Started supplemental oxygen via NC, 2L, then 3L. Sats went up to 93% for a while, Sprvsr called. Unable to auscultate Left lung sounds. Called to update Res daughter. Called to page NP, writer went back to assess Res and O2 sats were 88%, turned O2 to 4LPM, called 911 for transport to Hospital ED. Left around 1030. NP called back afterwards, was updated. Family updated that Res was sent to Hospital ED. Note Text: Received phone call from daughter as well as information from hospital. Resident has pneumonia with septic shock. She is on abx and had thoracentesis performed for large pleural effusion. [linked]		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported mild flu like symptoms from vaccination later that evening. Next morning LTCF staff found pt deceased		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Two days later passed away; difficulty breathing, shortness of breath; difficulty breathing, gurgling; Not feeling well; Achiness; Severe fever; Chills; A spontaneous report was received from a physician concerning a 56-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed fever, chills, achiness, shortness of breath, gurgling and unresponsive. The patient's medical history was not provided. Concomitant product use was not provided. On 19 Jan 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Lot 042L20A) intramuscularly in the left		No prior vaccinations for this event.

arm for prophylaxis of COVID-19 infection. After receiving the vaccine on 19 Jan 2021, the patient experienced fever, chills, shortness of breath, gurgling and achiness. On 21 Jan 2021, the patient was found unresponsive. Emergency medical services were called to perform life saving measures however, they were unsuccessful. No further treatment information was provided. The patient died on 21 Jan 2021. The cause of death was reported as unknown. An autopsy was planned.; Reporter's Comments: This case concerns a 56-year-old, female, who experienced a serious event of death, with many other events after receiving second dose of mRNA-1273 (Lot# 042L20A). Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

He had rigors starting 6 pm the day after the vaccination. He was treated with one 500 mg tylenol. He had increased wheezing but did not complain of SOB. At 0400 the next morning, he died.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Vaccine given in clinic per protocol - patient monitored for 15 minutes, no adverse reactions noted at the time. Patient stated he felt fine following 15 minute monitoring time. Patient left facility- it was later reported that pt had a fall at home. Upon review of pt's medical record - Pt's wife had to initiate CPR and call EMS for transportation and life saving measures enroute to the Emergency Room. Pt was intubated as pt was in asystole upon arrival to the ER, ACLS was continued, pt was noted to have a traumatic brain injury from his fall at home, and pt was pronounced dead at 1620.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

patient passed away within 60 days of receiving COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Fever by the next day, difficulty breathing, pneumonia, and then DEATH within a few days. (Died 02/01/2021)

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Vomiting, death. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient presented with spontaneous IVH of small vessel origin with essentially no past medical history. She then acutely developed mesenteric ischemia. Died due to all dead small bowel which also appeared to be small vessel disease and not embolic/thrombotic. This process started one week after

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

We were informed by EMS that the patient was found deceased on 2/11/2021 at her home. EMS

No prior vaccinations for this

states she was dead for some time, no medical care given. event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt died on 2/15/21. On 2/13/21, pt complained of muscle aches. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient was found unresponsive at 8 am on 2/12; patient was deceased No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Daughter called to report that the patient died on 02/15/2021. No report of symptoms from the vaccine on 02/13/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Short version The patient has long-standing health issues. The patient received the first dose of Moderna COVID-19 vaccine on 1/16/2021 (unknown location). The patient suffered an event in his home on 1/24/2021. CPR and treatment was begun and he was transported to the ED. He was pronounced dead in the ED at 0846. Long version 70-year-old male with past medical history of CAD with pacemaker, A. fib, COPD, hypertension/hyperlipidemia presenting in cardiac arrest. 911 call at 0724. Per EMS, patient was witnessed by family to have seizure-like activity and then collapsed and became unresponsive. Patient was noted by family to be pulseless and CPR was started right away. Patient received two doses of epi by police were on scene first (AED defibrillation x2) and six doses of epi (plus 6 more AED shocks) by EMS when they arrived. Patient had CPR performed for 45 minutes prior to arriving at the hospital. On route, patient had episodes of paced rhythm and V. fib. Patient received one amp of bicarb and one amp of calcium en route. Patient also received No prior vaccinations for this event.

300 mg of amiodarone en route. Arrived in ED at 0810 Patient received ongoing compressions, shocks and additional medications (epinephrine x6, lidocaine IV, sodium bicarbonate) until time of death called at 0846 in the ED.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the vaccine on 1/31/2021. Patient complained of bleeding 2/7/2021. Went to clinic where labs were conducted. Patient had an INR of 12. Previous INR results were normal prior to vaccination. Patient was also diagnosed with UTI and given antibiotics. Patient was encouraged to go to ER. Patient died on 2/12/2021.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient is deceased. Family called the pharmacy on 2-17-21 to let us know he would not be coming for his second appointment. When the pharmacist tried to call the family back for more info, the phone number on file doesn't work.		No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient died at home in hospice care from complications of stage 4 bladder cancer No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

death 2-5-21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient passed away on 2/2/21 after being admitted on 1/31/21 after receiving COVID19 Moderna Vaccine on 1/26/21. On initial report to the hospital patient reported having a cough for over 2 weeks (starting approx. 1/17/21). He had a postive COVID19 PCR on 1/31/21. Intubated on 1/31/21 and passed away on 2/2/21 | No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

"Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive MI, PE or ruptured AAA"". Death certificate notes indicate ""signficant conditions contributing to death after cardiac arrest; ASCVD""." | No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Feb 10th died in her sleep. No apparent reason. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

passed away 2 days after vaccine was given No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient reported at review of questionnaire had headache that day. Temp was taken, 97.8, okay. proceeded. Conversing customer friend in store afterward. When timer went off, said he was fine, he and his wife left. Daughter called to store Wednesday morning, said Pt had passed away Tuesday, that it was unknown the cause, and just wanted to let us know. We did not take down her phone number and last name. The patient was a long time customer.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient was at a gym watching his daughter. He slumped over unconscious. EMS was called. He was found to be in fine ventricular fibrillation and resuscitation efforts failed. He was brought to Hospital ED where he was pronounced dead. He had underlying cardiac disease but his family requested I report this event as possibly related to the recent COVID vaccination.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

She had pain in the injection site Tuesday night and then during Tuesday she got worse with nausea and some fever. By Wednesday she was complaining that she could not pee even though she was drinking a lot of fluids. She continued to complain it was the worst she ever felt and then at 0600 Thursday morning she woke us up and said she needed to go to the hospital. We arrived at the hospital just before 0700 and she

No prior vaccinations for this event.

immediately threw up in the trash can. We went into a treatment room and they took blood and started fluids as she became incoherent. She said she had taken Tylenol so they started a drug to counter that but her liver function was all wrong and they started to look for a hospital that could transplant a liver. She was air evade about 0930 to Medical center and just over 30 hours latter she was dead. There is a pending autopsy. She was a healthy 39 year old mother who got the shots because she worked as a surgical tech and she was the single mother of a 9 year old little girl.

DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient went into new-onset atrial fibrillation, resulting in a catastrophic stroke. Patient passed away on 2/11 as a result of the stroke.		No prior vaccinations for this event.

DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Died the next day; A spontaneous report was received from a consumer concerning a male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and died the next day. The patient's medical history was not provided. Concomitant medication use was not provided by the reporter. On 12 Jan 2021, approximately one day prior to the event, the patient received one of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 13 Jan 2021 the patient died. No additional information was provided in regards to the event. Action taken with mRNA-1273 in response to the event was not applicable. The patient died on 13 Jan 2021. The cause of death was unknown.; Reporter's Comments: This case concerns a male patient of unknown age. The medical history and concomitant medication were not provided. The patient died approximately one day after receiving their first of two planned doses of mRNA-1273 (Lot unknown). Very limited information regarding this event has been provided at this time.; Reported Cause(s) of Death: Unknown cause of death		No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Passed away; tired; nonresponsive; cold; difficulty breathing; swelling; sore arm; feeling weird and funny; A spontaneous report (United States) was received from a consumer concerning a 63 year old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and the patient experienced limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal and the patient passed away . Medical history included treatment for tuberculosis and dialysis. Concomitant medication included calcium acetate, Renvela, glipizide, omeprazole, aspirin, vitamin D, losartan, furosemide, rifampin, and Sensipar. On 14 Jan 2021, the patient received the first of their first planned doses of mRNA-1273 (lot number 030L20A) for prophylaxis of COVID-19 infection. On 13 Jan2021, the patient tested negative for COVID-19). On 16 Jan 2021, the patient experienced a sore arm, and feeling weird/funny. On 17Jan2021, the patient experienced difficulty breathing and swelling. On 18 Jan 2021, the patient declined dialysis, was tired and wanted to lay down. At 8 am, the patient was found nonresponsive and cold and is believed to have passed away around 4 am. The coroner tested the deceased for COVID-19 and the test was positive. No autopsy was reported. No death certificate was issued at the time of the report but the reporter believes it will list cause of death as COVID complications. Action taken with the mRNA-1273 was not applicable. The outcome of the events of limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal, was fatal. On 18 Jan 2021, the patient was died. Cause of death was COVID-19. Autopsy details were not provided.; Reporter's Comments: The events developed on four days after first dose of mRNA-1372. Dyspnea, unresponsive to stimuli, and death were consistent with infection in pandemic set up confounded by age of patient and refusal of dialysis Cause of death was reported as COVID-19. Autopsy details were not provided. Based on reporter's causality the events are assessed as unlikely related to mRNA-1273.; Reported Cause(s) of Death: COVID-19

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Pt. received vaccine on 2/3/2021. Coded at home on 2/17/2021. No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**	
Per EMS/Hospital report patient had difficulty breathing and cardiac arrest with prolonged CPR (greater than 45 mins in the ER) who was resuscitated. Family subsequently arrived including son and daughter and all family members were in the ER room are in agreement that patient would not want further aggressive cares given her extremely poor prognosis in light of chronic debilitation with numerous medical issues and now a very long period of CPR. Hospital Course After updating family they stated patient would not want further aggressive cares given her grim prognosis and chronic severe and debilitating medical issues. She continued to have myoclonic jerking. She was extubated to comfort cares in the ER and did not pass immediately therefore brought to a room. She received comfort cares and passed away at 0450 with family present.		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Moderna COVID vaccine administered 2/9/21. Patient expired in home on 2/10/21, at around 2100. Patient had h/o CVA in2001 with long standing sequelae. On day of administration, team attempted to draw lab specimen with vein finder, but patient was possibly Narrative: Moderna COVID vaccine administered 2/9/21. Patient expired in home on 2/10/21, at around 2100. Patient had h/o CVA in2001 with long standing sequelae. On day of administration, team attempted to draw lab specimen with vein finder, but patient was possibly dehydrated. CG/wife reported to APRN on 2/10/21, patient was sleeping and snoring and then began to sleep more quietly. She checked on patient and found that he had no pulse and had passed away		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
The patient fell the day after receiving the Moderna COVID-19 vaccine. She broke her hip in this fall. During surgery to correct the broken hip, she went in to sudden and unexpected cardiac arrest. The anesthetist did		No prior vaccinations

not notice any ST changes or A fib; dysrhythmia was very unexpected. The patient had a DNR. She died at 13:00 on 02/07/2021. Causes of death are listed as 1. Cardiac Arrest 2. Recent hip fracture with hip placement 3. History of Breast Cancer 4. Hypothyroid and 5. Dementia

for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

"86yo female alert, stable with ankle abrasion eating 100% prior to vaccine in assisted living facility. On 2/1/2021, received Moderna vaccine. Starting thereafter, eating 50% on 2/2/21. Temperature was 98 tympanic. On 2/3, the leg abrasion started having moderate bleeding. On 2/4, the caregiver noted patient ""not looking good, unable to talk, arms moving aimlessly, grasping"". BP 95/41, temperature 98, oxygen on room air 92-93%. POA did not want hospital transfer. 2/5 Hospice started, oxygen given, morphine given. 2/5-2/8 comfort care given, patient responsive to tactile stimuli, resting, not taking oral medications or food. 2/8/2021 patient expired."

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

death attributed to unknown cause No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

"The patient came to the Emergency Room at approx 3:30 am on 02/03/2021 with pain in right arm (same arm the COVID vaccine had been administered in approx 12 hours earlier) and feeling generally unwell. Patient was concerned about possibility of gout flare or that something was wrong with her arm. Elevated blood pressure was noted; this was attributed to anxiety. She was evaluated, given 500 mg Tylenol, and discharged since the pain was decreasing and blood pressure was stabilized. Patient instructed to follow-up with physician. The next day, on 02/04/2021, the patient arrived at the Emergency Room by ambulance; cardiac arrest was the chief complaint. The patient's daughter stated the patient had been ""feeling generally

No prior vaccinations for this event.

poor and then suddenly collapsed."" Daughter described ""gurgling respirations"" and being unresponsive. 911 was called, police arrived within 5 minutes and initiated CPR. Epinephrine, atropine, lidocaine and bicarb administered after arrival to Emergency Room. Shockable rhythm never demonstrated. Patient never recovered spontaneous respiration or movement. The death was called at 23:04. Coronary artery disease with cardiac arrest is the cause from the ER records; the coroner is putting COVID-19 vaccination in Part 1 of the death certificate."

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident getting rehab therapy in the facility and has a long history of Parkinson's Disease. On 01/29/21, he received the COVID vaccine on left deltoid, resident was recently hospitalized due to Pneumonia and was on antibiotic IV and was recently placed on GT feeding due to severe dysphagia from his Parkinson's disease. On 01/31/21, started having increased congestion. On 02/02/21, started having increased temperature and WBC went up >20,000 on 02/03/21, started on Vancomycin IV on 02/04/21 but was transferred to the hospital. Facility was notified today (02/18/21) that resident expired in the hospital.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient was found unresponsive and had passed away. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient collapsed and could not be revived. There was no prior warning. She was otherwise in good condition for her age. The death was listed as probable cardiac arrest but no autopsy was performed. Since it occurred so close to the vaccine shot I thought someone may want to know.

No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Death due to hemorrhagic stroke. No prior vaccinations for this event.		
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**	
Toileting and had expired while doing so; Severe abdominal pain; Diarrhea; Vomiting; Mild injection site pain; A spontaneous report was received from a healthcare professional concerning an 88-year-old , female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced the events, toileting and had expired while doing so (death), mild injection site pain, severe abdominal pain, diarrhea, and vomiting. The patient's medical history was not provided. No relevant concomitant medications were reported. On 20 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 029L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 20 Jan 2021, the patient felt mild pain at the injection site after receiving the vaccine. On 21 Jan 2021, the patient reported severe abdominal pain, diarrhea and vomiting. These symptoms were intermittent for a week and no other adverse events were noted. On 27 Jan 2021, the patient passed away while toileting. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 27 Jan 2021. The cause of death was unknown. An autopsy was not performed.; Reporter's Comments: The gastrointestinal events were consistent with increased risk associate with elderly age of patient. The cause of death was unknown. Autopsy was not performed. Very limited information regarding the events is available at this time. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Reported Cause(s) of Death: unknown cause of death		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
unknown if related to vaccine. patient received 2nd vaccine at 0830, observed 15 minutes, discharged, arrested at 0915 upon entering her home. vaccine was administered by DOH at their community location.		No prior vaccinations for

patient was pronounced lifeless in the ED. this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient previously had dizzy spills, but about a week after receiving the vaccine her dizzy spills began to get worse. The whole prior she kept saying I am just not right. On the 2/7/21 she a COVID test done, a nurse came to her house and preformed. On the morning of the 8th patient was on the phone with someone else and patient asked this person to call me and go check on her. Within 5 minutes I was over at her house, and I found her on the floor, she on her belly facedown. It looked like she was on the toilet, and it looked like she fall getting her off, she was still wet, she still felt warm. I called the ambulance and immediately began CPR. When EMS arrived they took over the CPR and transported her to the Hospital. The EMS was there for about 40 minutes and used an machine to preform the compressions. She was pronounced deceased at the hospital. No autopsy was done. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

CLIENT EXPIRED 1 WEEK FOLLOWING THE VACCINE. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient described feeling nervous, anxious the next morning (Wednesday) after the vaccine. He later fell in the bathroom after using the restroom, his legs gave out (his words) and consequently was on the ground for 23 hours before being transported to the hospital. That was Thursday afternoon. He was diagnosed with COVID-19 on Saturday night and died the following Friday morning. No prior vaccinations for this event.

DEATH **COVID19 (COVID19**

(MODERNA)) (1201)

Death- ~ 7 hours after vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19**

(MODERNA)) (1201)

death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

Patient called son around 6:30am on 2/18/21. When son tried to contact patient around 8:30am, he was not able to get a hold of patient. Son sent someone over to check on patient. They found patient on the floor. He was coherent at first but then lost consciousness. It believed he experienced a stroke sometime around 8:30-9:00am of 2/18/21. Patient was taken to hospital and then transferred to another hospital. He was put in a medically induced coma. He passed between 4:00 and 4:30 pm on 02/19/21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

Pt received second Moderna COVID-19 vaccination administered in left arm at her assisted living facility by Pharmacist at 1153 on 2/19/2021. Pt was monitored for vaccine reaction with no known adverse reaction. Approximately 18 hours post-vaccine, she was found deceased in her sleep at 0540 on 2/20/21. Per circumstances/pt history, it is presumed that the patient aspirated while sleeping, perhaps secondary to a seizure. Coroner was notified and declined as coroner's case. VAERS notification being made due to pt death within 24 hours of receiving a vaccine.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Moderna COVID 19 Vaccine: Patient started with symptoms of covid 5 days after first vaccine. She was hospitalized and passed due to COVID 19 on 2/6/21. Patients family informed us when she was due for the second dose.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Stomach upset, sudden heart failure, death No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

death; hemiparesis; respiratory failure; Aphasia; SARS-COV-2 test positive; cough; A spontaneous report was received from other health care professional concerning a 32- year -female patient who received Modena's COVID-19 vaccine (mRNA-1273) and experienced aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive. The patient's medical history was not provided. No relevant concomitant medications were reported. On 28-Dec-2020, the patient received their first of two planned doses of mRNA-1273 (lot/batch 039k20A) intramuscularly on left arm for prophylaxis of COVID-19 infection. Approximately, one day later, patient developed cough and on treatment with azithromycin for one week. On 03-jan-2021, she experienced left sided weakness and aphasia and was shifted to hospital. Patient was confirmed COVID-19 positive which required intubation for acute hypoxic respiratory failure secondary to COVID-19. No laboratory data was provided. Action taken with mRNA-1273 in response to the events aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive not applicable. On an unknown date, the outcome of the events aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive was fatal. On 04 Jan 2021, the patient passed away due to the unknown cause. Autopsy results were unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the event of COVID-19 is assessed as unlikely related. The cause of death was not reported. Autopsy results were unknown.;

No prior vaccinations for this event.

Reported Cause(s) of Death: Unknown cause of death

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

COVID infection, death No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

He was found deceased in his home by Sheriff and paramedics evening of 2/21/21. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Death. My father-in-law was found unexpectedly deceased in his home Saturday morning. He worked the previous day. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

When family members came to receive the second dose of their COVID vaccine, they informed us that the above patient had passed away. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient passed away with in 60 days of receiving a COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient passed away within 60 days of receiving a COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient passed away within 60 days of receiving a COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt was hospitalized Jan 18, 2021 after he had fallen outside overnight and lay there approximately 12 hours until he was found. Hypothermic & rhabdomyolis diagnosis. Gradually improved w/ strength & mental status - was in swing bed @ hospital. He got his first Covid 19 shot on 2-8-21. Was fine @ 0300 on 2-9-21 and @ 0430 he was found unresponsive. Dx: probable arrythmia & pronounced dead @ 0454. Noted on pain scale @ 2/8/21 @ 21:11, clients pain was a 7/10 They offered pain med & he refused They repositioned & distracted him @ 2047 on 2/8/21 Pain had decreased to 3/10 and nothing given. Then @ 0300 check he was sleeping and @ 0430 unresponsive.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Deceased 02/18/2021 with an unknown cause of death No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

jaundice->hemolytic anemia-> hemorrhagic shock->multi organ failure->death pt admitted to ICU 2/16 with Hgb=3.4, treated with steroids, supportive care , pressors, pt died 2/20/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt had expired before second dose was delivered. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

Patient felt fine on Friday afternoon and evening after shot. Felt fine on Saturday until the afternoon when she started feeling fatigued and chilled. Decided to take a warm bath at about 6pm. Was found dead in bathtub at approximately 7pm with blisters on arms, legs, and face. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

According to patient's caregiver, patient presented with symptoms of fever (101.6 F) and purple blotches all over the body within an hour. Since patient was in hospice , caregiver called Hospice and a pharmacy and was told to give patient Benadryl and Tylenol. Patient was given both medications and the fever subsided in a few days but the purple blotches never went away. Patient passed away at the facility a week later. No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient was admitted to hospital on 2-9-21 for urinary tract infection and tested positive for Covid. Developed pneumonia and expired on 2-12-21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Vaccine was administered 2/1/2021 at approximately 9am. Due to self reporting of allergic reaction (hives) to Augmentin, patient was monitored on site for 30 minutes. After the monitoring period, she was cleared to go with no issues reported at the time. We were later informed that the patient passed away from a pulmonary embolism on 2/12/2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Resident yelling for assistance in apartment. Nursing personnel found resident on floor at 6:10 AM on 2/18/2021. Resident was transported to Hospital on 2/18/2021. Status update on 2/18/2021 from son, resident CT & X-rays were done all normal. Labs done and WBC count was elevated and awaiting results. Resident stable and admitted to hospital for observation. Resident passed away on 2.21.2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient experienced an episode of emesis and loss of consciousness several hours after vaccine on 2/16/21. He was taken by EMS to the hospital and was noted to be hypoxic and hypotensive. He was admitted to the hospital and subsequently intubated. He was also found to have a small bowel obstruction and a nasogastric

No prior vaccinations for this event.

tube was placed to decompress the bowel. He required pressor support as well. He expired on 2/17/21.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was given vaccine on friday, one week later she passed away. The family called the pharmacy to inform us on Saturday, Feb 20, 2021. After the phone call was over, we saw in her pharmacy profile that she had received the vaccine one week prior		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient passed away Saturday at 14:04pm. Patient's wife reports his death was sudden, he passed away sitting in his chair his heart just stopped she said. They tried to perform CPR, 911 was called and paramedics arrived at the scene and he was given medication but never had any return of vital signs and so his death was called at the scene. Wife reports he was not ill, did not have any symptoms prior to the event. They are not going to be doing a autopsy. She wanted us to know based on timing that there may be some possible correlation with his COVID19 vaccine. He obtained the vaccine on 02/09/2021 - wife reports he had no symptoms, not even arm soreness after the vaccine. Had no fever, shortness of breath. Did not complain of chest pain. We can update chart to reflect the patient is deceased and lets make a card for the family.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient rcvd 1st covid 19 vaccine on 1/26/2021. Patient had house guests on 1/30/21. Those house guests tested positive for covid on 2/1/2021. Patient started getting symptoms on 02/2/2021. Patient tested postivie on 2/4/2021. Patient was hospitalized 2/7/2021. Patient passed away on 2/21/21.		No prior vaccinations for this event.

DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
I was notified on 2/22/21 that this patient passed away over the weekend. I do not know the details, nor can I confirm anything beyond what I was told. I believe the death occurred on 2/20/21 due to a massive stroke.		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
When calling to get billing information we were notified that patient had passed away. Patient's daughter said patient was having cvd a/s on 2.1.2021 got vaccine 2.2.2021 and passed away 2.5.2021. Cardiologist said not related		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine was administered at Nursing Facility. Patient is an 89-year-old female with prior medical history of CVA with dysphagia, history of possible dementia, GERD, hyperlipidemia, and a pacemaker. She is a resident from town. She was sent for hypotension with a blood pressure of 90/52, tachypnea respirations of 54, possible aspiration pneumonia. Status post Covid vaccine earlier today. History is limited as patient is nonverbal on my exam. Death within 24 hours of vaccination		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was		No prior vaccinations for this event.

holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Individual developed severe body aches, severe shoulder discomfort, high fevers (documented max temp. 103.7 F). Daughter reported that she became non-responsive with high fevers, and when the fevers decreased she was more lucid. Her condition rapidly progressed to nausea vomiting, diarrhea and patient died on 2/9/2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Died 7 days after receiving 2nd dose of Moderna vaccine. Had underlying hx Lung CA w/mets.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Per family, patient has been feeling sick since he was vaccinated, patient went to ER on 02/15/2021, and after few hours at ER patient passed away.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Passed away; Found unconscious; Coma; Lack of oxygen to the brain; A spontaneous report was received from a consumer, concerning his mother, a 71-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and passed away, prior to death, patient experienced lack of oxygen to the brain and was found unconscious and went to coma. The patient's medical history reported included seizures. Concomitant medications included phenobarbital, lamotrigine and levetiracetam. On 27 Jan 2021, approximately six days prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (lot number: 030L20A) intramuscularly for prophylaxis of COVID-19 infection. On 01 Feb 2021 at 4 am, the patient was found to be unconscious on the couch, hence she was rushed to the hospital with lack of oxygen to the brain. Later, she went into a coma, hence she was in hospital for 30 hours and then was transferred to a different hospital for a second opinion on 06-Feb-2021, where she was passed away at 02:20 PM. Treatment information was not provided Action taken with mRNA-1273 in response to the events were not applicable. The outcome of events, lack of oxygen to the brain, found unconscious and coma were considered unknown. The outcome of event passed away was fatal as she died on 06 Feb 2021 at 2:20 pm. The cause of death was not provided. Plans for an autopsy were unknown.; Reporter's Comments: This is a case of 71-year-old female subject with a history of seizures who died 6 days after receiving first dose of vaccine. Very limited information has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Passed away

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Passed away; Slight soreness in arm; A regulatory report was received from a pharmacist concerning a 72-year-old male patient who received Moderna covid-19 vaccine and death occurred 4 days after the vaccine and also experienced soreness in his arm after the vaccine administration. The patient's medical history includes diabetes mellitus, Hypertension, Hypercholesterolemia, CVD, previous stroke and Depression. No relevant concomitant medications were reported. No information on allergies. On 4-FEB-2021 at 10:43 am, prior to the onset of events, the patient received his first of two planned doses of covid-19 vaccine for the prophylaxis of covid-19 infection. He had soreness in his arm the day following the shot, but he had no other

No prior vaccinations for this event.

symptoms. He passed away on 08-FEB-2021 at 10 am. As per his wife, they never made it to the hospital, and he had poor health prior to vaccination. Action taken with 2nd dose of Moderna Covid-19 vaccine was not applicable. The outcome of the event death is fatal.; Reporter's Comments: This is a 72 year old male with hx of diabetes mellitus, hypertension, hypercholesterolemia, and CVD who died 4 days after the vaccine was administered. No autopsy report provided. No further information is expected in this regulatory report case.; Reported Cause(s) of Death: Unknown cause of death

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

unknown, was informed by Health Director that person had passed away No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient passed away within 60 days of receiving a COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Hepatorenal syndrome- Death No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient passed away within 60 days of receiving a COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient passed away with in 60 days of receiving the COVID vaccine series No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

While at counseling appointment on February 17 patient had witnessed sudden cardiac arrest and was not able to be resuscitated. She was pronounced dead at 12:09. At the time of death her glucose was about 500.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient passed away within 60 days of receiving the COVID vaccine series No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

911 called to patients house for trouble breathing and abdominal pain. Patient coded, wife presented DNR paperwork. Patient presented to Hospital DOA at 0958.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

"Agency contacted 2/19 In evening by employer representative- client Died Suddenly after work"""

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA))

(1201)

Patient passed away within 60 days of receiving a COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient discovered unresponsive in cell, blue coloration to skin, vital signs, undetectable. CPR initiated, Ambulance summoned. Following EMS arrival with additional unsuccessful attempts to revive patient, patient was determined to have expired. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient admitted to the hospital the day after receiving a COVID vaccine x 5 days. Patient passed away on 2/23/2021. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

He vaccine on 2/5/2021 I went to see my husband the next day he was shaking and his mouth was open shaking, and he had fever of 105, they gave him Tylenol suppositories and he passed away 2 hours later. They should not have given him should not have given him the vaccine that is on hospice, it was not the right decision. I am worried about the elderly and those very sick. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient passed away No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Approximately 2 weeks after the first COVID vaccine she developed shortness of breath that was much more significant than she had previously. This was the first time she had expressed this symptom to me as being something she was concerned about and difficult for her to manage (we have spoken almost daily for many years). Within 24 hours of the second dose of the mRNA vaccine, they called an ambulance to get her and she was taken to the hospital and diagnosed with bacterial pneumonia. The doctors said it was unrelated, but I found a study with a different vaccine (LAIV) that also seemed to increase the incidence of bacterial pneumonia. They hypothesized through diverting the immune system. So while I don't think the vaccine gave her the bacteria, I do think it may have caused her immune system to be temporarily compromised allowing the bacteria to grow out of control. I feel this is important to report to look for these types of patterns as perhaps it can help others avoid the death spiral that happened to my mother. There were also intervening events between her hospitalization and her death including two successful surgeries (one for a broken hip and another to put in stents in her leg). So to summarize, the first vaccine was within about 2 weeks of the onset of her breathing problems. Within 24 hours of the second vaccine she was hospitalized and diagnosed with bacterial pneumonia. As she was battling bacterial pneumonia in the hospital she broke her hip and was found to have reduced peripheral circulation and had 2 surgeries to correct those. They were successful according to the surgeons, however she died within a week or so of the surgeries. She had other comorbidities as well which I'm sure predisposed her such as diabetes, hypertension and cancer for many years.

Breathing issues ~2 weeks after first dose of mRNA vaccine in the series but were not nearly as acute or severe as they were fol

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Vaccine administered 02/08/2021 , by Thursday 02/11/2021 patient almost nonverbal, by Monday 02/15/2021 patient went to the hospital with bruising, sores on her stomach and clots reported as

No prior vaccinations for this event.

thrombocytopenia, deceased by Friday 02/19/2021.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt had passed away before second dose No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Received call that patient is now deceased No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

pt woke up at 0400 with fever, chills, and body aches progressing over 4 hours to the point when she became unresponsive. husband called 911, pt was declared dead at the time of EMS arrival around 1200 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

cardiac arrest, death: 2/21/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

2/12/2021 woke up with sore arm and back. 2/13/2021 woke up with headache around 1am. Headache and nausea all morning. Mid-late afternoon started having seizures. Admitted to Hospital 2/15/2021 expired. Reported per wife on 2/25/2021. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt's wife reports death 2/23/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

FOUND DEAD IN HIS OWN BED No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient passed on 01/28/2021 per family member. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient was found at 6 AM on 01/21/2021 - he passed away during his sleep No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

No details - patient died on 1/22/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Client died on 02/21/2021 and had received the second dose of the vaccine series on 02/19/2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

This is a hospice patient under the care of Hospice at an affiliated nursing home. Pt received the vaccination around noon on 2-16-21 by a representative from Pharmacy. The following afternoon 2-17-21 at 14:45 the pt started to experience severe SOB resp rate 36, audible wheezing and use of respiratory accessory muscles.

No prior vaccinations for this event.

BP180/80, 113 pulse temp 98. Pt was given morphine and ativan. The respiratory distress was eased however pt never returned to baseline and died 2-22-21 around 4am.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Death occurred 02/14/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient suffered a stroke and passed away No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt tested positive for COVID-19 on 2/10/2021 and died from illness related to COVID-19 on hospice at home on 2/18/2021, per care facility. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt tested positive for COVID-19 on 2/10/2021 and was hospitalized on 2/15/2021 and deceased on 2/18/2021 at the hospital of admission, per caregiver. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt tested positive for COVID-19 on 2/10/2021 and was deceased on 2/16/2021 per the caregiver. No prior vaccinations for this event.

DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt tested positive for COVID-19 on 2/10/2021, and was deceased on 2/16/2021 at.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt tested positive for COVID-19 on 2/10/2021, and deceased on 2/12/2021, per caregiver at.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Massive ischemic stroke with aspiration, unable to arouse on the morning of 1/21/2021 and placed on Hospice with death 1/24/2021	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Was given without consent from POA patient got severely sick and never recovered later passed away only live 1 month POA did not allow second vaccine to be given just wanted to report this vaccine was given illegal without POA knowledge	Hives	
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
"My grandpa had a stroke on the 15th of February. He claimed he had been feeling ""off"" for a few days, but didn't say anything. A blood clot had formed in his brain. He was doing better and about to go to rehab to strength his right side of his body. On the 22nd he took a turn for the worst. He was having trouble breathing	No prior vaccinations for this event.	

and they sedated and partially paralyzed him to put a tube in his mouth. I believe another blood clot had formed and oxygen wasn't properly going through his body. They could not stabilize him, and he passed away the same day."

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

The medical facility did not treat patient as her primary care, but were informed that she passed away on 15 February 2021 of a stroke. I do not have further information on the medical aspect of this as we were not her treating provider but did administer the vaccine on 12 February. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient's husband reported her death that happened after first COVID-19 vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient with severe dementia in Hospice Care No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient was transferred from hospital for further evaluation and care by pulmonologist. He started having symptoms a week before with fatigue, emesis, decreased p.o. intake, shortness of breath, vomiting and diarrhea. The two previous takes before death required increasing oxygen and family wanted everything done including intubation. He was transferred to ICU. No prior vaccinations for this event.

DEATH **COVID19 (COVID19**

(MODERNA)) (1201)

on 2/218/2021 the patient was at home and developed chest pain. Patient was transported by family to urgent care then to the ED where the patient later died. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

"""Feeling Hot"" without fever and nausea 10 hours post vaccine and resolved within 1 hour. Seizure, Hypotension, Unresponsive followed shortly by cardiac arrest and pulseless electrical activity 21 hours post vaccine. Pronounced dead 22 hours post vaccine" No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident expired on 2-25-21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

PATIENT DIED IN HIS SLEEP NIGHT AFTER ADMINISTRATION No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Fever, chills, fatigue, muscle aches, nausea, death 48 hours after injection No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Unknown symptoms overnight. Appears patient passed away sometime after waking up next morning after receiving vaccine. No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Cardiac arrhythmia, EMS on site within minutes, outcome of death. No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

30 hours after the first Covid vaccination, the resident was lethargic, non responsive with shortness of breathe.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient received Covid Vaccine Moderna at 1145, multiple syncopal episodes at pharmacy, sent to ER. Outcome Death

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

death Narrative: This was reported to VAERS by another entity and records were requested.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to

No prior vaccinations for this event.

a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Hypoxia, Decreased responsiveness, Narrative: 86yo male with PMHx HTN, Afib not on AC after head trauma, CVA, and colon cancer who was brought to the ED by his family on 2/17. Per documentation the pt

No prior vaccinations

was in his usual state of health until 2/16. Received Moderna covid vaccine #2 on 2/16/21 at 0900, and was monitored for 15 minutes following immunization no noted issues. Later that night, had myalgias and took Tylenol. Per the family he slipped on the ice and fell on his butt. Overnight, had several dark stools and vomitus. was brought to the ED by his family because he was being less responsive. Pt arrived to the emergency department in extremis. No pulse identified. CPR immediately initiated for several rounds lasting about 25-30 minutes. ROSC unable to be achieved. Patient expired on 2/17 at 1941. Of note, per previous documentation had waxing and waning mental status at baseline. No symptoms noted with 1st dose of Moderna vaccine, which was administered on 1/16/21.		for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Do not know if patient informed her physician that she received vaccine on 1/29/2021. She had appt at 3:15 pm on 1/29 and afterwards stated she received the Moderna vaccine. Reporter is uncertain if this was at a health office or clinic. She drove herself to the ER at about 3am on 1/30/2021 with increased cramping and pain.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Day after second dose decedent had fever and tremors, subsided on day three (less than 72 hours) after dose with exterem wekness followed by death less than 72 hours after second dose		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
I am the patient's daughter as well as an RN-BSN. My mother was given the Moderna vaccine on Feb 11, 2021 and on Feb 15, 2021 she had a CVA and MI. She was found on her apt. floor unconscious. She was transferred to the Hospital by ambulance where a CT scan and other tests were done. It was determined she		No prior vaccinations for this event.

had a stroke and heart attack. My mother was in great health, took no medications, and lived alone in her apt. before this incident. The medical professionals determined she would not recover so she was admitted to hospice and died on Feb. 21, 2021. I believe there is a relationship between the vaccine and the CVA and MI.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Died at home; Gasping for air/difficulty breathing; Soreness; A spontaneous report was received from a physician concerning a 45 years-old, female patient who experienced soreness/MedDRA PT: pain, gasping for air/difficulty breathing/MedDRA PT: dyspnoea and subsequently died/MedDRA PT: death. The patient's medical history included blood pressure (disorder not specified), thyroid disorder, depression and anxiety. Concomitant product use included blood pressure medication, thyroid medication and possibly depression and anxiety medication. On 28 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot #007M20A) (route of administration and injection site not provided) for prophylaxis of COVID-19 infection. On 28 Jan 2021, following the vaccination, the patient was fine but had experienced some soreness. Per patient's coworker, the patient did not take any medication as it made the patient sick. The physician was not aware of any complaints from the vaccine. On 13 Feb 2021 at 3:31am, the patient called 911. Per the 911 call, the patient was gasping for air on the call and having difficulty breathing. The patient subsequently died on 13 Feb 2021 at home. The physician inquired whether Moderna gets involved with the autopsy and logistics of the death of patients and wanted to know the time frame for reporting a death of a patient who received the vaccine. The physician did not know who administered the patient's vaccine. Action taken with mRNA-1273 in response to the events was not applicable as the patient deceased. The event died was fatal. The outcome for the events soreness and gasping for air/difficulty breathing was unknown. The patient died on 13 Feb 2021. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter's Comments: Very limited information regarding the event of dyspnea and death has been provided at this time. Further information has been requested. Patient's medical history of blood pressure is considered a risk factor. Based on the current available information and temporal association between the use of the product and the onset of the pain, a causal relationship cannot be excluded.; Reported Cause(s) of Death: Died at

No prior vaccinations for this event.

home

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Death; A spontaneous was received from a consumer concerning a male patient, who received Moderna's COVID-19 vaccine and who died. The patient's medical history was not provided. No relevant concomitant medications were reported. On 23-Jan-2021, prior to the onset of the event, patient received their first of two planned doses of mRNA-1273 (Lot number:013620A) intramuscularly for prophylaxis of COVID-19 infection. On 25-Jan-2021, approximately 2 days after injection, patient Died. On 26-Jan-2021, neighbor Reporter called in to report a potential AE death. She shared that she lives in a condo building with other elderly. She shared that she and 2 other neighbors went to a vaccination site in Miami at a fire department. She shared that she is fine but that her neighbor died two days after shot. She shared that she didn't know if he had symptoms and that she knows that he had a lot of medical issues and was on about 15 medicines. She shared that she didn't know his age but guessed 70. She said we can contact his wife, but it must be a Spanish speaking agent because she speaks little English. She is concerned because they all received the vaccine at the same time. She wanted to reiterate that she was fine but believed we should know about the neighbor's death. No treatment information was provided. Action taken with the second dose of mRNA-1273 in response to the event death is not applicable. The patient died on 26-Jan-2021. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested. The cause of death was not provided.; Reported Cause(s) of Death: Unknown		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
2-24-21 patient with development of cough, fatigue, increasing on chronic disability worsening debility and falls. scheduled for office visit 2-25.21 0900 call from spouse 0210 am patient was not breathing and lvad		No prior vaccinations for this event.

alarming low flow alarm on arrival of ems confirm asystolic not breathing and dead

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

92 yo female who received her first dose of Moderna vaccine on 1/11/2021 with no known adverse effects. Admitted to the hospital on 1/17/21 with a spine compression fracture. Discharged and readmitted on 1/19 /21 with nausea and vomiting. Found to have new atrial flutter and elevated troponin attributed to NSTEMI. Discharge on Aspirin and Plavix. No cath. Second dose of Moderna vaccine 2/25/21. No immediate reaction. One hour later began to feel progressively weak. EMS called shortly after getting home. Intubated in the field. Died at 0658 on 2/26/21 s/p PEA arrest without ROSC. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

patient passed away within 60 days of receiving a COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient passed away within 60 days of receiving a COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Patient was a Resident on our LTC wing. Per the LTC Manager: Resident had hx of CVA with deficits in speech and extremities. Hx of decreased circulation to BLE's which resulted in wounds to bilateral feet on and off that needed treatment. Average meal consumption 25-50% of meals, started refusing more often in December and January. Would consume small amounts 60-120mL of fluids here or there. Vaccinated on 1/7/21. Stopped eating 1/18/21. Attempted bolus NS fluid 1/25/21. Resident refused all treatment afterwards. No prior vaccinations for this event.

Went hospice on 2/3/21 and passed away on 2/7/21.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Pt got his vaccine 1/27 and was found dead at his residence on 2/7/21. I heard from our county health officer who talked to the coroner who said that they estimated that the patient had been deceased for 2-3 days prior to when they were found. No apparent cause of death was found. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Called pt for Dose 2 appt. Pt had passed away. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

"Patient died on 2/25/21 in the AM after receiving his COVID-19 Moderna vaccine #1 at approximately 2:30P on 2/24/21. I do not have a time of death. I contacted the County Medical Examiner's office who stated that they received his body after he was determined to be deceased at the shelter. No autopsy was performed and his body was released to a funeral home on 2/26. The ME's office said that ""permit for burial/cremation is pending"" and no other information on COD was available. Per staff, he was also tested for COVID as part of shelter protocol on 2/24 and PCR was negative. He arrived to the shelter on 2/19/21." No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Resident had severe CAD, DM type 2, and hx of RBKA and left 5 digits on foot amputation. Hx of osteomyelitis post surgical. After last surgery, resident did not have a good appetite, more restless, increased confusion with dementia. Significant other passed away on 12/30/20, resident began refusing meals, No prior vaccinations for this event.

decreased eating. Vaccinated on 1/13/21. On 1/25/21 Resident labs showed kidney failure. Dr. spoke with family and transitioned to Comfort care, on 2/5/21 went hospice. Patient passed away on 2/13/2021.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Hx dementia, CVA, CAD. 2-3 year history of only consuming 25% of 1-2 meals daily. All meds d/c early 2020 because of refusing to eat or drink anything. Suddenly began drinking april/may, gained weight back. Vaccinated on 1/7/21 & 2/4/21. On 2/22/21 had significant changes in respiratory status. Passed away 2/23/21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Resident had Hx of DM T2, Hx of prostate CA. Started having swallowing difficulties in November. Increased c/o nausea and decreased appetite. 25% per meal average. Decreased energy to participate in activities and refused getting out of bed or meals. Was vaccinated on 1/13/21. Hospice care started on 1/25/21. Resident passed away 2/23/21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

NO SPECIFIC ADVERSE EVENT DUE TO THE VACCINE BUT THE PATIENT PASSED AWAY 02/10/2021 DUE TO COVID

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

Death on 2-28-21. Not felt by this provider to be likely related to vaccination. No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
It was reported to staff that this gentleman suffered thrombocytopenia following his vaccine, a platelet infusion was done and he expired on 2-14-21	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
My grandpa got his second covid vaccine on Thursday. Saturday he complained of stiff neck. Sunday he had low grade fever, nausea and vomiting, chills, and mild headache. He was feeling bad enough to call squad at 3 pm. The paramedics did evaluation and thought he was just experiencing normal side effects from vaccine and felt no need to transport to hospital so my grandpa decided to stay home and just rest. At 2 am that same night he went into cardiac arrest and was not able to be brought back	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR	No prior vaccinations for this event.

pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Received vaccination at 14:20 2/26/21. Was observed until discharged at 15:15. Discharged per wheel chair to lobby in alert/stable condition, to wait on bus to take him home. At 18:00 his neighbor heard him fall, could not get patient to answer phone, found him unresponsive. Neighbor called 9-1-1, ambulance personnel could not revive patient. Coroner's office ruled his death as Natural Causes due to Hypertension, Cardiac disease, Diabetes, ESRD. There were no indication of anaphylactic reaction noted when I questioned the coroner's office. The Coroner's office/EMS were aware the patient had received the Moderna COVID 19 vaccination that day.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

died No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

History of terminal cancer, entered hospice care 1/2021, expired 2/28/2021. No reported adverse No prior vaccinations for this

events from patient or family after receiving vaccine	event.	
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**	
Patient received dose 1 of Moderna Vaccine on 1/14/21 administered by pharmacy. Patient was hospitalized on 1/31/21 due to shortness of breath and diminished O2 sats down to 88%. Patient was in atrial fibrillation. Patient discharged from hospital on 2/25/21 to home. Patient received dose 2 of Moderna Vaccine on 2/25/21 prior to discharge from hospital. Last hospital note stated that patient was pleasant and cooperative with good motivation. Patient passed away after discharge from the hospital on 2/26/21. Patient's son called the hospital to report his passing.	No prior vaccinations for this event.	
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**	
was reported to staff at Health Department that client passed away hours after receiving Moderna vaccine, also reported that client had multiple health conditions.	No prior vaccinations for this event.	
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**	
No pulse and no heart beat; couldn't wake him up; passed away; A spontaneous report was received from a daughter concerning a 84-year old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) experienced no pulse or heartbeat, couldn't wake him up and passed away. The patient's medical history, as provided by the reporter, included high blood pressure and prostate cancer. No relevant concomitant medications were reported. On 19 Jan 2021, the patient had a blood pressure reading of 133/84 at a cardiology visit. On 13 Feb 2021, approximately 3 hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (batch number 031M20A) intramuscularly for prophylaxis of COVID-19 infection. On 13 Feb 2021 at 3:30 pm, the patient could not be woken up and was found with no	No prior vaccinations for this event.	

pulse or heartbeat. Action taken with the drug in response to the events was not applicable. The outcome of the events, no pulse or heartbeat and couldn't wake him up, were not provided. The patient died on 13 Feb 2021. The cause of death was unknown.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. The patient's medical history of high blood pressure and prostate cancer remains the risk factors. The cause of death was unknown. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
On 3/2/2021, clinic was notified by patient's family that patient had deceased on 2/28/2021 from a heart attack. Unsure of any relation to the Moderna vaccine but reporting for due diligence.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
9 days after vaccination, the patient was found deceased in his home, sitting on his couch. Determined to be due to pulmonary embolism.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
DEATH Narrative: Son stated that patient was doing well, still working and driving places. He stated that he called his son and stated that he wasn't feeling well and died shortly after that.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**

DEATH Narrative: UNSURE DETAILS OF EVENT, NO DOCUMENTATION IN PROGRESS NOTES

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

DEATH No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

death Narrative: unclear of details, s/p spine surgery on 2/2/21 and discharged on 2/6/21 No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Case passed away on 2/28/21. During post vaccination monitoring, case did not have any adverse reactions. When writer spoke to him on 2/26/21 to schedule his second dose, he sounded well.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

approximately 24 hours post vaccine Patient developed a low grade fever of 99.5 and had increased fatigue. 48 hours later she had decreased neurological functioning. 02/23 she had difficulty swallowing. 02/23 She was admitted to hospice services. 02/26 she passed just before 10 am. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Spontaneous intracerebral hemorrhage and death on 2/20/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Death Narrative: Family was able to be present at bedside shortly after patient was extubated. Fentanyl bolus given 10-15 minutes prior. Patient passed away soon after endotracheal tube removed. Time of death 10:14am. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Within 10 minutes following the second vaccination, patient reported dizziness and nausea, had an episode of vomiting but recovered within 30 minutes. It was reported to our clinic that the patient was found deceased on March 1, 2021 at approximately 10 pm. Cause of death is not determined at this time. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

The day after the administration of the vaccine, the fever began, the patient claim that he had no blood No prior vaccinations

pressure problems. He was given acetaminophen every 4 hrs. and vitamin C and D. On February 11, he was stabilized, he had his regular meals without any problem but in the afternoon his temperature rose again and they put him to bed. The patient died that same afternoon around 4:00 pm | for this event.

DEATH | **COVID19 (COVID19 (MODERNA)) (1201)**

death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

2nd dose of Moderna at 9:00am. No side effect (except pinch at injection site) throughout the day and evening. At ~9:45pm, my wife suddenly fell unconscious. Immediate CPR & with Paramedic were not able to revive her. SHE PASSED AWAY at home. We believe it may be triggered by the vaccine. Did not have a chance to go to hospital or emergency room - it was too sudden. A sad day for us. | No prior vaccinations for this event.

DEATH | **COVID19 (COVID19 (MODERNA)) (1201)**

Beginning in the evening 2/19/21, fever/chills/fatigue; worsening of symptoms 2/20/21 with lethargy/lack of appetite/weakness; unable to arouse on 2/21/21 then breathing stopped, patient's spouse called 911 performed CPR, EMS continued for 15 min then while in ambulance to hospital where he was pronounced dead. Official time of death 2:20pm | No prior vaccinations for this event.

DEATH | **COVID19 (COVID19 (MODERNA)) (1201)**

From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering | No prior vaccinations

along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021

for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

expired at Hospital No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Client passed away 8 days after being vaccinated. It is unknown if it occurred from the vaccine or other comorbidities.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Admitted to hospital 2/22/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

The coroner called Dr. on 3.2.2021 to advise that he had a witnessed collapse and Mr. was taken to the ED where he was pronounced.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19

	(MODERNA)) (1201)
Passed away; UTI; Abnormal bleeding; A spontaneous report was received from a healthcare professional concerning a patient who received the Moderna COVID-19 Vaccine (mRNA-1273) and experienced abnormal bleeding, UTI, and passed away. The patient's medical history included a long term history of anticoagulation therapy. Concomitant product use included anticoagulation therapy. On 31Jan2021 prior to the onset of the events the patient recieved their first dose of mRNA-1273 (Lot number:not reported) intramuscularly for prophylaxis of COVID-19 infection. On 07Feb2021, the patient complained of abnormal bleeding. Patient was seen at clinic on 10Feb2021 and was diagnosed with a UTI and given antibiotics. An INR was also completed that day due to patient having a long term history of anticoagulation therapy. Results of that showed the INR to be 12. Prior to vaccination, patient's INR was normal and no changes to medications and diet were made after vaccination and prior to complaint starting. On 12Feb2021 the patient passed away. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12Feb2021. The cause of death was unknown. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns an 82 year old male patient, with history of long term anticoagulation therapy (unknown indication), who experienced a fatal event of death and abnormal hemorrhage, 13 days after receiving second dose of mRNA-1273 (Lot# Unknown). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Unresponsive; A spontaneous report was received from Pfizer concerning a 43-year old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had a sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 08 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 09 JAN 2021, the patient died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 08 Jan 2021.	No prior vaccinations for this event.

The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
chronic hypoxia respiratory failure; Unresponsive; A spontaneous report was received from Pfizer concerning a 51-year old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had developed hypoxia a sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 07 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 07 Jan 2021, around 6:00 pm, the patient became increasingly hypoxic. He was transported to the hospital for acute on chronic hypoxia respiratory failure. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Jan 2021 at 11:25pm. The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Death; A spontaneous report was received from a reporter concerning a 56-year old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and had experienced death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 23 Dec 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 08 Jan 2021, the patient died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 08 Jan 2021. The cause of death was	No prior vaccinations for this event.

not provided. Plans for an autopsy were not provided.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Unresponsive; A spontaneous report was received from Pfizer concerning a 58-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 30 Dec 2020, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 04 Jan 2021, the patient died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 04 Jan 2021. The cause of death was unknown/not reported. Plans for an autopsy were unknown/not provided.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Sudden death; A spontaneous report was received from Pfizer concerning a 60-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 12 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 13 Jan 2021, the patient was found to be deceased at 3:00 am. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 13 Jan 2021. The cause of death was unknown/not reported. Plans for an autopsy were unknown/not provided. .; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further	No prior vaccinations for this event.

information has been requested.; Reported Cause(s) of Death: unknown cause of death

DEATH	COVID19 (COVID19 (MODERNA)) (1201)
Blood pressure went down until he died; Couldn't hear his heartbeat; neck was sweating; He was cold; Couldn't get up; Death; Sick; immediately very tired; he was tired; Hands were shaking; Slept for too long; A spontaneous report was received on 18 Feb 2021 from a consumer concerning a 81-years-old, male patient who received Moderna's COVID-19 vaccine and developed immediately very tired, hands were shaking, neck was sweating, was cold, sick, couldn't get up, couldn't hear his heartbeat and blood pressure went down until he died. Patients' medical history, as provided by patient's spouse, was emergency room(ER) admission in November 2020 because he had a congested chest (he had fluid around his heart). At that time, they gave him pills for kidney function. Other concomitant medication reported was Coumadin, blood thinner. Two weeks before receiving the vaccine, patient's EKG was normal. On 11 Feb 2021, in the morning, patient received their first of two planned doses of mRNA-1273(BATCH/LOT # 007M20A) probably in the right arm for the prophylaxis of COVID-19 infection. On 11 Feb 2021, approximately after 15 minutes of receiving vaccine, they left and patient was immediately very tired, his hands were shaking. So, patient's spouse made them down sleep for too long. On Friday, 12 Feb 2021 she tried to pick him up, but he was tired, exhausted, and sick. On Saturday, 13 Feb 2021, she brought him a coffee and he couldn't hold it because his hands were shaking, so she gave him the coffee and then made him pee on the bed because he couldn't get up. At lunch time she made him eat something and he fell sleep again. His wife was hanging around him all day and around 7:30pm she realized that he was cold, and his neck was sweating, she couldn't hear his heartbeat. So, she called emergency services and when they arrived, her husband's blood pressure went down until he died. Treatment for the events were not provided. Action taken with mRNA-1273 was not applicable. Patient was pronounced dead on 13 Feb 2021 20:00. The cause of death was not provided. The plans for an autopsy were not provided. The events of blood pressure went down until he died and couldn't hear his heartbeat were fatal. The outcome for the remaining events were unknown.; Reporter's Comments: This case concerns an 81 year old, male patient, who experienced a serious event of death among others, 2 days after receiving mRNA-	No prior vaccinations for this event.

1273 (Lot# 007M20A). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Chills; headache; extreme fatigue; gas or chest pain that was thought to be gas and went away Died 4 days later

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

No reported adverse effects after vaccine was administered. Someone reported to our clinic that patient was found dead at home on Sunday

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

patient died. No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

passed away No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

Patient was found deceased later in the afternoon. No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

Prt was found deceased No prior vaccinations for this event.

DEATH COVID19 (COVID19 (MODERNA)) (1201)

DEATH Narrative: UNCLEAR WHY PATIENT WAS HOSPITALIZED AS LIMITED INFORMATION IN RECORD

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient passed away after getting the 1st dose of COVID vaccine. He seemed otherwise very healthy.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient seemed otherwise healthy before the vaccination. Patient was hospitalized then shortly passed after getting the 1st dose.

No prior vaccinations for this event.

DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received Moderna COVID-19 vaccine on 2/25/2021. Patient found dead by family the morning of 2/26/2021. Family requested an autopsy.		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
Death; A spontaneous report was received from a other health care professional concerning a 57-year-old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and died. The patient's medical history included chronic obstructive pulmonary disease (COPD). Concomitant product use was not provided. On 02 Feb 2021, prior to onset of the events, the patient received his first of two planned doses of mRNA-1273 (Lot number: 043L20A) in the left arm for prophylaxis of Covid-19 infection. 03 Feb 2021, it was reported that the patient died. The patient was not experiencing any symptoms prior to death. He was on hospice care, not hospitalized. No further information was provided. Treatment information was unknown. The cause of death was not reported. Plans for an autopsy were unknown. Action taken with the mRNA-1273 in response to the event was not applicable.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine administered with no immediate adverse reaction at 11:29am. Vaccine screening questions were completed and resident was not feeling sick and temperature was 98F. At approximately 1:30pm the resident passed away.		No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Spouse awoke 12/20 and found spouse dead. Client was not transferred to hospital.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Within 24 hours of receiving the vaccine, fever and respiratory distress, and anxiety developed requiring oxygen, morphine and ativan. My Mom passed away on the evening of 12/26/2020.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

RESIDENT CODED AND EXPIRED No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Injection given on 12/28/20 - no adverse events and no issues yesterday; Death today, 12/30/20, approx.. 2am today (unknown if related - Administrator marked as natural causes)

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death by massive heart attack. Pfizer-BioNTech COVID-19 Vaccine EUA No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

pt passed away with an hour to hour and 1/2 of receiving vaccine. per nursing home staff they did not expect pt to make it many more days. pt was unresponsive in room when shot was given. per nursing home staff pt was 14 + days post covid		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
pt was a nursing home pt. pt received first dose of covid vaccine. pt was monitored for 15 minutes after getting shot. staff reported that pt was 15 days post covid. Pt passed away with in 90 minutes of getting vaccine		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
pt received vaccine at covid clinic on 12/30 at approximately 3:30, pt vomited 4 minutes after receiving shot--dark brown vomit, staff reported pt had vomited night before. Per staff report pt became short of breath between 6 and 7 pm that night. Pt had DNR on file. pt passed away at approximately 10pm. Staff reported pt was 14 + days post covid		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received vaccine per pharmacy at the facility at 5 pm. Approximately 6:45 resident found unresponsive and EMS contacted. Upon EMS arrival at facility, resident went into cardiac arrest, code initiated by EMS and transported to hospital. Resident expired at hospital at approximately 8 pm		No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received vaccine in am and expired that afternoon. Tetanus toxoid	
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident found unresponsive without pulse, respirations at 04:30 CPR performed, expired at 04:52 by Rescue	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine 12/30/2020 Screening PCR done 12/31/2020 Symptoms 1/1/2021 COVID test result came back positive 1/2/2021 Deceased 1/4/2021	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine given on 12/29/20 by Pharmacy. On 1/1/21, resident became lethargic and sluggish and developed a rash on forearms. He was a Hospice recipient and doctor and Hospice ordered no treatment, just to continue to monitor. When no improvement of codition reported, doctor and Hospice ordered comfort meds (Morphine, Ativan, Levsin). Resident expired on 1/4/2021	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

LTCF Pfizer Vaccine clinic conducted 12/29/2020 Vaccine lead received a call indicating that a staff member deceased somewhere between 1/3/2021 and 1/4/2021. Cause of death is unknown, and an autopsy is being performed.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The resident was found deceased a little less than 12 hours following COVID vaccination, and he had had some changes over the last 2 days. He was 96 and had been on hospice care for a little while. Noone noticed any side effects from vaccine after it was given	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Expired 1/05/2021 No prior vaccinations for this event.	

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"Pt last seen at 1200 by nurse for ID band check. No visible signs of distress noted. Pt states ""I just want to be left alone"". 1230 nurse was called to pt room. Pt was noted unresponsive, no pulse and respiration noted. CPR started immediately, at 1239 first shock given. 1245 EMT took over, at 1319 EMT called time of death"

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient developed hypoxia on 1/4/2021 and did not respond to maximal treatment and passed way on 1/5/2021

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

patient declined 12/30/2020 and was transferred to hospital where he did not respond to treatment and passed away 1/4/2020

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated at 11am and was found at the facility in his room deceased at approximately 3:00pm. Nurse did not have cause of death

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

3:07 pm lung sounds diminished oxygen sats 68%, oxygen applied Oxygen sats remained low for next 36 hours (patient on Hospice care) expired 6:22 am 1-8-21

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Cardiac event, 2 days after vaccination, patient expired. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Diarrhea followed by death 24 hrs after vaccination No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1/7-21 - Received second dose of pfizer covid-19 vaccine 1/8/21 - Fever, dizziness, headache 1/10/21 0250 was found not breathing. EMS performed CPR and patient deceased

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

RECIEVED VACCINE 1/8/21 EXPIRED UNEXPECTED 1/10/21, NO ADVERSE REACTIONS NOTED

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient died, I have a copy of his vaccination card No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Acute anterior MI with death No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient went to bed around 11pm on Saturday PM and sometime between then and 1:30am on Sunday morning got up and went into the living room without waking up her husband (which is normal). At 1:30am, the husband got up to use the restroom and she was out of bed then, but the husband did not know if she was having any problems at this time. When he got up at 7:45am, she was in the recliner and did not move or anything, which is normal for her. At 8:45am, the husband went back into the living room and tried to wake his wife and that is when he noticed there was no pulse and he called 9-1-1 at this time. EMS got on

No prior vaccinations for this event.

scene and did CPR for 30 mins and she was pronounced dead at 9:21am.

DEATH	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
COVID-19; COVID-19; Pneumonia; respiratory failure; This is a spontaneous report from a contactable consumer. An 80-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 02Jan2021 for COVID-19 immunization. Medical history included Alzheimer's and others. No known allergies. Concomitant medications included unspecified medications. The reporter's mother in law was tested for COVID-19 at a nursing facility on 25Dec2020 and she was negative. On 02Jan2021, she received the first dose of Pfizer vaccine. On 04Jan2020, she developed a high fever, needed oxygen and was positive for COVID-19. Date of death was 04Jan2021. The cause of her death was listed as pneumonia, respiratory failure and COVID-19. No autopsy performed. No treatment received. No one knew if the vaccination contributed to her death. It was hard to know if her death was due to the administration of the vaccine or it exacerbated the COVID19 symptoms which led to her death. Since this was unknown, it could have been a possibility. The reporter wanted to give us this information because we might want to consider having high risk population, patients with underlying conditions, older population tested for COVID-19 prior to the vaccination, as this is not currently a recommendation or a requirement. All is very new and they are all learning so the reporter wanted to share this information with us. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There are medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. The outcome of the events was fatal. Information about Lot/Batch has been requested.; Sender's Comments: The association between the fatal event lack of effect (pneumonia, respiratory failure and COVID-19) with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well	No prior vaccinations for this event.

as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19

DEATH	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was okay, but he was very agitated; reported as not like this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall	No prior vaccinations for this event.

asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

There were no adverse reactions. Resident Died, she had a history of issues with her health prior to the vaccine.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

My mother was given Pfizer vaccine on Thursday and she died 3 days later yesterday on Sunday!!!

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Difficulty breathing, death. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident was found deceased at approximately 6pm in her apartment No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

unsure if related to vaccine, but was notified by her next of kin that she died on 1/4/2021. No reports of side effects or hospitalization were reported to the facility prior to the notification of death.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Hospice Resident received first Covid 19 vaccine dose on 1/6/21. 1/7/21 resident had decreased appetite noted in am but ate 100% of meal at dinner. 1/9/21 resident had decreased appetite with emesis x 2, loose BM x 2. Call placed to hospice. 1/10/21 5:44 am resident able to take HS meds, ingest 2 cups of shake. No

No prior vaccinations for this event.

emesis or loose stool noted. 12PM nurse noted resident not eating meals but ingesting milkshake and medications without any problems. Hospice contacted for change in condition. 1:00 pm hospice ordered Phenergan 12.5 mg Q 6 hrs PRN. Labs to be drawn 1/11/21. Hospice notified POA. 1/11/21 12:24am Resident had blood in stool. Resident denies any pain, on 2L of O2 for comfort.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	patient passed away after receiving the Covid vaccine; This is a spontaneous report from a contactable nurse. An 81-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), intramuscular into the right arm on 07Jan2021 at 0.3 mL, single for covid-19 immunization. There was no medical history and no concomitant medications. On 08Jan2021, the patient passed away after receiving the COVID vaccine. The patient died on 08Jan2021. An autopsy was not performed. Investigations indicate that unspecified labs were done, but nothing two weeks prior; no further details were provided. The patient received the first dose the day prior. The reporting nurse discussed it with the medical director, and he thought that he potentially passed away from the COVID vaccine. The relatedness of the event to the suspect vaccine was reported as related by the reporting nurse per The Agency. The batch/lot number for the vaccine, BNT162B2, was not provided and will be requested during follow-up .; Sender's Comments: Based on the limited information available, it is medically not possible to make meaningful causality assessment, it is unlikely the vaccine could have contributed to the death of the patient based on the known safety profile. However case will be reevaluated when additional information is received during the follow-up The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Stated that the patient passed away after receiving the Covid vaccine	No prior vaccinations for this event.

DEATH	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"Cardiac Arrest; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; This is a spontaneous report from a contactable other healthcare professional (HCP). A 66-year-old female patient (pregnant at the time of vaccination: no) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284) via intramuscular at left arm on 11Jan2021 12:15 PM at single dose for COVID-19 immunization. Medical history included diastolic CHF, spinal stenosis, morbid obesity, epilepsy, pulmonary hypertension and COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19). The patient received medication within 2 weeks of vaccination included amiodarone, melatonin, venlafaxine hydrochloride (EFFEXOR), ibuprofen, aripiprazole (ABILIFY), lisinopril, cranberry capsules, diltiazem, paracetamol (TYLENOL), famotidine, furosemide (LASIX [FUROSEMIDE]), ipratropium bromide, salbutamol sulfate (IPRATROPIUM/ALBUTEROL), buspirone, senna alexandrina leaf (SENNA [SENNA ALEXANDRINA LEAF]), polyethylene glycol 3350 and morphine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient used took Penicillin, propranolol, quetiapine, topiramate, Lamictal and had allergy to them. Patient used took the first dose of BNT162B2 (lot number: EJ1685) via intramuscular at right arm on 21Dec2020 12:00 PM at single dose for COVID-19 immunization. Since the vaccination, the patient been tested for COVID-19 (Sars-cov-2 PCR) via nasal swab on 06Jan2021, covid test result was negative. Patient was found pulseless and breathless 20 minutes following the vaccine administration (11Jan2021 12:30 AM). MD found no signs of anaphylaxis. Patient died on 11Jan2021 12:30 AM because of cardiac arrest. No treatment received for the events. Outcome of pulseless and breathless was unknown. the autopsy was performed, and autopsy remarks was unknown. Autopsy-determined cause of death was unknown. It was reported as non-serious, not results in death, Life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.; Sender's Comments: Based on the available information this patient had multiple underlying medical conditions including morbid obesity, diastolic CHF, epilepsy, pulmonary hypertension and COVID-19	No prior vaccinations for this event.

diagnosed prior to vaccination. All these conditions more likely contributed to patients cardiac arrest resulting in death. However, based on a close temporal association (""Patient was found pulseless and breathless 20 minutes following the second dose of BNT162B2 vaccine administration, contributory role of BNT162B2 vaccine to the onset of reported events cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Cardiac arrest; Autopsy-determined Cause(s) of Death: autopsy remarks was unknown. Autopsy-determined cause of death was unknown"

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Actual event and cause of death were unknown; This is a spontaneous report from a non-contactable consumer. A 90-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06Jan2021 at single dose for COVID Prevention. The relevant medical history included aortic valve replacement from Nov2019. Concomitant medications were not reported. The consumer stated that she was taking the reporting responsibilities to report that a friend of hers, informed that the patient passed away on Friday, and had received the COVID vaccine on Wednesday. The consumer stated that it was unknown to her at this time, if the friend had called to complete a report herself, regarding the incident. Their conversation was very brief. The patient was 90 years old, and it was her friend's mother that was the patient. Actual event and cause of death were unknown. The patient had her vaccine on Wednesday 06Jan2021, and then the patient collapsed in front of the reporter at Friday night on 08Jan2021 and passed away that same day. The autopsy was unknown. The outcome of the event was fatal. No follow-up attempts are possible; information about lot/batch number	No prior vaccinations for this event.

cannot be obtained.; Reported Cause(s) of Death: Actual event and cause of death were unknown

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
little bit of a reaction light headed after 5 minutes. vitals were low, so observed for 30 minutes after being light headed. Patient was found unresponsive and pronounced dead later that day.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death occurred 3 days after vaccine receipt; attributed to complications of her chronic advanced dementia with aspiration at age 87. No evidence of acute vaccine reaction.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.		Influenza Virus Vaccines - Unknown date/type or brand
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - anuerism lead to death approximately 14 hours after initial symptoms.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
resident coded on 09Jan at 8am and expired; This is a spontaneous report from a contactable Other Health Professional. A 70-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EL0140), intramuscularly in left arm on 05Jan2021 15:15 at single dose for COVID-19 immunization. Medical history included DM2(Type two diabetes mellitus), CHF(congestive heart failure), open wound, wound infection, heart failure. Allergies to medications, food, or other products: none. Concomitant medications included unspecified products (List of any other medications the patient received within 2 weeks of vaccination: yes). If the patient received any other vaccines within 4 weeks prior to the COVID vaccine: Unknown. Facility where the most recent COVID-19 vaccine was administered: Nursing Home/Senior Living Facility. The resident coded on 09Jan2021 at 8 AM and expired. The patient died on 09Jan2021. An autopsy was not performed. AE resulted in: patient died. Death cause: unknown at this time. Was treatment received for the adverse event: Unknown. Prior to vaccination, was the patient diagnosed with COVID-19: No. Since the vaccination, has the patient been tested for COVID-19: No. Serious: Yes. Seriousness criteria-Results in death: Yes. Seriousness criteria-Life threatening: No. Seriousness criteria-Caused/prolonged hospitalization: No. Seriousness criteria-Disabling/Incapacitating: No. Seriousness criteria-Congenital anomaly/birth defect: No.; Sender's Comments: The old patient had diabetes mellitus, congestive heart failure, open wound complicated by infection, all these pre-existing medical conditions contribute to the patient death. More information including complete medical history, concomitant medications and event term details especially death cause and autopsy results are needed for a full assessment of the case. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for	No prior vaccinations for this event.

adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate; Reported Cause(s) of Death: resident coded on 09Jan at 8am and expired

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident expired on 12/30/20, dx cardiac arrest. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident expired on 1/2/21. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Cardiac arrest within 1 hour Patient had the second vaccine approximately 2 pm on Tuesday Jan 12th He works at the extended care community and was in good health that morning with no complaints. He waited 10-15 minutes at the vaccine admin site and then told them he felt fine and was ready to get back to work. He then was found unresponsive at 3 pm within an hour of the 2nd vaccine. EMS called immediately worked on him 30 minutes in field then 30 minutes at ER was able to put him on life support yet deemed Brain dead 1-14-21 and pronounced dead an hour or so later

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

On 1/11/21 noted with headache, nausea/vomiting, severe melaise. On 1/12/21

No prior vaccinations for this event.

resident expired.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
71yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, VS taken at 10am, B/P 99/60, O2 sats, 95% (trach w/O2). At 11:30am, Patient showed no s/sx of distress, A&Ox3. At 11:50am, a nurse went to perform a COVID test and assessment (the facility is experiencing an outbreak), and found the patient unresponsive on the bathroom floor. CPR was immediately started; no shock advised per AED; 12:15pm EMS arrived and took over. At 12:38pm, EMT called time of death.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Has underlying dementia and often with difficulty eating. 1 week after immunization she developed a stroke with left sided weakness and difficulty swallowing. Comfort measures instituted. Not sure if this is related to the vaccine, but thought I should report		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"83yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, the patient reportedly got up in the middle of the night with c/o feeling ""blah"", restlessness, and nausea. VS normal, no other s/sx. At 4:15am, the patient was asked to go back to bed, assisted by a nurse and GNA. At 6am, GNA was going to do morning VS and found the patient unresponsive, no pulse, no respirations. GNA notified the nurse. At 6:03am, CPR started and EMS called. At 6:15am, EMS arrived and took over. At or		No prior vaccinations for this event.

around 6:30am, EMT called time of death"

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No reactions immediately after vaccine was given. Resident has dementia, has had multiple hospitalizations related to a renal stone recently. Had a tooth that was bothering her, went to see her dentist and it was extracted on 1/6/21. On 1/10 they noted feet and ankles are dark purple with white splotches appears to be mottling. Minimally responsive to voice and touch. Not eating. Compassionate visit with family. Family did not want hospice, did not feel it was needed, said, what more could they do for her than you're already doing? On 1/11 at 1950 was determined to be deceased.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
At approximately 10:30pm on 1/14/2021, resident was noted to have a rash on her face, hands, arms, and chest. VS:100.2, 113, 20,108/59, 84% room air. applied nasal cannula at 4-L, telephoned Physician orders 6mg Decadron one time order, a second set of Vitals , reads 99.3, 110, 20, 106/60, 90% on 4-L N/C. On coming shift advised. At approximately 2:00am on 1/15/2021, resident congested and coughing. BP 151/70, pulse 124, temp 98.1 forehead, resp 20 and pulse oc 79% on 3L. At approximately 2:30am PRN cough syrup and breathing tx. Resident's condition began to worsen with breathing tx. This LPN updated at 0248 doctor on resident's condition. Doctor gave permission for resident to go to hospital. At 4:19am the Er called to say resident passed away.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH))**

		(1200)
died two days after receiving the vaccine; Fever; This is a spontaneous report from a contactable consumer (patient's stepchild). A 66-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 07Jan2021 (at the age of 66-years-old) as a single dose for COVID-19 immunization. The patient's medical history was not reported. Concomitant medications included an unspecified statin. The patient experienced fever on 08Jan2021. The patient died two days after receiving the vaccine on 09Jan2021, which was reported as fatal. The clinical course was reported as follows: The patient had a fever the day after getting the vaccine and then he just died in the middle of night. It was reported that it was not clear what exactly happened, but they are looking into this. The clinical outcome of fever was unknown and of died two days after receiving the vaccine was fatal. The patient died on 09Jan2021. The cause of death was not reported. An autopsy was not performed (was reported to be taking place soon). The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: died two days after receiving the vaccine		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient reportedly expired the day following receipt of the vaccine. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Expired on 1/12/2021; unknown cause of death No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Veteran was found by family slumped over and unresponsive at the breakfast table on 1/13/21, had expired

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile

No prior vaccinations for this event.

stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient became sick 3 hours after the vaccine and was found deceased 1 day after his vaccination. He passed away in his sleep.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 1/17/2021 at 4:35 am resident found apneic and pulseless, at 4:40am death confirmed

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

resident expired; This is a spontaneous report from a contactable healthcare professional. An 82-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EL0140), intramuscular in the left arm on 05Jan2021 15:00 at a single dose for COVID-19 immunization. Medical history included metabolic encephalopathy from, failure to thrive (FTT), diabetes mellitus (DM) 2 , chronic obstructive pulmonary disease (COPD), arthritis, weakness, hyperlipidemia, chronic kidney disease (CKD), dementia. Known allergies was none. The patient took unspecified concomitant medication. On 11Jan2021, the resident expired. The patient underwent lab tests and

No prior vaccinations for this event.

procedures which included nasal swab: negative on 09Jan2021. There was no treatment given for the event. The patient died on 11Jan2021. An autopsy was not performed.; Sender's Comments: Lacking information on the cause of patient's demise, the Company cannot completely exclude a causal relationship between COVID 19 vaccine, BNT162B2, and patient's death of unknown cause, as a cautionary measure and for reporting purposes. The patient's pre-existing medical condition of metabolic encephalopathy from, failure to thrive (FTT), diabetes mellitus (DM) 2 , chronic obstructive pulmonary disease (COPD), arthritis, weakness, hyperlipidemia, chronic kidney disease (CKD), dementia may have provided the contribution to the event in this 82-year-old male patient. The impacts of this report on the benefit/risk profile of the product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: resident expired

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

patient suddenly developed pneumonia 7 days after vaccination and died the evening of developing pneumonia

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

REPORTING ONLY AS RESIDENT EXPIRED ON 1/17/2021 3 DAYS AFTER. S/S HYPOXIA/CONGESTED LUNG SOUNDS

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

The day following the vaccine, the patient complained of throat issues and anxiety. This was not new... however . That evening he reported difficulty breathing and was placed on oxygen; a COVID test was performed and was negative. On 12/30/2020, patient complained of sternal pressure and was transferred to the hospital. The patient died 12/31/2020 and records obtained from the hospital indicated the patient died from a massive myocardial infarction.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

71 year old woman at rehabilitation center for physical therapy with history of cirrhosis of the liver, asthma, and heart condition was tested for COVID-19 on 01/07/21, received 1st dose of Pfizer COVID-19 vaccine on 01/08/21, positive test result for COVID-19 received on 01/09/21. She was sent to the hospital and admitted on 01/12/21 after O2 was 70% and was in a confused state. Patient passed away on 01/17/21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident received vaccination on January 15, 2021. She was found unresponsive with shallow respirations on the morning of January 16, 2021 and was sent to ER via ambulance. The resident was admitted to medical center ICU where she passed away later that day.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

patient received vaccine 12/29. Unexpected death 1/5. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of

No prior vaccinations for this event.

0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Family was told that Patient expired in his sleep during the early morning hours of 1/15. I spoke with him the evening before (on 1/14), which was a day after he had received the Covid vaccine. He was not having any symptoms of allergy or reaction then. He did say that he felt tired, but he often complained of feeling tired over time.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident was found deceased in his bed at 7:15 am. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death 3 days after receiving 2nd dose of COVID vaccine, unknown if related to vaccine administration.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death by suicide Narrative: death by suicide; 12/26/20, self inflicted gun shot wound; found deceased by family member	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death on 1/15/2020	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated	No prior vaccinations for

medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."	this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"died; tested positive for COVID; tested positive for COVID; This is a spontaneous report from a contactable consumer from a Pfizer-sponsored program, Pfizer First Connect. A 97-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 30Dec2020 at 97-years-old at a single dose for COVID-19 immunization; administered by the nursing home. Medical history included glaucoma from an unknown date and unknown if ongoing. Concomitant medications included: ""used a sav for skin tears"", and ""eye drops for glaucoma"" from an unknown date to an unknown date. On 07Jan2021, the patient experienced: tested	No prior vaccinations for this event.

positive for COVID (medically significant). The patient died (death, medically significant) on 17Jan2021. The clinical course was reported as follows: The reporter stated that in regard to the patient's height and weight: ""was probably getting down to about five foot eight. Shrinking."" The reporter stated that If she remembered correctly, they were trying to maintain the patient's weight 135 to 136 pounds. The reporter stated that her father was in a nursing home. The patient received his first dose of the COVID vaccine on 30Dec2020. The patient died on 17Jan2021. The reporter stated that she ""wanted Pfizer to know that the little old people in the nursing might not be strong enough for the vaccine."" The reporter stated that she was ""not calling to complaining."" The reporter stated that there was nothing wrong with her dad. He was elderly with no health issues. ""He was literally on no medications. The only reason he was in the nursing home was because he was afraid to walk."" The reporter stated that she received a call about giving the patient the vaccine and she said yes because she wanted him to have the vaccine. One week after the vaccine, the patient tested positive for COVID ""like all the other people"" (no further details provided). The reporter stated that her dad had no symptoms of COVID. The director of nursing said the patient was doing so well. The patient ate his lunch, he laid down for nap, and at 14:30 he was gone. The patient ""went peacefully in his sleep."" The reporter then again stated that the patient literally had nothing wrong with him. ""They were shocked. They fed him and he took a nap. He was sleeping, but it was eternally."" The reporter stated that, ""it might not have been the Pfizer vaccine, maybe his heart wore out."" In regard to an autopsy: the reporter stated that they would get it done if needed. The patient underwent lab tests and procedures which included COVID-19 virus test: positive on 07Jan2021. History of all previous immunization with the Pfizer vaccine considered as suspect: none. It was unknown if there were additional vaccines administered on the same date of the Pfizer suspect, but the reporter doubted it. There were no prior vaccinations within 4 weeks. There were no adverse events following the prior vaccinations. The clinical outcome of the event, died, was fatal. The clinical outcome of the event, tested positive for COVID, was unknown. The patient died on 17Jan2021 due to an unknown cause of death. An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: died"

DEATH	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
At approximately 930am I arrived at Memory Care. I met with the director of the facility and she directed me to where my team would be setting up. My team consisted of (technician), (nurse) and I. As we were setting up, the director asked how she can help. I explained to her that we would need a designated area for patients to be monitored after vaccination for 15 minutes and maybe even longer . I also explained that we would need one of her staff monitoring while we vaccinate. She agreed, and proceeded to designate her staff and the cafeteria area, facing the vaccination station,the monitoring station. Throughout the day, nurse and I were both vaccinating,while the staff of the facility would monitor the vaccinated patients. I would also stop occasionally to mix the vaccine and check the temperature of the aero safe. At approximately 12:50pm, the director rushed in and stated that a patient is not responding, and that she had been vaccinated. At that point, I grabbed epipens and a thermometer and I also instructed nurse to grab an Epipen and come with me. We followed the director to pt's room. Once we got to the room, the patient was in bed and there were 4 staff members standing bedside and one of them turned and stated the patient has passed. At that point I asked the staff how long ago did the patient get the vaccine, they stated about 30 minutes ago. They also stated that the patient was a hospice patient and that the patient had declined, and was rapidly detiorating and had not eaten or drank anything all day . They also stated that the patient had been monitored for 15 minutes post vaccination. I then left the room and grabbed the patients COVID Vaccine intake consent form. I looked at the answered questionaire and all the responses were circled NO. Patient had a temp of 96.5 at the time of vaccination.The vaccine administration information for Immunizer Section was filled out by Nurse. I then proceeded to ask the director once again if there were staff that was monitoring her for 15 minutes, the director stated they had staff monitoring her. She also stated the Hospice nurse has to announce her death, so they waited for the Hospice Nurse to come. I then called Corporate and explained the situation. After speaking to corporate, I also asked nurse, if she remembered the patient. She stated that she did and at the time of the vaccination the patient was not alert, there were two staff members with the patient. She was non oriented and she kept closing her eyes. At that point, Nurse stated	No prior vaccinations for this event.

that she asked the two staff members with her if this is how she usually is and if its ok to vaccinate her. Both Staff members stated that it its ok,this is how she is. The Nurse then proceeded to vaccinate. At approximately 3:10pm, as I was leaving I spoke to the director, and one of her Staff members. Staff that the patient has actually not eaten/ or drank anything for the past several days, including today(01/18/21). Staff also stated that on Friday, Jan 15th,2021, they had informed the family that the patient was rapidly detiorating. Staff also stated that the family knowingly gave the consent to vaccinate her. She also stated that the hospice Nurse believes that the death was primarily caused by her detiorating state. She also stated that the hospice Nurse informed that the death was not due to the Vaccine. Per Lead Pharmacist at the clinic.		
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient developed 104.4 temp approximately 48 hours after being given the vaccine. I treated him with antibiotics, IV fluids, cooling methods. CXR does show a new right perihilar infiltrate. However, his fever came down within the next 24-48 hours. Unfortunately, he suffered a cardiac arrest on 1/21/21 in the early morning and expired.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
This is a 94-year-old male who is brought in by ambulance after being found on the floor with unknown downtime. He was in asystole upon EMS arrival. He remains in asystole. No advanced airway is in place. The patient is getting compressions from Lucas device upon arrival. It was reported that he was last talked to by family at 2 PM. The patient got his SARS-CoV-2 vaccination this morning. The patient is evaluated emergently. CPR was ongoing with 3 rounds of epinephrine given. The patient remains in asystole. He has		No prior vaccinations for this event.

rigor mortis. The patient's pupils are fixed and dilated. The patient has compressions paused and ultrasound is used to evaluate for cardiac activity. None is detected. The patient has no electrical activity on monitor. The patient's time of death is 2113.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
approximately 3 hours prior to expiring the patient was experiencing forceful emesis. later was found to have expired, patient was comfort care only.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/13/2021 12:00 PM: Patient received COVID-19 Vaccine. 1/14/2021 21:00: Nurse performed routine rounds and the patient appeared okay. 1/14/2021 22:00: CNA discovered patient unresponsive in bed, began CPR, and called 911. 1/14/2021 23:08: Pronounced deceased.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
tired; legs felt heavy; stopped breathing; This is a spontaneous report from a Pfizer-sponsored program a non-contactable consumer. A 93-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 11:00 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Patient received vaccine around 11:00 a.m. About two hours later, he said he was tired and couldn't continue with the physical therapy he was doing. He was taken back to his room, where he said his legs felt heavy. Soon after, he stopped breathing. A nurse declared a do-not-resuscitate order. The patient died on 04Jan2021. It		No prior vaccinations for this event.

was not reported if an autopsy was performed. Outcome of stopped breathing was fatal. Outcome of tired and legs felt heavy was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: stopped breathing		
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient's wife called this morning stating that her husband has passed away last night. After receiving first dose of Pfizer COVID-19 vaccine at around 0830, patient remained in the Immunizations Department for the 15-minute monitoring period. Per wife, patient's only complaint was pain at the injection site. At 1300, wife states that patient complaint of dizziness which ""dissipated after a few minutes"" followed by a headache which ""dissipated after a few minutes"" as well. Then patient complained of nausea, no vomiting and ""couldn't relax."" Per wife, from around 1400/1500, patient stayed on his recliner while still having a conversation with her--""he didn't get up to eat."" Last conversation they had was around 2000/2100. Per wife, at around 2100/2200, patient was quiet and when she checked on him, ""he wasn't responding anymore."" Wife then called 911, ""but they couldn't revive him.""""		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Admitted to hospital after vaccination with Acute hypoxemic respiratory failure, Septic shock; Aneurysm of arteriovenous dialysis fistula; expired 1/16/2021		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
We do not believe that the patient's death was an adverse event from the vaccine. Patient received COVID		No prior vaccinations for

vaccine from Pfizer Dose #1 12/19/2020 (lot # EK5730) and Dose #2 1/7/2021 (lot # EL1284). No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Patient died 1/10/2021 from chronic respiratory failure and congestive heart failure after recent aspiration pneumonia requiring hospitalization. Death was anticipated and not sudden. We were told to report his death to VAERS even though his death was anticipated and not related to his vaccination.

this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient deceased No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient did not have any adverse reaction to the COVID vaccine, but we were asked by our health dept to submit a VAERS report since the patient died between his first and second dose. Received Pfizer Dose #1 12/17/2020. No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Date of death 12/23/2020 from aspiration pneumonia complicated by end-stage heart failure and ischemic cardiomyopathy. Death was anticipated and not sudden.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

patient expired 1/15/2021; had been treated as outpatient for pneumonia, likely COVID-19 but no positive test result in December 2020. PMH diabetes

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-

	BIONTECH)) (1200)
Admitted 1/14/21: Patient is an elderly 93-year-old female with multiple medical problems including chronic combined CHF, P 80, diabetes mellitus, HTN, hyperlipidemia, CKD stage 3, has been complaining of generalized weakness, fatigue, decreased appetite for the past few days. She had an outpatient COVID-19 vaccine earlier today. Within 2 hr of admitting the patient to the hospital, condition clinically deteriorated. Patient elected to be DNR/DNI while in the ED. Patient was pronounced dead at 10:30 p.m. earlier today. Preliminary cause of death: Hypoglycemia induced lactic acidosis.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On Saturday, 1/16/2021, Patient went to the grocery store. Upon her return, she indicated she was experiencing N/V and some throat swelling. Patient subsequently collapsed and expired before she could be brought to an emergency room. During investigation by Coroners Office, it has been reported that Patient may have gotten some takeout food while she was out. Labs are pending and the Coroners investigation is ongoing. Spouse believes that her death was caused by the vaccine.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21	No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death; This is a spontaneous report from four non-contactable consumers via a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. A 78-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 28Dec2020 at a single dose for COVID-19 immunization. Ongoing medical history included Alzheimer's Disease, encephalopathy, hypertension, acute kidney failure, urinary retention and recent urinary tract infection (UTI), all from an unspecified date. Concomitant medication included acetaminophen (MANUFACTURER UNKNOWN), bisacodyl (MANUFACTURER UNKNOWN), bupropion (MANUFACTURER UNKNOWN), escitalopram (MANUFACTURER UNKNOWN), hydrocodone bitartrate, paracetamol (HYDROCODONE/ACETAMINOPHEN), loperamide (MANUFACTURER UNKNOWN), ondansetron (MANUFACTURER UNKNOWN), senna alexandrina (SENNA PLUS), vitamin d3 (MANUFACTURER UNKNOWN). The patient had no known drug allergies. The patient experienced death on 30Dec2020. The vaccine was given on 28Dec2020 with no adverse events and no issues on 29Dec2020. The patient died on 30Dec2020, at approximately 2:00 AM. It was unknown if an autopsy was performed. It was unknown if the event was related to the suspect drug, the administrator marked as natural causes. No follow-up attempts are possible; information about batch/lot number cannot be obtained.; Reported Cause(s) of Death: Death		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death, which I believe is unrelated to vaccination		No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Death - Hospice patient with metastatic CA admitted to facility and received vaccine during stay. No		No prior vaccinations for

adverse sequelae noted from vaccine administration, but reporting as required because pt died 7 days later. Narrative: Reporting this event because patient died 7 days after receiving vaccine in the facility where he was in hospice care for metastatic cancer. Vaccine was administered by protocol without complications. The patient had been asked and denied any prior severe reaction to this vaccine or its components and gave permission to receive it. No vaccine adverse sequelae were documented after the immunization as monitored for 15 minutes nor in facility notes for 7 days after the immunization. The patient's death was felt to be due to underlying terminal illness.		this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt on hospice in facility for severe cardiomyopathy unable to perform interventions received vaccine without adverse sequelae died 5 days later. Reporting as required. Narrative: Reporting as required patient death 5 days after immunization with Pfizer vaccine. However, no adverse sequelae were noted to the vaccine in the 15minute observation period, nor in the days following the immunization related to the vaccine. The patient denied any prior severe reaction to this vaccine or its components, and the patient gave verbal consent to receive the vaccine. Patient had been in the facility on hospice since 11/18/20 for severe decompensated HF and newly diagnosed cardiomyopathy, unable to perform interventions, also LE ischemic wounds with very poor potential to heal due to advanced PVD.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness; respiratory distress Narrative: Patient tolerated his 1st dose of the COVID-19 vaccine well, on 12/16/2020, and received his 2nd dose on 1/6/2021. Patient had some mild clinical decline the past few days prior to 2nd vaccination, with a decreased appetite and some increased fatigue per		No prior vaccinations for this event.

nursing report, but no significant changes. He experienced nausea on the evening of 1/6/21, which was effectively managed, but by early morning he spiked a fever of 102.9 with a sat of 86.1%. He continued to deteriorate from that point on and died 1/7/21 @13:20. Clinically, the presentation was most consistent with an aspiration pneumonia.

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death on 1-5-21 No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death 1-15-21 No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

resident coded and expired; This is a spontaneous report from a non-contactable consumer via Pfizer Sponsored Program. A 63-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EH9899) intramuscular at single dose at left arm on 28Dec2020 for Covid-19 immunisation. Medical history included no current Illness, no known allergies, but preexisting conditions: dysphagia, violent behaviors, depressive disorder, schizophrenia, aspiration, gastrooesophageal reflux disease (GERD), hyperlipidaemia, bipolar disorder, rectal bleeding, hypertension. The patient had no birth defect. Concomitant medication included asa (ASA) at 81mg, lisinopril (LISINOPRIL) at 10mg daily, ferrous sulfate (FERROUS SULFATE) at 325 (unit unknown), olanzapine (ZYPREXA) at 20mg, morniflumate (FLOMAX [MORNIFLUMATE]) at 0.4 (unit unknown), famotidine (FAMOTIDINE) at 20mg, ascorbic acid (VIT C), carbamazepine (CARBAMAZEPINE) at 250mg bid, valproate semisodium (DEPAKOTE) at 750mg bid, metformin (METFORMIN) at 1000 (unit unknown) bid, sertraline (SERTRALINE) at 100 (unit unknown) bid, albuterol [salbutamol] (ALBUTEROL [SALBUTAMOL]), buspirone hydrochloride (BUSPAR) at 10mg tid, polycarbophil	No prior vaccinations for this event.

calcium (FIBERCON). The patient died on 29Dec2020. The patient had no ER or Doctor visit and was not hospitalized. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: resident coded and expired		
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
passed away; This is a spontaneous report from non-contactable consumers received via a Pfizer-sponsored program An 88-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot EL0142) via an unspecified route of administration on 30Dec2020 at a single dose (1 dose) in the left arm (LA) (administered by: senior living) as Covid vaccine. Medical history included patient was 14 plus days post COVID and unresponsive. The patient had no listed allergies. Concomitant medications were not reported. The patient passed away with an hour and half of receiving vaccine on 30Dec2020. Per nursing staff, they did not expect the patient to make it many more days. She was unresponsive in the room when shot was given. It was unknown if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: passed away		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
respiratory distress; fever; anxiety developed requiring oxygen; Passed away; This is a spontaneous report via a Pfizer-sponsored program from a non-contactable consumer. A 63-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot and expiry not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. Medical history included anaphylactic reaction (broad), neuroleptic malignant syndrome (broad), anticholinergic syndrome (broad), acute central respiratory depression (broad), hypersensitivity (broad), respiratory failure (narrow),		No prior vaccinations for this event.

drug reaction with eosinophilia and systemic symptoms (broad), hypoglycaemia (broad), COVID-19 (broad) and chronic obstructive pulmonary disease (COPD); all from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine sodium and lorazepam (ATIVAN). Within 24 hours of receiving the vaccine, the patient experienced fever, respiratory distress, and anxiety developed requiring oxygen, morphine and lorazepam (ATIVAN). The patient passed away on the evening of 26Dec2020. The patient underwent lab tests and procedures which included SARS-COV-2 antibody test: negative on an unspecified date. The outcome of the event death was fatal, while of the other events was unknown. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Passed a

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Narrative: Please note that patient is a hospice patient. Death occurred 10 days post vaccination. Providers do not believe that there was a correlation. Facility requires that we reports all death even if we suspect no correlation between death and vaccine. Symptoms: & death

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

The employee found dead at her home on 1/21/2021. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to

No prior vaccinations for this event.

improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient unexpectedly died on o1/6/2020. No known signs or symptoms. No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Possible seizer, unknown at this time, aprox 1hr and 20min after vac given. Passed away aprox 2hrs after vac.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death - unknown cause, no reported side effects Narrative: Unknown cause of death

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Within 15 minutes of the injection, the individual became aphasia and stroke like symptoms. She was taken to the ER where she was later diagnosed with a cerebral hemorrhage and passed away.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient expired one week after vaccine. Cause of death unknown to me. No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

patient passed away with in 90 minutes of getting vaccine; This is a spontaneous report from three non-contactable consumer reporting on behalf of the patient via a Pfizer sponsored program, Corporate (Pfizer) Social Media Platforms. A 90 (unspecified unit) old female patient received first dose of BNT162B2

No prior vaccinations for this event.

(PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, lot number: EL0142, unknown expiration), via an unspecified route of administration in right arm (reported as AR) on 30Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient was a nursing home patient and received the first dose of COVID vaccine on 30Dec2020. The patient was monitored for 15 minutes after getting shot. Staff reported that the patient was 15 days post COVID. The patient passed away with in 90 minutes of getting vaccine on 30Dec2020. The patient did not require office/ ER visit. An autopsy was not performed. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Patient passed away with in 90 minutes of getting vaccine

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
reported causes of death :circulatory collapse; asystole; reported causes of death :circulatory collapse; asystole; This is a spontaneous report from a Pfizer-sponsored program received from the Regulatory Authority-WEB GB-MHRA-WEBCOVID-20201214111558, satety Report unique Identifier GB-MHRA-ADR 24542972 and EU-EC-10007191566 received via Regulatory Authority 908245. A contactable pharmacist and three consumers reported that an adult female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 13Dec2020 at a single dose for COVID-19 vaccination. The patient's medical history was not reported. Concomitant medications included acetylsalicylic acid, amiloride HCl, allopurinol, desogestrel, furosemide, levothyroxine, sildenafil, and spironolactone. The patient experienced circulatory collapse and asystole on 13Dec2020. The patient died due to asystole and circulatory collapse on 13Dec2020. It was unknown if an autopsy was performed. No follow-up attempts are possible, information about lot/batch number cannot be obtained. No further information Is expected.; Sender's Comments: The information available is limited and does not allow a meaningful case evaluation. However, based solely on a close chronological association (same day) a causal relationship between events circulatory collapse and cardiac arrest and BNT162B2 (PFIZER-	No prior vaccinations for this event.

BIONTECH COVID-19 VACCINE) cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: reported causes of death :circulatory collapse; asystole; reported causes of death :circulatory collapse; asystole

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
At approximately 12:15 pm the resident had a brief unresponsive episode that resolved quickly. Her Vital signs were stable and her mentation was at baseline. Later that evening approximately 10 pm she had labored respirations, shortness of breath, lethargy with bilateral crackles, Oxygen desaturated to 76% on room air, tachycardia and hypotension. She expired at 6:30 a.m. the following day.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
her mother passed away 7-8 days after receiving the vaccine; This is a spontaneous report from a contactable consumer, the daughter of the patient. A female patient of an unspecified age received the first dose of COVID-19 mRNA VACCINE (MANUFACTURER UNKNOWN), via an unspecified route of administration in Jan2021 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 19Jan2021 about 7-8 days after receiving the vaccine, the patient passed away. The patient was fine before she received the vaccine and then passed away 7-8 days later. The cause of death was not reported. It was not reported if an autopsy was performed. The reporter	No prior vaccinations for this event.

thought her mother's death had everything to do with the COVID-19 vaccine. The lot number for the vaccine was not provided and will be requested during follow up.; Reported Cause(s) of Death: Death

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Reportedly, this employee's mother died the night of the vaccine. The details are not known at this time.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient sent to hospital 1/2 and 1/5. Returned both times to nursing home covid unit without a hospital admission. Resident had been diagnosed with COVID later in the day on 12/30, when routine testing PCR results returned to facility, after resident had already had her first covid vaccination on 12/30/20 in the morning. Resident continued decline, was again sent to hospital on 1/24/21, and expired in hospital 1/25/21.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident expired on 1/23/21 . Resident receiving care under hospice ,diagnosis Acute Myeloid Leukemia.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under	No prior vaccinations for this event.

investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory

failure"""

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident passed away 1/25/2021 at 1048pm after the vaccine was given on 1/24/2021. Resident had been being monitored but death was not expected.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient developed fever to 102 within 24 hours with decreased mentation. Stopped eating/drinking despite aggressively treating fever. Was DNR B status. Family agreed to a trial of IV fluids on 1/21 but was not successfully started until 1/22 after several attempts. Family wanted only comfort measures with no transfer to hospital. Patient continued to have fevers to 102-103 range. Patient passed on 1/23 . Patient did test positive for COVID in early September without significant illness. She was in usual state of health prior to vaccination.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No immediate symptoms. No symptoms ever reported. Patient was found dead in her home on 1/25/2021 and last seen on 1/24/2021. Neighbor called for welfare check because they had not seen her and she had not checked mailbox. No evidence of foul play.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

decedent had shortness of breath and hypoxia, cardiac arrested in front of the EMS crew, ACLS initiated, arrived in the Hospital ED asystole and pronounced dead

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

The patient had a heart attack and died at a local hospital morning of 1/19/2021. No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a

No prior vaccinations for this event.

""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

See initial report No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Narrative: No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient stated he wasn't feeling well on January 25, 2021, wasn't eating and complained of abdominal pain. Patient noted to have indigestion and was constipated. Meds provided and labs ordered. On morning of January 26, 2021, patient became weak, lethargic and hypoxic and was sent to emergency department around 0700 hours on January 26, 2021. At approximately 1100 hours, emergency physician notified this writer that patient was not going to overcome his illness and would be placed on comfort care. At approximately 1130 hours, this writer was notified that patient had passed away from multi-organ failure.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"CC:full arrest HPI:HPI and ROS limited due to patient's condition. History is via EMS, medical record, and son. Per Son patient had Covid vaccine on Saturday morning. Slept all day Sunday. Woke up Sunday night a bit ""like coming out of a deep sleep per son, around 10 pm. Shortly after that patient was having a hard time breathing. Emergency called. Arrested around the time EMS arrived. King airway, I/O and CPR initiated. Patient has been in v fib. Was shocked multiple times, given 4 rounds of epi, bicarb and amiodarone. ACLS continued on arrival. Multiple rounds of epi, and attempted defib. Patient given epi, bicarb. Rhythms included fine v fib, asystole, and PEA. Unrecoverable with no cardiac motion. Time of death 11:50 pm."

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

(Report per patients wife) Patient took his usual nap around 12pm. She found him lying in the bed unresponsvie at 2pm. EMS was not called. Patient's wife called the Funeral home.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

No symptoms appeared immediately after vaccination, although patient passed away around 6:00 pm unexpectedly. Staff talked with her last time at 5:30 pm and then found her at 6:00 pm passed away. Unknown at this time if death is directly related to receiving the vaccine.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty

No prior vaccinations for

breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.	this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient arrived at ER with complaints of CPR in progress. Per EMS, patient became short of breath while performing yard work on 1/26/2021. At arrival, patient was in fine v fib with a total of 6 shocks delivered along with 300 mg amiodarone followed by 150 mg amiodarone, 1 amp epinephrine and 2 epinephrine drips adminstered en route to ED. CPR initiated at 1755 and EMS reports asystole at 1829. TOD 1909 pronounced by ED DO Dx: Cardiac arrest	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per EMS, the patient was last seen walking and talking to wife 10 minutes prior to EMS arrival. EMS reports via patients wife, that patient was upstairs to change for his doctor appointment then patient's wife found him down. The patient received his COVID-19 vaccine on 1/25/21. EMS states they gave 5 rounds of EPI then patient moved into vfib then was shocked once but returned to asystole. In ED, the patient initially	No prior vaccinations for this event.

in asystole CPR was started immediately. The patient was given 3 rounds EPI, 1 round bicarb. The patient stayed in PEA throughout. Patient was given tPA. Patient continued to be in asystole and time of death was called at 11:35 am.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt began experiencing shortness of breath 3 days after vaccine and expired later that day.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient noted to have a change in status at 11:23PM that night. Her oxygen saturation had dropped from normal on room air to 82% and required oxygen. She was also noted to be lethargic with altered mental status and not responding verbally. She then began to mottle. Her oxygen saturation worsened to 51% on 4Liters of oxygen by the next day and she expired on 1/14/21.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient with inoperable pancreatic cancer received second Pfizer vaccine approximately 12:30 pm on 1/27/21. At approximataely 16:30, patient complained of abdominal pain and was given Levsin 0.125mg and morphine 5mg orally. At approximately 19:30 patient was found on the floor covered in a large amount of emesis, unresponsive without a pulse.		No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Expired in sleep on 1/24/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Was at work on 1/26/21 and collapsed, no known complaints a the time. CRP was initiated immediately, transported to ER and pronounced dead

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

All residents had been in isolation due to multiple cases of COVID in the facility. Resident voiced no health related complaints. He continued to visit with staff and required moderate assist with toileting. Resident had fall 0130 on 1-15-2021, which resulted in laceration with surgical repair. Resident was noted to change in mental status and respirations on morning of 1-16-2021 during morning blood sugar check. Resident had O2 @1.5l/m via n/c and respirations of 10 with periods of apnea and unresponsive to verbal stimuli. Blood sugar was 583. Resident deceased upon re-check after calling PCP to report status change.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Client was being treated with antibiotics by her PCP for diverticulitis flare up. It had not been resolved on the date of her death which occurred 01/27/21, She was found unresponsive by staff, 911 contacted, and paramedics pronounced her deceased at 7:48 AM. After consultation with PCP manner of death was noted

No prior vaccinations for this event.

as cardiac arrest. PCP was to sign off on death certificate.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient passed su hospital on 23Jan2021 stopped breathing; complained of not feeling well; had an inflamed gall bladder; This is a spontaneous report from a contactable consumer. A 98-year-old female patient received bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL8982 and expiry date unknown), via an unspecified route of administration on 16Jan2021 at single dose for covid-19 immunisation. The patient medical history was not reported. The patient concomitant medication reported as has received other medications (unspecified) within 2 weeks. The patient passed in hospital on 23Jan2021 with stopped breathing. Day after vaccine on 17Jan2021, the patient complained of not feeling well, went to hospital where was told she had an inflamed gall bladder. The events caused patient hospitalization for 4 days. The cause of death reported as stopped breathing. It was unknown if autopsy done. Prior to vaccination, the patient not diagnosed with COVID-19. The outcome of the event breathing arrested was fatal, outcome of the other events was unknown.; Reported Cause(s) of Death: Stopped breathing		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
TESTED POSITIVE FOR COVID-19 1-7-2021, TRANFERRED TO HOSPITAL ON 1-18-2021. HE READMITTED TO THE FACILITY ON 1-21-2021 WITH HOSPICE SERVICES AND EXPIRED ON 1-25-2021.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19**

(PFIZER-BIONTECH)) (1200)

Patient was an 87 y/o female admitted for septic shock. She was started on and eventually maxed on 3 pressors. CT abd showed colonic obstruction with dilatation of large and small bowel. Patient was made DNR in the ED. Palliative care consulted on case. Family opted for comfort care. Patient was asystole on monitor. No spontaneous breath/cardiac sounds ausculted. Patient did not withdraw to pain. Pupils fixed and dilated. She was pronounced and 1230 on 1/28/21

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

COVID-19 + 1/11/2021, EXPIRED ON 1-24-2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

family states seemed short of breath since after the covid vaccine. Staff said beginning on 1/22/21 the patient seemed sluggish, more tired, and nausea noted. She stayed in her room more after the vaccine because worried about giving/getting COVID to others. was talking on the phone at 11:30 PM on 1/26/21 to staff person about temperature of room. at 12:15 AM on 1/27/21 staff noted not breathing, started CPR and called EMS. When EMS arrived they stopped the code because she was too long deceased.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident was vaccinated on 1/13/21. Resident passed away on 1/16/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

passed away-heart attack; This is a spontaneous report from a contactable consumer, the daughter of the patient from a Pfizer Sponsored program Pfizer First Connect. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration on 19Jan2021 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 24Jan2021, the patient passed away due to a heart attack. It was not reported if an autopsy was performed. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Reported Cause(s) of Death: passed away-heart attack

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient tested Covid positive, cough, low oxygen levels, COVID Pneumonia, patient is now deceased

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident was vaccinated on 12/31/20. Then on 1/14/21 he tested positive for SARS-CoV-2 on routine surveillance PCR testing. Another resident on the same hall was COVID positive on 1/11/21. Results of the PCR test were obtained on 1/16/21. He appeared asymptomatic at that time. Given his COVID positive status, all aerosol generating procedures had to be stopped. Overnight on 1/16/21 into 1/17/21, he had the

No prior vaccinations for this event.

onset of acute respiratory failure and was transported to the hospital. Per notes, he was put on BiPAP for several hours, but his CO2 level did not improve. Per prior advance directives completed with the resident and his two brothers, he had DNR/DNI orders. The hospital physician spoke with his brother and the decision was made to move to comfort care. He was discharged to inpatient hospice and died around 4pm on 1/18/21. This outcome does not appear to be vaccine-related, but death from COVID-19 infection is listed as a reportable event following COVID-19 vaccination.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received vaccine uneventfully with no acute concerns. Left clinic and by report went out with friends. Spoke to father on phone at or around 9:00 pm. Failed to show up to work and was found dead at home. Other details pending

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Cardiac arrest on 1/24/21 in the early morning hours then passed away on 1/25/21 around 1:51am in the hospital

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient died. Patient had been declining in health rapidly prior to receiving the vaccine

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

The patient was observed to be lethargic on 1/29/21 at 1515. BP-80/50, P-75, RR-27, T-100.1. He was given a bolus of NS 150 mlx2. and Rocephin 1 gram IM.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Died No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

REC'D CALL FROM PT'S DAUGHTER, HER FATHER WAS VACCINATED ON 1/22/21, WOKE UP 1/23/21 WAS SHORT OF BREATH AND DIZZY. PT PRESENTED TO ED OF LOCAL HOSPITAL AND WAS ADMITTED, PT PASSED ON 1/25/21. DAUGHTER STATES THAT FAMILY AND DOCTORS AGREE THAT THE VACCINE DID NOT CONTRIBUTE TOWARDS PT'S DEATH, BUT FELT IT NEEDED TO BE REPORTED. PT'S DAUGHTER CONTACTED THIS RN AT LOCAL HEALTH DEPARTMENT TO REPORT TO VAERS.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-

BIONTECH)) (1200)

After being observed for approximately 20 minutes and patient walked to her car without assistance I was called to assess the patient in the parking lot for troubles breathing. EMS was called as I made my way outside. Upon my arrival patient was leaning out of the car and stating that she could not breath. She was able to tell me that she was allergic to penicillin. Oxygen was immediately placed on the patient with minimal relief. Lung sounds were coarse throughout. She then began to vomit about every 20-30 seconds. Epipen was administered in the right leg with no relief. Patient continued to complain of troubles breathing and vomiting. A second epipen was administered in the patients right arm again with no relief. A few minutes later patient was given racemic epinephrine through the oxygen mask. There appeared to be mild improvement in her breathing as she appeared more comfortable, but still complaining of shortness of breath and vomiting. When EMS arrived patient was unable to transport herself to the stretcher. When EMS and clinical staff transferred patient to the stretcher she became unresponsive. She appeared to still be breathing. She did not respond to verbal stimuli. Per ED report large amount of fluid was suctioned from the patients lungs following intubation in the ambulance. When patient arrived to the ED she was extubated and re-intubated without difficulty and further fluid was suctioned. At that time patient was found to be in PEA, shock was delivered. Shortly thereafter no cardiac activity was found and patient pronounced dead.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received first dose of the COVID-19 Moderna vaccine on 1/19/2021 at an outside facility (no lot #, route, or site available to me in electronic charting). Pt began having hypoxia, SOB, and a dusky appearance of extremities on 1/29/2021 and was brought by EMS to our hospital. PT is a DNR and family

No prior vaccinations for this event.

had been looking into a hospice sign up due to dementia and general decline in the weeks prior to hospitalization. Pt tested positive on admission for COVID-19 via PCR test on 1/29/2021. Pt continued to have respiratory decline, was put on comfort care per wishes of family/advanced directives, and he passed away the evening of 1/30.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident was noted on 1/25 with an increased functional decline as she would not feed herself with utensils, but would eat finger foods if placed in her hand. She was started on Rocephin IM for possible infections. Labs had been obtained on 1/21/21, unremarkable for CBC and CMP. 75,000 colony count on urine. On 1/26/21 she was noted with right sided weakness and further decline. She was sent to Hospital for further evaluation. We were notified that she expired on 1/28/2021. Resident had been noted with a decline in function about 2 weeks earlier when she would not stand or transfer any longer. She was still responsive, taking meds, and feeding herself until 1/26/21. Further information on admitting diagnoses and progress notes from hospital have not been available to date.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/28/2021- Seen by FNP for indigestion, chest pressure and palpitations. EKG reviewed and referral made to Cardiology. 1/29/2021-1800 Presented to ED in cardiac arrest-onset PTA. Patient was found unresponsive by his wife at their home. The last known well was at 1530 when she called him on the

No prior vaccinations for this event.

phone. The patient was pronounced at ~1850.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Tested positive for COVID19 on 12-30-2020, Admitted to Hospital on 1/5/2021 with active COVID, Patient died 1/29/2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1st COVID immunization 1/7/2021, COIVD positive results on 1/16/21, 1/24/21 O2 sats decreased to 78%, 1/24/21 reveived the Bamlanivimab infusion 50 ml/hr. 1/24/20 chest x ray 1/24/21 She was sent to hospital and admitted. 1/27/2021 Expired

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

The next morning after vaccine, patient ran a fever, vomited, and was very tired. Mom laid her down to sleep and when she checked later, patient had passed away.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 1/9/21-Diaphoresis, O2 90%, respirations 22, increased weakness, wheezing bilaterally. Send to ER for evaluation and treatment. She was sent to ER, where she was admitted for 2 days, then expired

No prior vaccinations for this event.

there on 1/11/21

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
she was injected, sh stopped eating and talking, the doctor watched her for 2 days. had her transported to the hospital. i was told she had tested positive for COVID 2 times once at the home and once at the hospital. with in 2 DAYS at the hospital she wa on a ventilator 2 days later she died. i talked with the rehab center and confirmed she tested negative for COVID on Dec 27th 2020 and was given the Vaccine on the 29th Dec 202 was in the hospital 4 day later, was on a ventilator 4 days after that then died a few day later as her heart stopped beating. all the while i had POA and was not contacted by Hospital staff until after they had made the next step.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Heart stopped; Could not swallow; This is a spontaneous report from a contactable nurse (patient's wife). An 85-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 21Jan2021 at a single dose for COVID-19 immunization. Medical history included blood pressure abnormal (verbatim: blood pressure) from an unknown date and unknown if ongoing, neuropathy from an unknown date and unknown if ongoing, weight issue from an unknown date and unknown if ongoing, diabetes from an unknown date and unknown if ongoing, walker user from an unknown date and unknown if ongoing. Concomitant medications included insulin aspart (NOVOLOG) taken for diabetes from an unspecified date to an unspecified date; and he was taking a long acting one as well. The patient previously received the influenza vaccine (MANUFACTURER UNKNOWN) for immunization on unknown dates (""had flu shots before with no reactions and everything,		No prior vaccinations for this event.

nothing before""). On 24Jan2021, the patient's heart stopped (death, medically significant), and could not swallow (medically significant). The clinical course was reported as follows: The patient's wife stated the patient was taking insulin aspart (NOVOLOG) and he was taking a long acting one as well. The reporter, the patient's wife and a retired registered nurse (RN) stated, her husband (patient) just died and she thought he died from the COVID vaccine (later clarified the reason of death was-heart stopped). The patient had the vaccine on 21Jan2021, which was on a Thursday, and he was fine. On the following Sunday around 1:30 (on 24Jan2021), the patient was feeling a little weak, however, the patient's wife thought maybe his blood sugar was low. The patient's wife checked, and the patient's blood sugar was 91. The patient's wife went to get some yogurt to feed him in order to get his blood sugar up a little; ""which was a normal thing for him, it was not that low for him."" Then, suddenly, the patient fell, and the patient's wife could not get a pulse or anything. The patient's wife called an unspecified number and she started compressions; however, he was dead. The patient's wife stated the patient just had his heart test, a three hour long one, and it was ""perfect three weeks ago."" The patient had just gone to the doctor the other day and his blood pressure was ""fine and everything."" The patient's wife stated that other than his diabetes, ""which he had for (sentence incomplete)."" Regarding lab tests, the patient's wife stated, ""No, he had it before but not in the last two weeks. He was going for one because we just went to the doctor last week and he was going to call yesterday to make the appointment request to get his blood work done. Blood work has been good except his A1C was always high, but other than that everything was good"" (as reported). Regarding causality, the patient's wife stated, ""I do, because he was fine until about half an hour before he died. He said to me, I feel a little weak today and then I was talking to him that your upper body strength is really good and then I said, we just have to work on your weight a little more because he did have neuropathy. And then, I went out of the room and all of a sudden I just heard him fall and that is when I just went in to check his blood sugar and it was 91 and I got him yogurt and he started eating that and then that was it, he started spitting it out and he said, I could not swallow and that was it, he just died."" The patient's wife further added, ""I just wanted other people to know that things like this happen and I am sure it was from that because he was healthy as could be. He was walking with his walker, the day before outside and he felt fine."" The clinical outcome of the event, heart stopped, was fatal. The clinical outcome of the event, could not swallow, was unknown. The patient died on 24Jan2021 due to ""heart stopped."" An autopsy was not performed. The

batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: Heart stopped"

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
passed away; cough; This is a spontaneous report from a contactable consumer, the patient's daughter. A 92-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration in the left arm on 13Jan2021 at 11:00 (at the age of 92-years-old) as a single dose for COVID-19 immunization. Ongoing medical history included nursing home resident, admitted to hospice on 13Jan2021 (prior to vaccination), and oxygen supplementation (due to low oxygen levels) from a few days prior to the vaccine (Jan2021). Other relevant medical history included congestive heart failure from Dec2020 and sulfa allergy. Prior to the vaccination, the patient was tested numerous times (as reported) for COVID-19 and was negative. There were no concomitant medications. The patient did not receive any other vaccines within four weeks prior to the vaccination. A few days before the vaccination, her oxygen level had gone down, and she had been placed on oxygen. Prior to receiving the vaccine, the patient was reported as being 'fine'. On 13Jan2021, the patient received the vaccine at 11:00. The patient coughed maybe 5 or 6 times and then dropped her head. Resuscitation was not performed as patient had a do not resuscitate (DNR) order. The patient passed away on 13Jan2021 at 13:05. The cause of death was not reported. An autopsy was not performed. The clinical outcome of the cough was unknown at the time of death. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Reported Cause(s) of Death: passed away		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient death on 2/1/2021 at 4:55am at hospital. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident found unresponsive in room this am at approx. 9:30 am. Resident was observed eating breakfast around 8:45 am. Housekeeper reported seeing resident between breakfast and time found unresponsive. Resident had voiced no complaints. Code was initiated until EMS arrived and transported resident to hospital. Resident expired.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Employee was found unresponsive in floor at her home. EMS arrived and person had expired.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Died in sleep No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

The vaccine was given on Monday. Tuesday afternoon he developed weakness in both legs and could not stand up. This was a new development; he had neuropathy in one leg but he had been able to stand up and walk three hours before. He was helped to the bathroom. He said he felt better and might want to stand up again. He was helped to bed. He was found dead around 5:30 Wednesday morning. He was 94 years old and had a lot of medical conditions. No one has indicated his death had anything to do with the vaccine.

No prior vaccinations for this event.

I'm sure it's just a coincidence that he died so soon after receiving the vaccine

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Vaccine-1/7 Covid positive-1/10 Hospitalized-1/17 Deceased-1/25 No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident was hospitalized for confusion, and hypotension and increased weakness; resident proceeded to have a NSTEMI and died on 5th day in hospital on 1/31/2021.	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Cardiac arrest; Patient transported by EMS to hospital 11:00pm on 01/29/2021. Patient received vaccine on 01/25/2021. Patient expired 01/30/2021 within the hour into the new day after midnight on 01/30/2021. Patient was feeling well prior to and any chronic health conditions were well controlled. Sudden cardiac arrest 4 days after receiving the vaccine. Details given by patients husband/POA.	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor,	No prior vaccinations for this event.

rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

patient received vaccine on Jan 23, 2021 passed away on Jan 24, she was already on hospice, so unclear if due to vaccine or other issues. Was at her baseline before and after vaccine per facility, had b'fast and passed away at noon on Jan 24

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

patient received vaccine on Jan 23, 2021. developed weakness on Jan 25, 2021. Sent to ED on Jan 27, 2021 with hypoxia requiring 6 L O2, low Bp, declining mental status. Per family request transitioned to hospice and passed away on Jan 30, 2021

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Vaccine was administered Thursday and my father Died early Monday morning

No prior vaccinations for this event.

unexpectedly

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
fatigue x 5 days, including day of vaccination, death the night of day 5/early morning of day 6	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient passed away subsequent to receiving dose on 02/01. Staff does not have reason to believe vaccine was involved.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident vaccinated-1/7/21 Resident covid positive 1/11/21 Resident covid PNA-1/12/21 Resident hospitalized 1/16/21 Resident deceased 1/20/21	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
dead; Collapsed; bnt162b2 was given to patient with immunocompromised w/ reportable conditions; bnt162b2 was given to patient with immunocompromised w/ reportable conditions; This is a spontaneous report from a contactable nurse. A 40-year-old male patient receive first dose of bnt162b2 (Lot number: EK9231, Brand: Pfizer), intramuscular in left arm on 21Jan2021 15:15 at single dose for COVID-19 immunization. Medical history included immunocompromised w/ reportable conditions from an unknown date and unknown if ongoing, positive for Covid in September from Sep2020 to an unknown date. The	No prior vaccinations for this event.

patient's concomitant medications were not reported. The patient experienced dead, collapsed on 26Jan2021. Therapeutic measures were taken as a result of collapsed. The outcome of collapsed was unknown. The patient died on 26Jan2021. It was not reported if an autopsy was performed. Received Covid vaccine here on 21Jan2021, was at work on 26Jan2021 and collapsed, no known complaints at the time, CPR (cardiopulmonary resuscitation) was initiated immediately, transported to ER (Emergency room) and pronounced dead. Unknown if other vaccine in four weeks. The patient had COVID prior vaccination. Unknown If COVID tested post vaccination.; Sender's Comments: Based on the information currently provided, the patient was immunocompromised and had prior COVID infection. The death and syncope more likely are associated with the patient underlying medical conditions. More information such medical history, concomitant medications, treatment indication and event term details especially death cause and autopsy results are needed for fully medical assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Dead

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death 2 days later; This is a spontaneous report from a contactable Other HCP. A 97-year-old male patient received the 1st dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL0140) via intramuscular in the left arm on 18Jan2021 12:00 PM at single dose for covid-19 immunisation. Medical history included prostate cancer, macular degeneration, type 2 diabetes, atrial fibrillation. No known allergies. Concomitant medications included glipizide, warfarin and metformin in two weeks. The patient had no other vaccine in four weeks. The patient experienced death on 20Jan2021 at 09:00 PM. Death cause was undetermined. No autopsy was performed. No treatment was received for AE. The patient had no covid prior vaccination, no covid tested post vaccination. Outcome of the event was fatal.; Sender's

No prior vaccinations for this event.

Comments: Event unknown cause of death is assessed as Related until sufficient information is available to confirm an unrelated cause of death or if there is sufficient information to allow an unrelated causality assessment. Case will be reassessed when follow-up information is received. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Death 2 days later

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

she was hurting at her chest/ Chest pain; on her left arm hurt real bad that's what the clot on her left arm; on her left arm hurt real bad that's what the clot on her left arm; She passed away; heart attack; This is a spontaneous report from a contactable consumer. An 87-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Jan2021 at single dose for COVID-19 immunisation. Medical history included diabetes mellitus, for which she was taking a pill like an hour before she would take her meal. On Monday (Jan2021) the patient experienced was hurting at her chest/ chest pain, her left arm hurt real bad as she had a blockage in her left arm/clot on her left arm, and they wanted to put in a stent and after the surgery it went well and she all go home in two days. The patient was hospitalized in Jan2021 due to the events. She had a heart attack and that the chamber between the dividers had a hole in it and her heart tissue was too thin so much thin she couldn't repair it. The patient passed away on 26Jan2021. The patient was tested negative for COVID-19 on unknown date. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: She passed away

No prior vaccinations for this event.

DEATH

COVID19 (COVID19

	(PFIZER-BIONTECH)) (1200)
Patient with past medical history of CAD, CKD, sCHF, LGL Leukemia admitted to Hospital on 1/19 with pleural effusion. Pt expired on 2/1/2021. Hs of essential HTN, complete heart block, T2Diabetes,thyroid issues, stroke, papillary CA of thyroid, dyslipidemia, anemia, hypercalcemia, pulmonary nodule, hypoparathyroidism, pacemaker, bilat carotid stenosis, afib, pleural effusion, pancytopenia, cardiomyopathy, severe aortic stenosis, sick sinus syndrome, Dressler syndrome, empyema, ESRD	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
in addition to above, pt had the following diagnosis: portal HTN, abnormal blood chem, essential tremor, depressive disorder, abnormal glucose tolerance test, hyperlipidemia, hypothyroidism, insomnia, localized osteoarthrosis, calculus of kidney, pancytopenia, odule on liver, hepatocellular CA, hyotension, hypovolemia, hepatorenal syndrome additional meds: zoloft, aldactone, thiamine,demadex, ultram, kenalog, vitamins, bactroban ung	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt son, reports patient passed away on 2/1/21 in the early hours. Pt wife, told Pt's son that patient started feeling ""bad"" with common cold like symptoms on 1/31/21, had a temp of 99.0. Pt's wife went to take a shower, when she got out patient was unresponsive. She called EMS, they pronounced patient deceased upon arrival. á Pt's son also reports patient and Pt's wife both had their 1st COVID-19 vaccine 13 days prior. He was told by EMT on sight to notify the facility where they received their vaccines. He did contact	No prior vaccinations for this event.

them and was told to notify PCP."

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Myocardial infarction Narrative: PMH significant for aortic valve stenosis, mitral valve stenosis, CKD, CHF, DM, HTN, obesity, hypothyroidism and dyslipidemia. Per report from primary care - the patients wife reports that the patient went on Saturday (1/30/21 - about 1050) morning to receive his COVID vaccine. He returned home and told her about the experience and denied any side effects. He then proceeded to sit in his easy chair for a while and around 1:30, she asked him if he wanted any lunch. The patient's wife reports he ""grumbled"" at her, and then got up to go to the bathroom. She then heard a loud crash and found him lying on the floor of the bathroom, with his head knocking hole in the wall as he fell. She could not detect a pulse. She called 911 and began compressions. First responders to the scene likewise tried to revive him but were not successful in her efforts. Per primary care documentation - Uncertain if related to Pfizer vaccine; vaccine administered on 1/30/21 and approximately 3 hours later suffered fatal MI at home."		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death	No prior vaccinations for this event.	

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 1/29/21 patient began not feeling well and saw her provider. The doctor gave her fluids and tramadol for pain. They noticed increased confusion, but thought that could have been due to the tramadol. They also increased her gabapentin as she was experiencing nerve pain. Patient also developed a rash and was diagnosed with shingles on 2/1/21. Patient died on 2/3/21

No prior vaccinations for this event.

DEATH	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
According to medical report, Pt presented to the ED on 1/14/21 w/ cc of SOB for 1 day. She received her COVID-19 vaccine on 1/9/21. Pt stated that she developed a dry hacking cough 2 days prior to the vaccine on 1/7/21. Over the last few days prior to admission, she developed generalized weakness, SOB, loss of sense of taste and smell w/ associated decreased appetite and nausea ultimately SOB in the24 hours prior to admission. Final Diagnosis- acute hypoxic respiratory failure secondary to COVID-19 pneumonia. Pt died on 2/3/21. See Medical report for more information.	No prior vaccinations for this event.

DEATH	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
death Narrative: Pt attended arthritis clinic appt 0900; labs shortly after; rec'd vaccine in clinic ~ 1113; seen on surveillance camera walking to parking garage ~ 1145; medical center rec'd call from wife ~ 1900 that pt never returned home; police found vehicle running in parking garage, code called, pt obviously deceased by that time 1930, body sent to medical examiner for autopsy.	No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received vaccination at 9:12 am, she was monitored and checked at the 15 minute interval 9:27 am, reassessed, vitals were fine. Within 20 (9:32 am) minutes of receiving the vaccine she was unresponsive, pupils were fixed at 9:45 am, no vital signs noted; hospice came out and reported her time of death 10:21 am. This person was on hospice.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient's primary care provider received a death certificate to be signed for this patient. He spoke with the patient's husband and son, who reported that the patient had pain and swelling at the vaccine administration site after receiving the vaccine and was feeling unwell after receiving the vaccine. The patient's family reported that they found her unresponsive on 2/2/21 and called 9-1-1. The patient was pronounced dead upon arrival of emergency responders.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began with vomiting and diarrhea. C/O chest pain. Bradycardia. Hypotension. 2 seizures in 45 minutes after not having one in years. We gave fluids. Gave Zofran. Comfort measures. Pt passed at midnight. Was completely fine one day before. Had minimal issues with COVID though did have a pneumonia that was treated w ATB early on and resolved.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Possible transverse myelitis developing 2 days after vaccine injection. Death on day 9 after vaccination		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My father was in weak condition to begin with. He didn't get out of bed for the next few days after receiving the vaccine. The little amount that he ate was consumed in bed. He began aspirating his food which lead to pneumonia. He wasn't strong enough to fight off the pneumonia even with antibiotics. He died on 1/23/21. While he might have passed soon in any case, I believe that the vaccine may possibly have increased his weakness/exhaustion thereby hastening his demise.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient expired. Per Emergency MD note: ""This is a 72-year-old male with what sounds like diabetes, atrial fibrillation, and hypertension who presents via EMS in cardiac arrest. It sounds like he received his Covid vaccine last week. Initially he had some mild effects from it. However over the last day or so he has felt very unwell. He apparently called his wife today and told her that he was not feeling well and so she returned home. Shortly thereafter he attempted to get up from his chair. He then collapsed and fell forward onto his face. Sounds like his wife had some difficulty rolling him over to perform CPR. When EMS arrived they found him in PEA. He received a total of 5 rounds of epinephrine. At some point they did have return of spontaneous circulation. However just prior to arriving in the emergency department they lost pulses		No prior vaccinations for this event.

again. The patient was intubated with an 8 oh endotracheal tube prior to arrival."""

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient tested positive for COVID-19 on 1/8/21. She demonstrated a decline in appetite and the ability to feed herself d/t this illness, but no respiratory or other symptoms. She received COVID-19 vaccine #2 on 1/26/21. She demonstrated an SDTI wound to the Lt. heel on 1/27/21. On 1/31/21 she was noted to have a significant weight loss. She was admitted to services on 2/1/21 with comfort care orders. On 2/2/21 she was observed to be without vital signs. Orders were for DNR, and CPR was not initiated in accordance with that order. She was pronounced dead at 0112 on 2/1/21.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death. No known symptoms or complaints. found unresponsive in bed. Released to funeral home as the Medical Examiner will not perform and autopsy. Dr. will sign the DC.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her		No prior vaccinations for this event.

stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt had 2nd vaccine, went home and started having ""cramping"" in all of her muscles. It became bad enough that she was taken to local ED where she then started coughing up blood, required intubation and about 6 hrs later, died."	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had one occurrence of thrombotic thrombocytopenic purpura in 1996 for which she had plasma exchange therapy in 1996. No other occurrence since 1996 until she received her first dose of the Pfizer covid vaccine.	No prior vaccinations for this event.

DEATH	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
view 2/5/2021 09:23 e Progress Note Note Text: Patient passed away in the facility this morning. view 2/5/2021 08:39 Orders - Administration Note Note Text: Resident passed. view 2/5/2021 08:33 Nurses Note Note Text: Body released to funeral home at this time. Personal effects sent with resident include: 1 pair of glasses, 1 yellow wedding band, 1silver spoon ring, 1 ring with black and clear stones. Resident has own teeth view 2/5/2021 08:32 Nurses Note Note Text: cause of death per CRNP failure to thrive. view 2/5/2021 07:44 Orders - Administration Note Note Text: Take and document temp & PO2 every 4 hours for MONITORING Resident passed. view 2/5/2021 06:49 Nurses Note Note Text: Son returned call and was updated of resident's passing this am view 2/5/2021 06:33 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Unknown Resident expired @ 0604 [linked] view 2/5/2021 06:06 Nurses Note Note Text: Res found without pulse or respirations. Pronounced at 0604. Updated. N/o's for RN to pronounce, release body to funeral home, dispose of medications per facility policy. Daughter updated. Funeral Home called to release body. view 2/5/2021 05:26 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Pulse ox 60% on O2 @ 5L/min via mask. Resps 44 per minute. view 2/5/2021 01:57 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/5/2021 00:52 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Residents resps are 40 per minute, pulse ox 76% on O2 @ 5L/min via mask. Resps are labored, shallow and rapid. view 2/5/2021 00:48 Nurses Note Note Text: Nonresponsive to verbal and tactile stimulation. Appears comfortable. view 2/4/2021 22:01 Nurses Note Note Text: Resident resting comfortably, breathing becoming increasingly shallow, wearing O2 via mask at 5L via mask, no dyspnea noted, feet are mottled, oral and peri care provided Q2H. No s/s of pain or discomfort. view 2/4/2021 21:40 Orders - Administration	No prior vaccinations for this event.

Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective [linked] view 2/4/2021 19:32 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger medicated for air hunger, RR 28 to 32/ min view 2/4/2021 19:22 Nurses Note Note Text: Daughter updated on N/O to increase Morphine Sulfate 20mg/mL 0.25mL to Q2H prn from Q6H prn. view 2/4/2021 18:06 Nurses Note Note Text: POA Daughter and daughter aware of residents current condition. view 2/4/2021 11:58 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/4/2021 11:13 Nurses Note Note Text: Pt. noted to be lethargic at this time. Does respond to verbal and tactile stimuli by opening her eyes but non verbal currently. Skin warm and dry. No mottling or apnea observed at this time. O2 sat 88% with O2 at 2 LPM via n/c. On increased to 3 LPM via mask as pt. noted to be mouth breathing. Respirations 28. F/U O2 sat 93%. HOB elevated. Pt. medicated with morphine by LPN. Daughter updated on pt.'s condition. Does not want pt. sent out to hospital and would like comfort measures to continue. Daughter also in agreement with delay in d/c d/t pt.'s condition.CRNP updated on pt.'s condition, delay in d/c and daughter's wishes. No n/o's at this time. view 2/4/2021 10:56 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB Resident showing s/s of discomfort. SOB at this time and high respirations. Repositioned, changed for incontinence care and mouth care provided. view 2/4/2021 10:34 Progress Note Note Text: Spoke with RN regarding change in condition. Updated Sr Living regarding change. Recommendation to cancel d/c/transfer for today, see how resident does through the weekend and re-evaluate on Monday. Daughter updated on cancellation of d/c today. view 2/4/2021 10:04 Nurses Note Note Text: Daughter aware that resident's O2 sat was 88% on room air on 3-11 shift and that oxygen was applied via nasal cannula. view 2/4/2021 10:03 Nurses Note Note Text: N/O: Discharge 2/4/21 with scripts to Sr. Living. Daughter aware. view 2/4/2021 09:53 Nurses Note Note Text: Pt. to be d/c'd to another facility this am as per MD order. Pt. alert and responsive. Skin assessment done as per facility policy. No pressure areas noted at this time. No s/sx of pain or discomfort observed at this time. V.S. 97.0 67 20 O2 sat 95% with O2 at 2 LPM via n/c. view 2/4/2021 07:45 Nurses Note Note Text: Resident seen by Dr. for discharge. Orders pending at this time. view 2/4/2021 07:36

Nurses Note Note Text: CRNP and Dr. updated on O2 sat 88% on RA with f/u of 93% with O2 on at 2 LPM as well as rest of VS, 3-11 shift 2/3/21. No n/o's at this time. view 2/3/2021 21:17 Nurses Note Note Text: Resident Sp02 88% on RA. Pulse 124. Respirations 40. PRN morphine given and O2 applied via NC at 2L/min. After recheck pulse ox up to 93%, pulse 100, and respirations 22. Resident appears comfortable at this time. view 2/3/2021 20:05 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective [linked] view 2/3/2021 19:48 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN given for SOB after elevation of HOB not effective. view 2/3/2021 11:51 Nurses Note Note Text: CRNP updated rapid COVID test done for d/c tomorrow was negative. No n/o's at this time. view 2/3/2021 11:44 Nurses Note Note Text: Daughter notified of rapid covid swab being negative. view 2/3/2021 09:50 Orders - Administration Note Note Text: Obtain Rapid Covid test on 2/3/2021 for discharge. Please give copy of results to Social Worker every day shift for covid testing for 1 Day Completed and negative. view 2/3/2021 08:45 Skilled Nursing Note Reason for skilled service: Therapy describe skilled service: Nursing, therapy assessment: V.S. 97.8 79 18 138/84 Orientation: Oriented to self only. Oxygen: O2 sat 94% on RA Edema: Trace edema noted BLE. Pedal pulses present. Pain: Denies pain or discomfort at this time. Nursing note: Pt. alert and responsive. Skin warm and dry. Lung sounds diminished. No respiratory distress observed at this time. Abdomen soft. BS+ in all 4 quads. Continent/Incontinent of B&B. 1 assist with ambulation, transfers. 1 assist with ADL's. Working with therapy on gait training, therapeutic exercise, therapeutic activities & neuromuscular reeducation. view 2/2/2021 14:37 Progress Note Note Text: Per health professional at Sr Living, prepared to accept patient to their Memory Care Unit 2/4. Transportation arranged for 11 AM per family request. Daughter (POA) updated on d/c time on 2/4/21. Facility requesting rapid COVID test completed prior to d/c and results sent to them. All other information sent for continuity of care.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

73-year-old man s/p first dose of Pfizer at 10:20 AM Ambulated comfortably to exit after 20 minutes in observation but 10:45 collapsed while exiting the building 10:47 CPR initiated 10:49 medical team/EMS found no pulse, agonal respirations, ventricular fibrillation Paramedics and team performed ACLS; of note patient was intubated 7.5 ETT with bilateral breath sounds on ventilation; paramedic reported easy intubation with no apparent throat swelling; 11:02 transported to Emergency Department 11:30 Pronounced dead at Emergency Department

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient Expired No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA No prior vaccinations for this

1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021 event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Developed heart arrhythmia and was unable to be revived. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

My mom received the Covid 19 vaccine on Jan 5, 2021 and became very about a week later. I was informed that she tested positive for Covid 19 on January 14th. One January 17th she became very tired and weak and would not eat. Hospice called me and told me that she was in a decline state. I saw her on January 25 and 26 and she was just sleeping and could not open her eyes. Her vitals were good and she seemed to understand when I talked to her - she would squeeze my hand and moan but she could not talk or open her eyes. My mom passed away on January 27, 2021 just 22 days after receiving the Covid 19 vaccine. She was very think to begin with and being to weak and tired to eat resulted in her losing even more weight. Some of the other residents were given fluids to help and they recovered. My mom was not given fluids. I believe there were 20 deaths in her care home for the month of January when they vaccinated. This was an alarming number of deaths for the home. The facility had very few Covid deaths in 2019 and 2020. I asked every week if they had any Covid and or Covid deaths and this amount was shocking to me and the workers there. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

unanticipated death No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 2/5/2021 resident noted to be azotemic. Creatinine up to 3.8 and BUN in 80's. He was started on NS hydration. On 2/7/2021 he was noted without VS, per MD notes, possible VF arrest, renal failure; death unclear exact cause.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Narrative: Patient with history advanced vascular dementia, hypertensive cerebrovascular disease and stroke, T2DM. Received her second dose of Pfizer COVID-19 vaccine at approximately 14:00 and was reported to have expired at home at 20:55. Dr. (Medical Director) spoke with patient's son/caregiver 2/4/21. Son reports that patient was in her usual health yesterday morning, deemed well enough by son to travel for vaccination. He reports she had no bothersome symptoms after either first or second vaccinations. Specifically denied rash, wheeze, and difficulty breathing. Son was with patient throughout the day. In the evening, when preparing for bed, he noted she became suddenly unresponsive in a similar fashion as she has done several times in past years. While in all previous such episodes she recovered within minutes, last evening she did not regain consciousness, experiences a brief period of labored breathing, and died. Patient's son called 911 and the patient's body was brought to the medical examiners. The medical examiner declined to proceed with autopsy. Patient's son is not interested in autopsy. Patient's son reports confidence that his mother's underlying hypertensive/diabetic cardiovascular disease is the natural cause of

No prior vaccinations for this event.

her death. Other Relevant Hx: Symptoms: & Death Treatment:

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Resident on Hospice. 1/18 Hand Shaky. 1/19- Covid +19. 1/20 Desat 85% on RA, provided 2L O2 supplement= 97% 1/20 congestive cough, 1/28- RR-28;1/29- Hypoglycemia 1/30-NPO. 1/30-resident passed away.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient that received his first dose of Pfizer vaccine on 2/1/2021 passed away on 2/2/2021. No further information is available at this time.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was administered second dose of Pfizer vaccine in Nursing Home on 2/5/2021 around noon and was found unresponsive at 5:03AM the following day 2/6/2021. Patient arrived to Hospital in cardiopulmonary arrest and was pronounced dead.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient complained of soreness in muscles morning after receiving the shot. She went about her day had a smoothie, spoke to people and also went for a walk came home and went into her jacuzzi tub and consequently passed away while in the tub. She was found by her husband at around 545pm, time of death is unknown and cause of death is currently pending.	No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated at 11:30am. By 7pm he started presenting symptoms of fatigue, chest pain. Patient urinated and defecated in himself. Was not feeling well. Patient died at 10:30pm.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Unsure if related to vaccine, but wanted to report event of death due to brain bleed on evening of administration of the vaccination.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Four days after being vaccinated, she developed pneumonia and died 8 days later.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Xrays showed covid Poss pockets all in her lungs on 15Jan; Xrays showed covid Poss pockets all in her lungs on 15Jan; This is a spontaneous report from a contactable consumer. An 85-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for covid-19 immunisation. Medical history included dementia. Concomitant medications were not reported. Patient popped hot 02Jan2021 along with 4 others on the hall she lived. Within 9 days 50+ patients were positive. All had the vaccine the same day. Patient was test positive on 02Jan2021. She was on day 12 of her quarantine when she started to get worse. She was unresponsive by		No prior vaccinations for this event.

16Jan2021 and passed 18Jan2021. We were with her from 14Jan2021 to 18Jan2021. But had not been allowed to visit with her since Mar2020. And what post treatment pairs well with it? Publicly we hear Remdesivir and Bamlanivimab but these patients only received a general antibiotic and some vitamins. Death cause was Xrays showed covid Poss pockets all in her lungs on 15Jan2021. No autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information; Reported Cause(s) of Death: Xrays showed covid Poss pockets all in her lungs on 15Jan

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
bowel perforation; pain in her upper abdomen; This is a spontaneous report from a contactable consumer. An 86-year-old female patient received the 2nd dose of bnt162b2 (BNT162B2) at single dose on 13Jan2021 for Covid-19 immunisation, administerd at nursing home/senior living facility Medical history included dementia, arthritis. No known allergies. Patient was not pregnant. Patient had not COVID prior vaccination. Concomitant medication in 2 weeks included: memantine (manufacturer unknown) 10 mg BID, diclofenac (manufacturer unknown) BID, carbidopa, levodopa (manufacturer unknown) 25-100 mg TID, quetiapine (manufacturer unknown) 12.5 mg q HS, escitalopram oxalate (LEXAPRO) 10 mg q HS, paracetamol (TYLENOL) 650 mg BID, glucosamine (manufacturer unknown) drink. The patient received the 1st dose of bnt162b2 (BNT162B2) at single dose on 24Dec2020 for Covid-19 immunisation. No other vaccine received in 4 weeks. The patient experienced bowel perforation and pain in her upper abdomen on 18Jan2021 07:30. The events resulted in Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event), and death. On 18Jan2021 07:30 AM, less than a week	No prior vaccinations for this event.

after the second shot, she had pain in her upper abdomen and was taken to the ER on 18Jan2021. CT showed a bowel perforation in the small bowel. She had never had bowel surgery or diverticulitis. She had been healthy other than her dementia and arthritis. Patient received treatment for the events: hospice and pain management. COVID-19 was not tested post vaccination. The cause of death was bowel perforation. An autopsy was not performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: bowel perforation

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was weak, fatigued and had a fever of 101. F the following morning after receiving the 2nd dose of vaccine. Later in the day she was feeling better and vital signs were WNL. The next morning, she was found unresponsive and pronounced dead by paramedics.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
her arm was sore but no other adverse reactions until Saturday, Feburary 6th 2021 she had stroke between 4 and 6pm. She died within 6 to 7 hours later.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom only had site soreness after her covid vaccine on 1/21 which resolved within a couple days. However, she died in the early morning hours of 1/25, she was fine the day before, no sign of injury. We found her collapsed on the ground and although we tried cpr she was already dead. She had gone to the hospital on 12/28 for shortness of breath, angina and symptomatic anemia, her ekg was unchanged and	No prior vaccinations for this event.

blood work normal except for anemia. The cardiologist did not think a cardiac cath was needed. Her shortness of breath improved with a blood transfusion and a dose of lasix (no heart failure).

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient received 2nd dose of Pfizer vaccine on 2/2/21 and on 2/6/21 he died in his sleep in the a.m. No other signs or symptoms were observed prior to death. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident coughing in dining room, staff suctioned, physician stated to transfer via 911 to hospital, 6:33 PM. Hospital notified Nursing Home staff resident passed away at 8:25 PM. No adverse reaction noted to the Covid vaccine 24 hours after each dose at Nursing Home. There was no airway obstruction, cardiorespiratory arrest, death was natural at hospital. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident expired 01/26/21 at 5:25am. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Individual collapsed 9 days post-vaccination with no known reason. Despite being healthy prior to vaccination, individual's condition deteriorated rapidly. Individual passed away on 1-17-2021. No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident passed away 2 days after receiving the vaccine. oxygen level has decreased shortly 1 day after receiving the vaccine.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received the vaccine on 1/26/2021 and per employee at facility patient passed away on 2/01/2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Day after receiving the vaccine, the patient complained of abdominal pain which worsened over the day. She went to the ED and was hospitalized. Abdominal pain complaints increased and continued, she decompensated rapidly, was intubated and subsequently died 3 days later. Imaging results showed, progressive ovarian cancer in the bowels. Blood culture revealed that she had E.Coli in her blood. It is thought that this is NOT related to the vaccine.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Dr. received an urgent request to call a local Justice of the peace regarding one of her patients who was found dead in her home today. At this time no foul play is suspected. Dr. said the patient was relatively healthy with no major issues other than some hypertension

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient got the injection and quickly developed a fever and felt weak. Family was contacted and he was sent to Hospital. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

This 96 year old resident was diagnosed with COVID on 10/28/2020. She has a significant, complicated medical history and did not return to her pre-infection level of health. She began declining in early January and was made care and comfort measures only on 1/2/2021. Most of her medications were d/c'd except for those that provided comfort. No obvious reaction to the vaccine was seen and we do not suspect that her death was vaccine related, however we were directed by Dept of Epidemiology to report her death as it was within one week of receiving the vaccine. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

death- unexplained cause No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, No prior vaccinations for this event.

sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver failure, pneumonia, and DIC>"

DEATH	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas	No prior vaccinations for this event.

which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Client was administered the vaccine while symptomatic (01/25/21) although client did not know he was symptomatic for COVID-19. He had been exposed to a family member who had tested positive and should have been in quarantine but wasn't either because it was not felt he was considered a close contact by his family opinion or his family member never notified public health of this close contact...?. Clinet had presented to the ED following day after vaccination for shortness of breath and fatigue and an antigen test showed he was positive for COVID-19. He was sent home that same day 01/26/21. He was back in ED on

No prior vaccinations for this event.

01/28/21 for worsening symptoms and admitted to hospital and later placed on ventilator. He passed away on 02/09/2021 (date of death was per his wife).

DEATH	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel	No prior vaccinations for this event.

horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the

No prior vaccinations for this event.

cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death. I actually not sure which Covid Vaccine she took. I just know the date and time she took it at her local school where she worked. Died in her sleep after complaining of a headache. I talked to her around 5pm on sunday through a videochat and she seemed happy and well. But a local friend commented that she had complained of a headache late in the afternoon.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient found unresponsive in room with no pulse or respirations. She was pronounced dead by paramedics at 06:25am on 2/5/2021.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt with acute resp failure, COVID PNA, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior toa admit, then shortly after progressed with other covid symptoms and was admitted. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. Pt passed soon after(2/2).	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pfizer-BioNTech COVID-19 Vaccine Hospital Emergency Room Provider reported cause of death as COVID vaccine administered 11 days prior to death. Additional information being reported from LTCF.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
One week to the day after patient's first vaccine he died of a heart attack; This is a spontaneous report from a contactable consumer and from a contactable physician. A 71-year-old male patient (husband) received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 12Jan2021 at single dose on the right arm for COVID-19 immunization. The patient medical history included past heart conditions. No known allergies. Patient took other medications in two weeks. Facility	No prior vaccinations for this event.	

type vaccine was doctor's office/urgent care. No other vaccine received in four weeks. One week to the day after patient's first vaccine he died of a heart attack on 19Jan2021 18:30. Cause of death was heart attack. No COVID prior vaccination. No COVID tested post vaccination. It was unknown if an autopsy was performed. The physician reported that the patient arrived DOA. Physician signed the death certificate based on the patient's prior diagnosis. Physician would not provide additional cause of death medical background without consent. He was not aware of any adverse events experienced from the time of vaccination to the date of death. Follow-up (05Feb2021): This is a follow up spontaneous report from a contactable physician. This physician reported in response to HCP telephonic follow up activity which the following: patient death and cause of death were confirmed. Follow-up attempts are completed. No further information is expected. Information about Lot number is not available.; Sender's Comments: Based on the temporal relationship, the association between the event fatal heart attack with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: One week to the day after patient's first vaccine he died of a heart attack

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

24 hours after shot had high fever 101, chills, weakness, became listless, family called 911, client became unresponsive and died in the Emergency room.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death 2/9/21 No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt suffered Cardiac Arrest and respiratory arrest on 2/9/21 and passed away at a local hospital. He had multiple health conditions likely contributing to this. he arrested at home and CPR was attempted and unsuccessful. Pt received his Covid vaccine #1 on 1/27/21. No issues were noted after vaccine and was due for his 2nd dose next week. However, we were notified he passed away on 2/9/21. Very likely death not at all related to vaccine but wanted to document as patient was in the middle of the covid vaccine series.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death ""cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its components or a severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed. MDs recommending hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative status. 1/29 Pt passed away."

No prior vaccinations for this event.

DEATH

COVID19 (COVID19

	(PFIZER-BIONTECH)) (1200)
Was contacted by the person's daughter on 2/5/21. Patient started vomiting 2 days after vaccination. She aspirated and passed away 1/16/21. Patient had history of stroke and swallowing problems.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/15: Pfizer vaccine dose 1 administered 1/16: Fever, chills 1/22: Sore throat, coughing w/white phlegm, taking Tylenol and Mucinex. Fever and chills from 1/16 subsided. Had telehealth consultation with PA. Per her notes, patient said he gets these symptoms annually, requested for an antibiotic. PA referred him for a COVID test. Ordered hydrocodone/chlorphen ER suspension for his cough and an antibiotic. Antibiotic was recommended if symptoms do not subside. 1/23: COVID test administered 1/25: Reported positive for COVID 1/26: Telehealth session w/PA: she informed patient of his positive test, advised to quarantine and seek medical help at hospital if symptoms worsen. Patient reported that his sore throat mostly subsided but is still coughing at night. Said that the pharmacy didn't receive the prescription order for the antibiotic, so this was re-ordered. 1/31: Partner found him dead at 8:18AM on his bed. Death certificate issued by state says cause of death: COVID. Autopsy was not performed. Buried on 2/9/21.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
7 days after receiving the vaccine, patient suffered excessive diarrhea and slight coughing. 9 days after vaccine, patient was tested for Covid 19, and received positive results. Patient was transported to hospital via ambulance but hospital returned her to the nursing home since chest was clear, no respiratory issues, and no fever. 10 days after receiving the vaccine, patient was turned over to hospice care but still in the nursing home. Hospice was called in to provide better physician advice and access 24/7. 14 days after	No prior vaccinations for this event.

receiving vaccine, patient began experiencing excruciating body aches, coughing, low oxygen levels, and no appetite. 18 days after vaccine, patient died.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
New onset dizziness with hypotension, tachycardia, and vomiting blood. Sent to ER - told he went into cardiac arrest and died.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received the vaccine at an outside healthcare facility on 2/11/21. At approximately 1 pm she		No prior vaccinations for

screamed out and fell out of her chair. EMS was called and patient was found to be in Vfib. ACLS was performed for approximately 42 minutes prior to arrival at ED. At that time the patient had been pulseless for 25 minutes. Patient received 450 mg of amiodarone, epinephrine x7, sodium bicarbonate x2, and 7 AED shocks. In the ED 3 more doses of epinephrine were given, one more dose of sodium bicarbonate, and 5 additional shocks. ROSC was not achieved and time of death was called at 1416.

this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Complained of dizziness on January 18,th seen by MD this date. Passed away on 22nd.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 2/7/21 resident complainted of not feeling well, nausea, vomiting and weakness sent to ER passed away.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

DEATH 2/12/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

death 2/12/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

At 10:33 am Patient pushed her pendant for staff, staff arrived to her apartment and Patient was found unresponsive in her bathroom. Patient received her second COVID-19 Pfizer vaccine about 75 minuets prior to this, she had no adverse reaction's within the first hour of receiving the second dose. CPR was started until paramedics arrived, they took over and tried to resuscitate. Patient was pronounced dead at 11:33 am at scene.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient stated he had a migraine after the vaccine. We were advised of a change in appetite on Thursday February 4th. Patient died on February 6th.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

The individual received the vaccine around 12:00pm on 02/11/21. Around 9pm the individual went to lay down on the couch at home and started to have difficulty breathing. Within 30 minutes the individual became week and unresponsive. She was transported to the hospital where she was pronounced deceased at 11:44 pm on 02/11/21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Had a stroke 3 days after round one of Covid vaccine and subsequently died the next week due to

No prior vaccinations for this

complications of stroke. Upon admission to hospital, was in afib.		event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient reported to Emergency room on 01/23/2021 with complaint of nausea. According to ER record patient reported he received a COVID 19 vaccine Pfizer the day before. Work up in the ER (CT ABD PELVIS) reveal a clotted of SMA. CT CHEST REVEALED BILATERAL PULMONARY EMBOLUS. THE PATIENT WAS TRANSFERRED TO THE STATE HOSPITAL. HE WAS SCHEDULED FOR EMERGENT VASCULAR SURGERY WHICH WAS CANCELLED AS THE PATIENT DIED SHORTLY AFTER HIS ARRIVAL.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Few minutes post vaccination, after moving to observation area via wheelchair, the patient complained of dizziness. She took glucose tabs she had brought with her. Staff wheeled her to Triage # 1. Her eyes rolled back in her head and she lost consciousness. Staff (paramedics on site) transferred her to gurney and started compressions. AED placed, V- Fib was rhythm, Shock # 1 given, CPR resumed. Shocked again. Fire truck and additional EMT arrived on site and took over care. Epinephrine was given 3 times via intra-osseous route, Amiodarone given intra-osseous route. Additional defibrillation with on site AED for a total of 6-7 times. Patient had good chest rise with ambu-bag, no airway obstruction or peri-oral edema noted. Code called at 12:40 PM.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Adverse reaction to the vaccine started with variable weakness beginning 1/29/2021. On 1/30/21 around 8:30pm, he needed assistance in the bathroom related to weakness and had what was later identified as a stroke with left side weakness and slurred speech. In accordance with his wishes, he had care at home. Due to his advanced age and frailty, a CT scan was not pursued. The 325 mg of aspirin that he was previously taking daily was discontinued. After the stroke, he needed total care. Hospice was established at home. Nursing assistant care was delivered by daughter. Death followed 9 days later (2/9/2021).

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident was given the Pfizer vaccine on January 22, 2021, nausea and shortness of breath was taken to the Hospital on the 23rd of January and passed on the 24, 2021

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient died on 02/08/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Swollen leg/pain- taken to urgent care- became unresponsive - CPR initiated- expired

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS

No prior vaccinations for

started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia

this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was found unresponsive on her kitchen floor about 9:45 AM on February 10, 2021 approximately 18 hours after receiving her first Covid-19 vaccination. Exact time of the event is unknown. She was known to get up between 6:30 and 7:30 AM. It appeared that she had not eaten breakfast nor taken any medication that morning. She was taken by ambulance to Medical Center where a CT scan showed an unrecoverable massive brain hemorrhage. She died at approximately 3:50 PM after the respirator was removed. She was sent to the local Medical Examiner afterwards.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

DEATH No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

She started having breathing problems/heart attack appearance. on 1/22/21 and went to the ER. Upon admittance was told it was an anaphylactic shock from the Covid shot. They kept her in ICU and released her 1/23/21. At 12:45 am on 1/24/21 she passed out and we called the ambulance. Hospital admitted her and worked through multiple organ failure issues and thought her numbers were under control. She was released on 1/27/21 and was driving on 1/28/21 around 4:15 pm and appears to have had heart failure and

No prior vaccinations for this event.

had a wreck. She passed away that day.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On December 17, 2020, my husband, received his first BioNTech BNT162b2 COVID-19 vaccination. On Thursday January 7, 2021, he received this second COVID-19 vaccination. The following three days after his second vaccination, he felt fine. The fourth day, on Sunday January 10, my husband felt extremely fatigued. On Monday the 11th and Tuesday the 12th, he worked a full shift but complained of extreme fatigue and extreme chills to the point that his teeth were chattering while on the phone with me. He decided to work through it. When he got home on Monday night, he started vomiting. On Wednesday January 13, he woke up and had swollen eyes. Once again, he felt extremely fatigued, even after a full nights rest. He had the day off but had an early meeting. After his meeting, he was still tired so he went back to sleep. I left to get lunch, and drop off our kids, and upon my return, I found him on the walk in closet floor, face up, having passed away. He felt as cold as ice. The rapid test done after they called the paramedics resulted in a negative COVID-19 test for him.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient (now deceased) received 1st dose of Pfizer-BioNTech vaccine around December 21, 2020 and was noticed to be scratching, fatigued, and unresponsive by a family member on December 24, 2020. He received the second dose of the same vaccine around January 22, 2021. Pockmarks and bleeding scratch marks were noted by a family member on the patient's face prior to this second dose. On January 28, 2021 a family member was alerted that the patient was suffering from severe bullous pemphigoid- a skin condition that has never been experienced by the patient, has been reported to be related to COVID-19		No prior vaccinations for this event.

viral infection, and to T-cell responses promoted by vaccines. A corticosteroid was given, but did not work. Blisters developed to the point hands had to be dressed.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient had no energy in the first 24 hours and then began a steady decline that started with vomiting after 48 hours, then an inability to swallow and ultimately the patients death on 2/5/21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 2/4/21, at around 3:00pm he began feeling very tired and he began burping in the evening. The following morning, he woke up early and was still burping and not feeling well. At around 5:00am, he collapsed. My mother called 9-1-1 and began giving CPR. The parademics arrived and tried to revive him, and transported him to the hospital but at 6:11am, he was pronounced dead of a heart attack. He was healthy.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

right arm swelling immediately after injection. followed by bilateral lower leg edema, chills and body aches that continued daily at 2 weeks post immunization admin 2/4/21 treated with dexamethasone 6mg PO x 7 days- this resolved his s/s 2/13/21 patient passed away at facility

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Taken to Emergency about 8 hours later and died in ER No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

deceased, 2/1/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident had slight/slow decline in health prior to vaccine but continued to be able to walk around with walker at community. The day of the vaccine she had a fever. 2 days after vaccine resident did not get out of bed all day and refused to eat. She had small amounts of orange juice as her blood sugar level was low due to not eating. Resident was diagnosed with a UTI and began an oral antibiotic. 3 days after and on day 5 after vaccine resident began feeling weak and had a fall on each day. The following day again resident spent the day in bed. The next day she was quite restless, was on the edge of her bed attempting to self transfer often throughout the day. Resident continued to be restless on the 10th of Feb, had further decline on the 11th of Feb. Resident passed away early the AM of Feb. 12th.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

COVID 19 symptoms and a positive test was confirmed on 1/6, employee noted previous exposure to positive family members Narrative: Employee noted exposure to COVID prior to presenting for 1st dose of vaccine on 1/5/21. On 1/6/21 employee reported the onset of symptoms and was tested and was confirmed COVID positive that day. Positive result was reported to employee health on 1/8/21. Employee Health continued to track employees progress and was informed of the need for hospitalization on 1/14/21. Course of hospitalization noted the need for intubation and significant issue with comorbid condition (rheumatoid

No prior vaccinations for this event.

arthritis). Employee died on 2/9/2021. Unable to confirm a direct connection to Vaccine vs. COVID infection, but felt it should be reported.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was not seen at our facilities prior to or after COVID-19 vaccination. Patient received first dose on 1/23/2021 and as reported by the family member, patient expired on 2/5/21. Symptoms were reported to have stared on 2/1/2021, 9 days after receiving the first dose with a drop in oxygen levels and fever. He was reported to also have a history of chronic lung disease. Patient's family member to be contacted if necessary.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient and her husband are elderly, but healthy and live independently. Patient took blood pressure medicine 'off and on' according to family. She was 5'2"", 120 pounds and slim and healthy and active, so was her husband, though he had pulmonary fibrosis so they had been staying home and not attending church etc, and masking when they did go out to protect against covid disease. They were both vaccinated with covid Pfizer vaccine (dose #1) on Thursday Feb 11. (02/11/2021) Thursday night as they went to bed they checked in with each other on how they each felt. Patient said she felt totally fine, and her husband said his arm was a bit sore. Patient woke before her husband on Friday Feb 12, went downstairs and, from what the family can tell, fixed herself a snack, then sat on the sofa. Patient's husband found her deceased on the sofa. He called 911 and they asked him to do CPR until the paramedics arrived. Because of proximity to covid vaccine, the ME wanted to examine the body in the home and also ordered an autopsy. Autopsy was completed on the same day as death, Feb 12, 2021"		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received dose #1 of COVID-19 vaccine (Pfizer-BioNTech) on 12/18/20 and dose #2 (Pfizer-BioNTech) on 1/8/21. On 1/30, patient was evaluated at urgent care due to back pain. No bloodwork done; metronidazole prescribed for 7 days. On 2/8, patient was admitted to outside hospital due to ongoing symptom progression. At time of admission, hgb 5 g/dL and plt 9k. Per Dr. (hematology/oncology), pt with schistocytes, LDH 1500, and elevated reticulocyte count consistent with thrombotic thrombocytopenic purpura (TTP). SCr >2 mg/dL. Patient immediately treated with plasma exchange and steroids, however continued to decline. Patient expired on 2/14/21.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"The day after the 2nd shot, patient developed blisters on his lips and mouth. The care facility said that he had a nut allergy -- but he had never been allergic to nuts. He stopped eating and drinking and his BP had dropped to 60/40. By Jan 16th they called to say he was dying and he passed away on 1/18/21. Patient had COVID19 from Oct 29th - early November. By Nov 21st he had lost 40 lbs. He was 6'3"" and had gone from 189lbs to 149 lbs with COVID. By Nov 21st when we could visit, he had recovered from COVID, but was very thin and weak. He could not bathroom alone and kept falling. He didn't seem to have a bad reaction to the 1st COVID shot, But he immediately reacted to the 2nd shot and passed away within 6 days."		Shingles - Glaxo 8/22/2020, resulted in hospitalization and LTC.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to		No prior vaccinations for

ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11. | this event.

DEATH | **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient received his first dose of Covid vaccine on Jan. 30, 2021. On Jan 31, 2021 at 6:08 AM, patient noted unresponsive per facility. Code blue was called and 911 dispatched. He expired in the ER. | No prior vaccinations for this event.

DEATH | **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death | No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Received Pfizer 1/22/2021. RNA+ 2/4/2021. S/S SOB, cough, confusion. COVID assoc. resp. failure, stage 4 lung cancer, COPD, HTN, former smoker. patient in hospice and died 2/10/2021. | No prior vaccinations for this event.

DEATH | **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased | No prior vaccinations for this event.

exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

patient passed away within 60 days of receiving a COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

PATIENT PASSED AWAY ON 2-1-2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Associate developed SOB on 2/12/21. Taken to Hospital on 2/13/21. Reported deceased 2/14/21.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
passed away; This is a spontaneous report from a contactable consumer (patient's granddaughter). An 82-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EN9581), via an unspecified route of administration on 08Feb2021 at 14:30 into right arm at single dose for COVID Prevention. Medical history included Heart valve replacement from 5 years before 09Feb2021 (2016), on Oxygen at night (reporter did not know the liter amount that the patient used at night). The patient's concomitant medications were not reported. Patient had no other vaccines on the same day as the COVID vaccine. It was reported that patient received his first dose of the Pfizer vaccine around 14:30 on 08Feb2021 and he was fine before that, and by 16:30, he had passed away on 08Feb2021. Reporter reported that the cause of death was unknown at this time and that the family would be having an autopsy performed but that it had not yet been performed. No investigation assessment could provide. The patient died on 08Feb2021 at 16:30. An autopsy was not performed.; Reported Cause(s) of Death: passed away	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

approxmately 1:30 Pm the resident passed away; This is a spontaneous report from a Pfizer sponsored program. A non-contactable consumer reported that a female patient of an unspecified age (reported as 85 without unit) received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL0140), intramuscular at left arm on 29Dec2020 11:29 at single dose for COVID-19 immunization. Medical history included dementia, aphasia, type 2 diabetes mellitus (DM), iron deficiency, asthenia, osteoporosis, polyneuropathy, anxiety, Major depressive disorder (MDD). Concomitant medication included gabapentin, memantine. The patient had allergies to codiene, phenobarbital, penicillin. The vaccine was administrated with no immediate adverse reaction at 11:29. Vaccine screening questions were completed and resident was not feeling sick and temperature was 98F. At approximately 13:30 on 29Dec2020, the resident passed away. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected. ; Reported Cause(s) of Death: approxmately 1:30 Pm the resident passed away

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt passed soon after; shortly after progressed with other covid symptoms and was admitted / acute resp failure, COVID pneumonia; acute resp failure, COVID pneumonia; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; This is a spontaneous report from a non-contactable Pharmacist. A 76-years-old non-pregnant female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE lot number EL3247), intramuscular on 19Jan2021 at single dose for COVID-19 immunisation. The patient medical history included COVID symptoms from 16Jan2021 and ongoing. Concomitant medications were not reported. The patient with acute resp failure, COVID pneumonia, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior to a admit, then shortly after progressed with other

No prior vaccinations for this event.

covid symptoms and was admitted on 25Jan2021. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. The patient died on 02Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events death, COVID-19 pneumonia, acute respiratory failure, hypotension, abdominal wall haematoma and abdominal wall haemorrhage cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pt passed soon after

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death on 1/17/2021. Found at home deceased. No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Healthcare was advised that this patient expired approximately two weeks after receiving her initial COVID vaccination

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-

	BIONTECH)) (1200)
Death on 2/8/2021 unknown signs and symptoms at time of death; multiple co-morbidities	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received her vaccine on 2/2/2021 in the morning. She was observed for over 15 minutes and had no history of any anaphylactic reaction of any sort. She felt fine and went home. 2/15/2021 we were notified by her family that she had passed away on 2/7/2021 at home. The cause of death was stated as myocardial infarct secondary to coronary artery disease. We do not think it had to do with the vaccine administration. The patient had many comorbidities.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had no reaction at the time of vaccination. Waited the required 15 minutes and was allowed to go home.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient found deceased at home on 2/15/2021. There was no known cause of death with no significant medical history.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-**

		BIONTECH)) (1200)
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he		No prior vaccinations for this

was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021. event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient was found unresponsive the following day and then pronounced deceased No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient had COVID in Sept. Minimal symptoms. Received 1st dose 1/18 without adverse reactions. Second dose on 2/8-had complaints of arm soreness several days after then appeared in usual state of health. On 2/14 @ 2 hours after having lunch, patient was found unresponsive with Respirations 60, pulse 130, PO 84%, blood pressure 105/68. Patient with lots of white foam coming out of mouth. Temperature to 101.3. Patient DNR B and family deferred transfer, wanted comfort measures only. Nursing received order for MSIR. Patient continued with temps in 99-100 range with tylenol suppositories. Patient passed on 2/16. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death on 1/31/2021 multiple comorbidities No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and No prior vaccinations for this event.

creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident did not exhibit any side effects from the vaccine. Staff spoke with him in his room at approximately 7:20am and returned to his room just a few minutes later and he was unresponsive. When the RN got to the room he had CTB. Physician documented heart failure and end stage kidney disease on the death certificate.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Multiple co-morbidities history of COVID-19 6/8/2020 and 12/28/2020. At time of vaccination		No prior vaccinations for this

fighting osteomyelitis. 1st dose 1/13/21, 2nd dose 2/3/2021 expired 2/8/2021.

event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient developed pneumonia Admitted to hospital on 12/25. Determined to have pseudomonas bacteremia and passed away on 12/27.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

unkown No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Diarrhea , fatigue on 2/10 Fall 2/12 out to hospital Resident Expired 2/14 No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Is patient deceased: Yes; Low pulse; This is a spontaneous report from two contactable nurses reporting for a patient. A 70-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot

No prior vaccinations for this event.

number EL0140 expiration date Mar2021) intramuscular on 22Dec2020 at 10:30 at single dose in right arm for COVID-19 immunisation. The patient was vaccinated at Nursing Home. Patient age at time of vaccination was 70 years. Patient's Medical History included ongoing Type 2 Diabetes Mellitus Without Complication onset date: admission 22Oct2020, ongoing morbid obesity due to excess calories onset date: admission 22Oct2020, cardiac disorder, essential hypertension, hypertension, schizophrenia, hyperlipidemia, benign prostatic hyperplasia (BPH), Gastrooesophageal reflux disease (GERD), depression, hypothyroid, epilepsy, pain, dry eyes, anxiety, restlessness, 17Jan2020 Slid out of chair to floor, no injury, on 27Jan2020, 28Jan2020, 29Jan2020 diarrhea noted. Concomitant medications included acetylsalicylic acid (ASPIRIN EC) for Cardiac Health, atenolol (ATENOLOL) for Essential Hypertension, atorvastatin calcium (ATORVASTATIN CALCIUM) for hyperlipidemia, finasteride (FINASTERIDE) for benign prostatic hyperplasia, tamsulosin hydrochloride (FLOMAX) benign prostatic hyperplasia, insulin glargine (LANTUS) for diabetes mellitus, lithium carbonate (LITHIUM CARBONATE) for Schizophrenia, losartan potassium (LOSARTAN POTASSIUM) for hypertension, lurasidone hydrochloride (LURASIDONE HYDROCHLORIDE) for Schizophrenia, omeprazole (OMEPRAZOLE) for gastrooesophageal reflux disease, sertraline hcl (SERTRALINE HCL) for depression, levothyroxine sodium (SYNTHROID) for hypothyroid, ergocalciferol (VIT D) for supplement, haloperidol (HALOPERIDOL) for Schizophrenia, levetiracetam (KEPPRA) for epilepsy, paracetamol (TYLENOL EXTRA-STRENGTH) for pain, propylene glycol (ARTIFICIAL TEARS) for dry eyes, lorazepam (ATIVAN) for a anxiety or restlessness. As antipyretic use was reported Tylenol ES (500 mg) Tab, 2 Tabs by Mouth Routine use three times a day given at time of vaccination and after. It was reported the patient was Covid+. He was tested on 21Dec2020 and was not admitted to hospital. Event Onset Date was reported as 24Dec2020 (clarification pending). On 30Dec2020 the patient was started on O2 at 2L for low pulse. O2 was increased over time to eventually O2 at 8L on 03Jan2021. Morphine Sulfate was started on 03Jan2021 at 5 mg sl/by mouth every 2 hours as needed for pain or airhunger. The patient deceased on 03Jan2021. The cause of death was unknown. It was not reported if an autopsy was performed. The AEs did not require a visit to Emergency Room or Physician Office. Outcome of Low pulse was unknown.; Sender's Comments: Based on the information available the events Death (unknown cause) and Heart rate decreased are attributed to patient's multiple underlying medical conditions including Type 2 Diabetes Mellitus, morbid obesity, cardiac disorder, hypertension, epilepsy etc. However, based solely on a

vaccine-event chronological association, contributory role of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the above mentioned events cannot be completely excluded. The case will be reevaluated should additional information, including the cause of death, become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Is patient deceased: Yes

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death, 2-17-21 at 1802 hours No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death on same day as vaccination No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death within thirty days of vaccine. Multiple co-morbidities and placed on hospice 12/28/20. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

(02/15/2021): vaccine (02/16/2021) : severe body aches and weakness, increased congestion and No prior vaccinations for this

mucous production. (02/16-17/2021) : death possibly during the night

event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident complained about back pain in the middle of the night and when they went to do a blood pressure examination, she passed away at 2:40 am.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Daughter of decedent reported that he quickly declined within 2 weeks of receiving vaccine and developed shortness of breath. Decedent received vaccine 1/30/2021 and died 2/15/2021. Only received first dose of series.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Death Narrative: Patient received first dose of COVID vaccine on 1/30/21. Reported by his wife to agency that he passed away at an outside hospital on 2/14/21. By report of his wife: ""due to sepsis (related to bed sores) and aspiration pneumonia"""

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

"death was from natural causes; collapsed; This is a spontaneous report from a contactable consumer. A 73-year-old female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 05Feb2021 at 73-years-old at a single dose for COVID-19 immunization. The patient's medical history included chronic obstructive pulmonary disease (COPD) from an unknown date and unknown if ongoing (on oxygen as needed, but not every day), oxygen therapy from an unknown date and unknown if ongoing. Concomitant medications were not reported. The patient previously received the influenza vaccine (MANUFACTURER UNKNOWN) for immunization on unknown dates (Gets flu shot every year around October). On 06Feb2021, the patient collapsed (medically significant) and experienced death was from natural causes (death, medically significant). The clinical course was reported as follows: The reporter stated that his grandmother received the first dose of the Pfizer COVID-19 vaccine on 05Feb2021 and passed away on the morning of 06Feb2021. The patient went to bed and woke up in the middle of the night around 03:00 to use the bathroom and collapsed and died within 10-15 minutes of collapsing. The patient was pronounced dead at the scene. The reporter asked: ""What do you know about the news in the media about reports of death in nursing home elderly patients?"" The reporter wanted to know the ingredients of the Pfizer COVID-19 vaccine. The reporter wanted to know about the use of the Pfizer COVID-19 vaccine in patients with underlying conditions. The patient had COPD and was on oxygen as needed, but not every day. The Medical examiner said the death was from natural causes and the family was not doing an autopsy. The patient had been tested for COVID and was negative. The patient underwent lab tests and procedures which COVID test: negative on an unspecified date. The clinical outcome of the event, death was from natural causes, was fatal. The clinical outcome of the event, collapsed, was unknown. The patient died on 06Feb2021 due to death was from natural causes. An autopsy was not performed. The batch/lot numbers for the vaccine, bnt162b2, were not provided and will be requested during follow up.; Reported Cause(s) of Death: death was from natural causes"

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

"Patient had swelling around her jaw after her second shot of the covid , Pfizer vaccine (.5 ml IM) on the Friday morning, January 29th, I took her to a follow up appointment with the cardiologist at 3:00 pm, as a follow up to a small heart attack event with hospitalization two weeks previously, at the cardiologist she was given the ok/all is well. That next morning early, she had a 911 event at her assisted living apartment and was sent back to the hospital, having had another heart attack. Patient died on the following Thursday, February 4, 2021. I do not know if the vaccination had any cause for my mothers death; but I feel it is necessary to report this series of heart attacks after she received the pfizer vaccine. Her Certificate of Death records the cause of death as ""Coronary Artery Disease""."

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death within 30 days No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Decedent had unwitnessed fall out of wheelchair 1/25/21 around 9:43am, denied head strike, pain, discomfort. Around 10:02pm, 1/25/21, decedent noted to have slurred speech and fluctuating HR, transported to Hospital and made cmo.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received first dose of covid vaccine on 1/22/2021. Patient had no immediate reaction. Patient presented to the Emergency Department on 1/26/2021 c/o shortness of breath and chest pain. ECG

No prior vaccinations for

showed a ST elevation myocardial infarction. Patient was treated and transferred to a cath lab where he died. Patient had significant coronary artery disease.

this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

she died 2/12/2021 at close to 2pm No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient died on 2-13-21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

On the 25th he was home alone, he called 911 and let them know he thought he was having a stroke. EMS arrived and transported him to Hospital. It was massive stroke, he was not able to comprehend anything, he was put into Hospice the following day and passed away on the 27th. There was no autopsy preformed.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

As per patient daughter - patient had some minor chills on the day of the vaccination - Friday 1/15/21; felt well next day -Saturday, than she was found slumped and lifeless on the couch on Sunday 1/17. Cause of death on death certificate was reportedly put as COPD, Lung Ca and ASHD.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH))

		(1200)
PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO WITHDRAWL EXTRME MEASURES		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My dad received the Pfizer vaccination on 2/5/21. He was admitted into the hospital the next day for C-Diff bacterial infection. He had been on dialysis treatments for kidney failure treatment since 2017 and had recently been diagnosed with stage 3 colon cancer in June 2020. He had completed his final treatment of chemotherapy on 2/4/21 and several weeks prior had been determined cancer free. On Tuesday 2/9/21 he was released from the hospital and went home. Early Thursday morning 2/11/21 @ approximately 1:30 am CST his eyes rolled back in head and he stopped breathing and was non responsive. My mother called 911 and attempted CPR. Paramedics arrived and were able to successfully get a pulse then transferred him to the hospital. He was put on a ventilator @ the hospital and then transferred to a different hospital a few hours later. He lost pulse/heartbeat several times @ the 2nd hospital he was transferred to. We were not allowed to travel with him or see him b/c of all of the COVID restrictions. We were communicating with the ICU doctor by phone who ultimately communicated to us that there was nothing further that could be done to save his life. He subsequently passed away @ approximately 8:55 am CST on 2/11/21.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Grandmother had trouble breathing the night she got the vaccine. She went to the hospital. They found pneumonia and a partial bowel obstruction. The obstruction cleared but she died from the pneumonia		No prior vaccinations for this

on 2/16/21.

event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient found in home deceased. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature

No prior vaccinations for this event.

again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as

treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was found with no pulse no heart rate by a staff member around 11 pm. Earlier that day seen by myself for fatigue, sorethroat, nausea.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
A few days after the vaccination my father had a sore throat and slight cough. This progressed	No prior vaccinations for this event.

into pneumonia like symptoms and he died on 2/11/21.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

patient passed away within 60 days of receiving a COVID vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

patient was not vaccinated at hospital. Caregiver reports that patient was vaccinated with second dose on Monday 2/15/21. Tuesday patient experienced n/v/d. Went to an ED on Wednesday and was cleared and sent home. Thursday reported shortness of breath to her caregiver and then collapsed. Patient was brought to as PEA arrest and ultimately died. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Received 2nd dose of COVID19 Pfizer vaccine at 1103 am on 2/19/21, was last seen at 1159, found around 1615 by kitchen staff who were serving dinner. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient passed away from chronic respiratory failure with cardiogenic shock 24 hours from 2nd dose of vaccine. Patient with longstanding history of pulmonary HTN and heart failure with desire for comfort care only. Entering into VAERS out of abundance of caution. No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death No prior vaccinations for this event.	
DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had no adverse events during the observation period after vaccine. He was conscious and having conversation with facility staff. He was observed for 15 minutes at least. When the facility staff returned later, approximately 60 to 90 minutes, patient had passed away.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No symptoms or signs on the day 1st dose of vaccine was received (2/11/2021). 3 days later, (2/14/2021) patient experienced chills for approximately 6 hours, followed by severe (visible) chest spasms, and then cardiac arrest. 911 was called upon witnessing chest spasms, but cardiac arrest/death occurred before	No prior vaccinations for this event.

patient could be transported to the hospital.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/23 - Mild injection site discomfort. Appetite loss compared to previous day. Beginning loss of mental acuity compared to previous day. 1/24 - Continued loss of appetite. Near complete loss of ability to move. Continued decline of mental acuity. Very little speaking. 1/25 - Stopped speaking completely. Loss of bowel control in the evening and continued until death. Complete loss of appetite. 1/26 - Near complete loss of ability to swallow. Moved to hospice 4:00pm. 1/27 - Died 4:00am		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received the 2nd dose of the Covid vaccine approximately around 1105 by pharmacy through the pharmacy LTC partnership vaccination program. Resident had no adverse effects until around 8:00 pm she began complaining of body aches, and chills, Tylenol was given at this time. Around 9:30pm resident was sleeping in bed. Around 12:00 am the CNA called nurse into room to assess resident as the resident stated she did not feel good. Temperature at that time was 102.2, and vomiting. RN came to assess @ 1220 am She was noted to be vomiting, diaphoretic, pale and having trouble breathing. Temp was 97.3 after vomting, Pulse 53, Resp 20, o2 sats were 40-45%, unable to obtain Blood pressure, Applied 5 L of oxygen at this time and had LPN call 911 immediately. Resident was repsonsive and able to follow staff members instructions but was only answering yes or no simple questions at the time time of assessment. Paramedics arrived at 0040 and resident was sent to Hospital. @ 0130 ER nurse called to nursing facility to notify resident had coded in the ER and passed away @ 0110.		No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient had sore arm on the day of vaccination. Per patient's nephew , the next morning patient experienced body pains, aches, headache . Onn Tuesday patient had fever. Patient's condition progressively got worse. He had difficulty breathing by Wednesday night. He had low oxygen levels at 80 per pulse ox reading. Patient was coughing up blood. Family took him to hospital on Thursday morning due to breathing difficulty and patient died 2.18.21 at 10 am

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient died 3 days after receiving his first dose of the Covid vaccine. He saw his doctor 2 weeks prior to his death with absolutely no complaints, very healthy. He had no prior heart conditions and was pronounced dead of a heart attack.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident deceased No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death after stroke . No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death on February 12, 2021 acute cardiac tamponade No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21- N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

02/07/21 through 2/13/21 slightly fatiqued, took all his prescribed medications, ate breakfast, lunch and dinner was drinking eight 10 oz bottles of water. On 02/14/21 was very tired had a difficult time breathing after taking the normal meds. He took a breathing treatment with his prescribed Ipratropium Bromide and Albuterol Sulfate via home nebulizer. This did not improve his breathing. He was very weak and breathing was labored. 911 was called by wife. 911EMTchecked pulse and breathing. Informed him they would give him a breathing treatment.He started to go limp. EMT's got him to Ambulance and to Medical Center to the ER. Heroics done. He died. Pulmonary and Cardiac Arrest	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident is a Hospice patient. On 1-23-2021 am shift resident was observed by nursing have chest congestion and had a emesis times 1 with SOB, Zofran 4 mg was given. HOB (02 sats 88%) was elevated resident on 02 via nasal canula with 02 sat now @ 90% . no respiratory distress noted. MD was called with response pending for orders. @ 1400 resident with no signs of life. vs 90%-24-97/71-97.6. Hospice on site and time of death 1436	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history	No prior vaccinations for this event.	

included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice, memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200 mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation: tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed, metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and

voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral patchy opacities

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Patient passed away on 2/1/21 at the Health System. She was there for congestive heart failure (CHF) which had been a problem for her since contracting COVID-19 (symptoms began 10/29/20 and tested positive 10/30/20). She had been to see her medical provider several times after her isolation period as well as a few trips to the hospital for, what they called ""CHF flare-ups"". Her last hospitalization began on January 30, 2021. Her social worker reported on t1/31/21 that ""she would likely be returning in another day or two""."

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death on 02.15.2021. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Notified on 2/24/2021 that patient passed away on 2/14/2021. Other cause of death - non-covid -19 related

No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Extreme difficulty breathing upon exertion, collapsed shortly after walking started, loss of conciousness, and death		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was into the clinic on the afternoon of 2/23/21 for a COVID-19 vaccine. He had a podiatry clinic visit after his vaccine same day. It was reported by the patients family physician that patient stated he didn't feel well and suddenly collapsed at home at approximately 4:45 pm. Emergency medical personnel were not able to revive him. Patient died at approximately 4:45 pm on 2/23/21.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Cardiogenic shock occurred on 2/10/2021, approximately 12 hours after patient received her 12th dose of pemetrexed/pembrolizumab and 4 days after COVID vaccine. Coronary angiography was done on 2/10/2021 and no significant coronary narrowing or blockage were noted. Baseline troponin on 2/10/21 was 0.02 and later on 2/10/21, troponins were 9.99 & 25.27. Creatinine increase from 1.2 to 3.4 within 24hours, and AST/ALT increased from 23 & 31 to 4,220 & 4,786 respectively on 2/11. Patient expired on 02/11/2021.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient felt achy, tired starting the day after the vaccine. Per his wife, he was very tired and ""losing		No prior vaccinations for

stamina"". On 2/13/21, he woke up feeling dizzy and weak. His wife asked him if he wanted to go to the doctor and he declined. He ate breakfast and went to rest in his easy chair. He passed away an hour later." this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient was hospitalized 15 days after receiving vaccine. Admission was not due to vaccine and was admitted for acute ascites and patient had reported fever and hypoxia. Patients admission resulted in death 7 days after being admitted to hospital. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident found unresponsive in his room. CPR performed and patient expired. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident found unresponsive, CPR initiated and EMS called. EMS called time of death after arrival. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident expired on 2/29/21. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident expired on 2/24/21, under hospice care. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"Pt received vaccine on 1/29/2021 and died on 2/13/2021. Wife called agency and noted the pt received his 1st dose of vaccine and was having ""side effects and began declining"". It is unknown what side effects he was having." No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

THE RESIDENT WAS ROUTINELY TESTED FOR COVID ON 1/29/21 AND POSITIVE RESULTS RETURNED ON 1/30/21; WAS ASYMPTOMATIC AT FIRST, BUT DEVELOPED SYMPTOMS ON 1/31/21 THAT PROGRESSED AND THE RESIDENT DIED ON 2/7/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient deceased 2/9/2021 when called for second dose vaccine appointment No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

patient deceased no show to 2nd appointment notified by family No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

No documented vaccine reaction Hospitalized due to co-morbities No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pale, Short of Breath, Hypoxic, Lethargic within minutes became unresponsive and died.	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death	No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)	
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema	No prior vaccinations for this event.

and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Three days after second COVID-19 vaccine, patient became lethargic. Due to advance directive that instructed that no life saving interventions to take place, patient continued to decline and expired on 29 January 2021.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19**

(PFIZER-BIONTECH)) (1200)

Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Extreme Fatigue, slurring speech, unable to stand, eat. Death on 2/5/21 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On the evening of 2/23/221 at 9:00 pm, resident reported feeling SOB, BP 80/44, Pulse 53, O2Sat 95% on 3L oxygen, hands cold, pulse weak. Temp 92.5F MD notified. EMS activated. EMS arrival and HR 20. Family refused transport to ER. Resident expired at 2:40 am on 2/24/21 Meds continued: duloextine, VITd2,hydralazine, synthroid, lisinopril, mag ox, folplex, pantoprazole, potassium chloride, ellipta, ensure, hydrocortisone cream, boost, deprox, xanax, morphine, lorazepam, tylenol, albuterol inhlation, ventolin inh.

No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had only complained of a sore arm after receiving the vaccine- pt died on 2/25/21 from what they feel was a massive heart attack- unsure if related to vaccine at all		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pfizer-BioNTech COVID- 19 Vaccine EUA Patient received COVID-19 Vaccine dose #2 on February 24, 2021. On February 25th at 10:36 AM,Patient's son called physician to report some side effects to second dose of Covid vaccine. She had diarrhea when she came home yesterday. Son has been up all night with her as patient has had a ""hacking cough,feels terrible, and now has had diarrhea x2"". Patient has taken Advil and will be taking tylenol periodically through out the day for her side effects. Patients son notified physician at 09:55 AM on February 26 that the patient has expired."		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient had declining health for the past 6 months, dementia and unable to walk. Patient had decreased appetite starting 1/1/21. After 1st vaccine shot patient appetite decreased further. After 2nd vaccine shot patient fatigue increased to the point where she could not get out of bed and had minimal appetite. Patient passed away 10 days after receiving 2nd shot on 2/22/21. Patient did not go to ED and was not hospitalized.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

death 2/25/21 No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal tunnel and sent her home. The morning or March 18th , 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/14/21 - Resident complained of SOB. SPO2 66% on RA, vs 105/66-96-20 T98.2 O2 administered Pox 97% Binax test revealed (+) COVID results. Resident transferred to COVID wing. Family (HCP) updated and declined transfer to hospital Resident continued with fever, hypoxia and lethargy. Family elected CMO and Hospice notified. Resident died on 1/16/2021 @ 930AM.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Possible Stroke per Medical examiner but Reported symptoms after covid vaccine 2/11 therefore being considered poss Covid vaccine related also. No hospitalization prior to death. (Symptoms reported to office 2/17) Fatigue, decreased appetite-

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Per Patients Wife - Same day - Flu like symptoms, Nausea, Headache. Restless that night. Next day - Weak, shortness of breath. Wife called squad to get him out of his wheelchair but patient refused hospital as it gets him agitated. Patient passed away around 11 AM the day after vaccination.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt expired 11 days after receiving vaccine. No indication his passing was related to the vaccine. Narrative: No updated notes regarding cause of death. Patient's wife called to notify the facility of his passing on 1/26/2021

No prior vaccinations for this event.

DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death Narrative: 86 year old MALE with PMH of Afib s/p AICD/PPM, HFrEF (EF< 20% 10/2019), DM2, HTN, HLD, BPH, Depression. Was stable and feeling well when he was administered Covid-19 vaccine on 02/17/2021- Pfizer COVID-19 Vaccine 0.3 ml IM. MVX (Manuf); PFR; Lot#; EL9267; Exp Date:05/31/2021 Administration Anatomic site: Right Deltoid; Pt was monitored for 30 minutes after administration and had no adverse effects. He was called later in the day and reports he feels well and has had no adverse reactions, he endorsed his arm is a little sore at injection site. ON 02/19/2021- his dghter found him on the floor, next to his bed, dead. She reported on 2/19/2021- that she was out with him to dinner on 2/18/2021, and he stated he did not feel well, that his insides did not feel right. He proceeded to have dinner and 2 drinks. HE was doing ok, when she took him home.		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
contracted covid after first dose Narrative: First covid vaccine dose 12/31/2020, tested positive for covid 1/7/2021, died from complications 1/25/2021		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death, unknown cause Narrative: Patient received COVID19 vaccine on 2/23/2021 at 14:27. On 2/24/21, patient's family found patient deceased at 12:08am. The local coroner had called the MC to let us know on 2/24/21 at 12:55am. Coroner did not suspect foul play.		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Death due to underlying condition for hospice pt. Narrative: This was a 95 yo patient residing at home with daughter. Patient reported to PCP on 1/4 c/o poor appetite and weight loss. Daughter reported that patient was very frail and requested a hospice referral. Outside medical records indicate that patient was dx with pneumatosis of the cecum and peritonitis. Patient also had severe atherosclerotic disease with near complete occlusion of the infrarenal abdominal aorta. Due to age and frailty, patient was placed in hospice care where he passed away on 1/22/21.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Severe headache, nausea and vomiting No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Unable to breathe and died. Doctors unable to save her upon arrival No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death. Patient was found unresponsive in the morning hours after her shot. No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Developed acute facial droop and slurred speech 2h after 1st dose of the vaccine on 2/17, found with R MCA stroke. Then became unresponsive on 2/27 and was found with an acute L MCA stroke. Was transferred from another hospital, was not a candidate for intervention, and was made comfort and died on 2/28		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient's daughter called to report that about 30 hours after receiving the vaccine he passed away at home. She said she didn't know the cause of death but she felt like she should let us know about it.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The recipient was feeling well immediately after the vaccination, all day on 2.8 and in the morning of 2.9. His daughter in law text him at 0930 and he did not respond to the text (atypical) and then he missed a morning meeting. His wife was downstairs in a meeting herself and after the meeting was over she called to him and he did not respond. She found him with no pulse and was not breathing. She called 911 and attempted CPR. They did not complete an autopsy, they stated that they believe the cause of death was either an embolism, Heart attack or aneurism. The wife stated that she does not believe the death was due to the vaccination; however, there were no tests completed to prove or disprove.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On date on second dose, 2/27/2021, the pt began have fatigue and diarrhea at around 10:30 am. This continued to the following day. On 2/28/2021, the patient was last seen around 4:20 pm by his wife in their residence. She found him unresponsive at 5:30 pm in their bedroom. EMS was called and the decedent was declared deceased. The pt had his first dose on 2/9/2021. Both doses were given at the hospital. Per family, the pt had no adverse affects following the first dose.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1. Fatigue ? day 1 - Tuesday 2. Loss of appetite ? day 1 Tuesday 3. Fever 102.0 ? day 2 - Wednesday 4. Chills ? day 2 - - Wednesday 5. Weak ? day 2 - - Wednesday 6. Non-ambulatory (unusual) ? day 2 - - Wednesday 7. Two emergency service ambulance assessment ? day 2 - - Wednesday 8. Symptoms		No prior vaccinations for this event.

improved ? day 3 - Thursday 9. Ambulatory - day 3 - Thursday 10. Symptoms worsened ? day 4 - Friday 11. Chills ? day 4 - Friday 12. Non-ambulatory again ? day 4 - Friday 13. Fever 102.0 ? day 4 - Friday 14. Left side flank pain ? day 4 - Friday 15. CPR and declared decease at home by paramedics - day 5 - Saturday morning @ 1:32am

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/26 /2021 - pt went to ER for chest pain 2/9/2021 - pt received Pfizer COVID vaccine 1st dose 2/17/2021 - cardiac arrest with death	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Minor arm pain on 2nd day of each vaccine Diarrhea 3 days after 2nd vaccine Massive heart attack (left ventricle) 8 days (2/24/21) after vaccine Home hospice 3:30pm 2/24/21 Stopped breathing 5:45 am, pronounced dead at 8:22 am on 2/25/21	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death; severe headache; This is a spontaneous report from a non-contactable consumer from a Pfizer-sponsored program. A male patient of an unspecified age (Age: 83, unit: Unknown; as reported) received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number:EH9899), intramuscularly in the left arm on 20Jan2021 at a single dose for COVID-19 immunisation. The patient's medical history included sulfonamide allergy from an unknown date and unknown if ongoing. Concomitant medications were not reported. The patient previously took azithromycin [MANUFACTURER UNKNOWN]	No prior vaccinations for this event.

and experienced allergy on an unspecified date. On 22Jan2021, the patient experienced severe headache (non-serious). On 28Jan2021, the patient experienced death (death, medically significant); 8 days after receiving the vaccine. The patient died on 28Jan2021 due to unknown cause of death. It was unknown if an autopsy was performed. The clinical outcome of the event, death, was fatal. The clinical outcome of the event, severe headache, was not recovered. No follow-up attempts are possible. No further information is expected. ; Reported Cause(s) of Death: Unknown cause of death

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient died; This is a spontaneous report from a contactable consumer (parent's patient). A 47-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via unknown route on 13Feb2021 (at the age of 47-year-old) at single dose for COVID-19 immunization. Relevant medical history and concomitant medications were not reported. On 18Feb2021 the patient died. The cause of death was unknown. An autopsy was not performed. No COVID prior vaccination. The patient had not been tested for COVID post vaccination. Information about lot/batch number has been requested.; Reported Cause(s) of Death: Patient died		No prior vaccinations for this event.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt received 2nd Pfizer BioNTech Covid 19 EUA vaccine @1:50 pm; Pt released from Observation @2:09 pm. Approximately 2:18 pm RN called to parking lot and observed pt having difficulties. Called for EMS & crash cart. Vitals taken 2:20 BP 83/55, no respirations noted, pt unresponsive. AED attached. EMS arrived 2:22 and took over care of pt. and transported @2:40 pm to Hospital. Per wife, pt has history of PE in Oct. 2020, HTN, diabetes with insulin pump, obesity, gastroparesis, home oxygen and uses motorized scooter.		No prior vaccinations for this event.

Wife also said pt had allergy to iodine not previously reported, and MD had stopped Zarelto subsequent to 1st Pfizer vaccine 2/8/21 ""due to breathing difficulty"". Patient was unable to be resuscitated. Time of death 14:59."

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

No known side effects; however, on 1/20 the decedent suffered lethargy. On 2/12/2021, the decedent had a possible seizure and was transported to emergency department where shortly after arrival, he was pronounced dead.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient had an unwitnessed cardiac arrest while outside walking his dog. AED in the field initially advised shock and was shocked 3 times without effect. At the time EMS ALS arrived, patient was in PEA arrest. He was transferred to Hospital with CPR in progress. Time of death called at 1857.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Caller is nephew of patient. Patient was admitted to Hospital on 2/15/21 with Covid like symptoms and decreased O2 sat. He tested positive for Covid 2/15/21. Treated with Remdesivir. Patient status continued to decline and he passed away in hospital 2/22/21 0612.	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.	No prior vaccinations for this event.

DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated approx 9a. Later that evening, patient was having trouble breathing so they called son who lives down the road to come, 20 mins after the call the patient has passed. Per medical examiner, pt died due to possible PE, MI, or his aortic aneurysm ruptured.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.

Influenza Vaccine

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH))

		(1200)
died; This is a spontaneous report from a contactable consumer reporting for a patient. An 86-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), on 10Feb2021 at single dose for COVID-19 immunization. Concomitant medications were not reported. Relevant medical history included bacterial infection, the patient was being treated for bacterial infection and had spent 1 week in hospital within one month prior to being dosed with vaccine. On 17Feb2021 the patient died. The cause of death was unknown. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: death		No prior vaccinations for this event.
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers		No prior vaccinations for this event.

turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away		
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/13/21 Patient had covid like symptoms 2/15/21 Patient admitted to Hospital with covid like sx and decreased O2 sat; tested positive for Covid on 2/15/21; treated with Remdesivir and convalesent Plasma. Sx worsened and patient died 2/26/21..		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient passed away 24 hours after receipt of 1st Dose Pfizer vaccine. Provider does not feel death was due to vaccination. but underlying conditions. No immediate side effects noted from vaccination.		No prior vaccinations for this event.
	DEATH	**COVID19 (COVID19 (PFIZER-**

	BIONTECH)) (1200)
DEATH Narrative: patient was placed on hospice care following vaccine, unclear cause of death, not documented	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"DEATH Narrative: patient's wife reported he had gone in an outside hospital, had held his brilinta as advised anticipating shoulder surgery ""and he threw a big clot and died.""""	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pfizer-BioNTech COVID- 19 Vaccine EUA: Wife of patient called Primary Care Physician to inform that patient had received dose #2 of Pfizer COVID vaccine, and later that evening experienced a seizure and expired.	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: PATIENT PASSED AWAY WHILE ON HOSPICE CARE	No prior vaccinations for this event.
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Presented to ED via EMS c/o increasing shortness of breath, O2 sat mid to high 80s on 4L. When EMS arrived , pt was in distress, intubated by EMS and transported to ED. Pt had a PEA arrest en route but resuscitated w/ return of spontaneous circulation after receiving a dose of epinephrine and chest compressions. Pt was hypotensive on arrival to ED. He was started on sepsis protocol , volume	No prior vaccinations for this event.

resuscitation and empiric antibiotics. Once stabilized, he was admitted to icu at hospital. Removed from respirator 2/22/21

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

DEATH Narrative: Pt he reports he developed chills SOB body aches the same night as receiving the COVID vaccine on 1.26.2021-pt is currently reporting CheSt tightness and SOB Admitted to hosp: ICU with Bilateral Pulmonary Emboli, LLE DVT, NSTEMI, Arrhythmia.

No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

death Narrative: no other details available, as nothing documented in record No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

DIED No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of

No prior vaccinations for this event.

Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was

due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

	DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Cardiac arrest- death	No prior vaccinations for this event.	
DEATH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Vaccinated 2/20. At that time, had symptoms of incarcerated hernia, went to ED for evaluation. Not felt to	No prior vaccinations for	

warrant hospital admission. Returned two days later with agitation, altered mental status, and incarceration. Went to OR, uncomplicated hernia repair. Postoperatively, did not recover mental status. Went into arrythmias POD 4, hypotension ensued, had multiple interventions and evaluations without satisfying answers for clinical course.	this event.	
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
He started vomiting 2 days later. we suspect he was having stool issues as well. he vomited blood at some point over the weekend. there was black vomit right before he passed. from 2am-6am he was wheezing and rattling and then he passed at approximately 6am 3/1/2021 at home. EMS did come and try to revive him and were unsuccessful.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient, age 101, was having a period of declining health prior to vaccine administration. This continued after the vaccine to include increased pain, inability to swallow and ultimately Patient passed away on 1/9/2021. The physician does not believe this is due to vaccine administration, however family asked that this information be reported for record keeping.	No prior vaccinations for this event.	
DEATH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received the vaccine around 11 am. He hadn't been feeling well (headache, dizziness) per report and initially called in to work. He then decided to come to work and was found down in a patient bathroom	No prior vaccinations for	

during his shift on our Facility while taking care of a patient (he was a nurse aid). Patient was coded and the team and was transferred to our Facility ED. He expired 3/3 2112

this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death No prior vaccinations for this event.

DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient hospitalized with shortness of breath and pneumonia (from 2/15/2021 to 2/21/2021) and patient died at another facility on 3/2/2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient hospitalized for NSTEMI (from 2/18/2021 to 2/20/2021) and discharged on hospice/comfort care. Patient died 2/21/2021.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

The same day that the person was vaccinated he started feeling dizzy and had difficulty breathing. He was hospitalized from February 5 to February 23. Patient died in the hospital on February 23, 2021

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Day After - severe headache, 2 days after headache continues, itchy scalp, day 3 rash visible at hair line headache continues, more confusion than normal, day 4 on site nurses check rash and think it is dermatitis, day 5 continues to get work nurse practitioner was to visit next day, day 6 NP thinks that she has UTI and sends her to hospital (2/11/21). Hospital determines - Rash is Shingles, UTI present, - MRSA is now present in shingles which is on right back of head and right neck and face. Next Sepsis is diagnosed. Since 2/11/21 patient was not conscious. 2/20/21 famiy is notified that she should be moved to Hospice. Moved to hospice on 2/20/21. The patient, my mother, died on 2/23/21 official cause of death is UTI.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Expired within 30days of vaccination. Received vaccine 1/22/21 did not have any complaints, during a bed check she was found on the floor with no apparent injury, no pulse or respirations.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

She passed away 2/24/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death within 30 days of vaccine No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death within 30 days of vaccination No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

DEATH Narrative: PT WAS PLACED ON HOSPICE ON 1/21/2021 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

DEATH Narrative: NO ADDITIONAL DETAIL PROVIDED OTHER THAN PATIENT DIED AT HOME No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

DEATH Narrative: NO DETAILS PROVIDED, NO NOTE REGARDING DEATH No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

RESPIRATORY FAILURE Narrative: PT PASSED AWAY WHILE IN THE HOSPITAL No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (UNKNOWN)) (1202)**

COVID 19 vaccine, unknown which company Chronically ill in a skilled nursing facility found diaphoretic, hypotensive, hypoxia to 85% arrived to Emergency dept in cardiac arrest Died within 65 minutes of nursing finding patient in distress Wife felt it may have been related to vaccine date of vaccination 1/6/20 hx covid 19 PNA in April 2020 No prior vaccinations for this event.

DEATH **COVID19 (COVID19 (UNKNOWN)) (1202)**

5 days after receiving his COVID vaccination the patient had a spontaneous (nontraumatic) subarachnoid No prior vaccinations

hemorrhage which was fatal. The patient had previously been stable on his coumadin dosing with therapeutic for this event.
INRs for the past several months per his wife. At time of presentation his blood pressure in the ER was
elevated to 223/94 and his INR was risen to 3.1

DEATH

COVID19 (COVID19 (UNKNOWN)) (1202)

Patient died several days after receiving the second dose of the vaccine. See additional information sent. An autopsy has been performed and results are pending.

No prior vaccinations for this event.

DEATH

COVID19 (COVID19 (UNKNOWN)) (1202)

Received first SARS-CoV2 vaccination yesterday at local store Experienced new symptoms of chills, nausea as well as worsening from baseline dyspnea at night. Wife states he had rough morning breathing and had sudden loss of consciousness and unresponsiveness and failed to respond to bystander CPR. He expired at his home.

No prior vaccinations for this event.

DECOMPRESSIVE CRANIECTOMY

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to emergency room on 2/1/2021 with a chief complaint of having a chronic headache and fatigue following receipt of the Moderna vaccine 10 days prior. Following examination by the physician, the patient was diagnosed with an acute subdural hematoma. The patient subsequently underwent decompressive surgery, however demonstrated worsening neurologic status over the next several days and ultimately expired on 2/4/2021.

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19

		(MODERNA)) (1201)
12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics		No prior vaccinations for this event.
	DECREASED APPETITE	**COVID19 (COVID19 (MODERNA)) (1201)**
Staff walked into resident's room around 10:00am and noted resident's left side of his face was flaccid. Nurse was called and upon assessment resident noted to have an unequal hand grasp with left worse. He was able to talk but was mumbled and hard to understand. Physician, hospice, and family were notified. Resident had a stroke at 10:06 am on 1/8/2020. He lost all ability to use his left side. Resident passed away on 1/11/2020.		No prior vaccinations for this event.
	DECREASED APPETITE	**COVID19 (COVID19**

	(MODERNA)) (1201)
Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21	No prior vaccinations for this event.
DECREASED APPETITE	**COVID19 (COVID19 (MODERNA)) (1201)**
resident had a pressure ulcer to RT hip, was getting treatment on. Was scheduled to have wound debrided and wound vac applied on 1-19-2021. Appetite was poor, not wanting to get out of bed, and decline in alertness. Passed away on 1-16-2021	No prior vaccinations for this event.
DECREASED APPETITE	**COVID19 (COVID19 (MODERNA)) (1201)**
Found dead at home slumped on the floor; Loss of appetite; Body aches; Feverish; A spontaneous report was received from a physician, concerning a 65-years-old male patient, who received Moderna's COVID-19 Vaccine and experienced feverish, body aches, loss of appetite, and death. The patient's medical history, as provided by the reporter, included diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia. Concomitant medications reported included metformin, glimepiride, lisinopril, atorvastatin, aspirin, methimazole, propranolol, and cilostazol. On 05 Jan 2021, prior to the onset of events, the patient received the first of two planned doses of mRNA-1273 (lot number 037k20a) for COVID-19 infection prophylaxis. On an unknown date in Jan 2021, some time after receiving the vaccine, the patient was feeling feverish with body aches and loss of appetite. On 09 Jan 2021 at approximately 21:30, the patient was found dead at home slumped on the floor. According to the paramedics, the patient was dead longer than when his wife found him, and no resuscitation was performed. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events, feverish, body aches, loss of appetite, was considered resolved. The patient died on 09 Jan 2021. The cause of death was not reported. The reporter assessed the event, death, as not related to Moderna's COVID-	No prior vaccinations for this event.

19 Vaccine. The reporter did not provide assessment for the events, feverish and body aches, in relation to Moderna's COVID-19 Vaccine.; Reporter's Comments: This case concerns a 65 year old male patient with medical history of diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia, who experienced the serious unexpected event of death, non-serious unexpected event of loss of appetite, and non-serious expected events of fever and body pain. The event of death occurred 5 days after the first dose of mRNA-1273. The events of fever, body pain and loss of appetite occurred an unspecified period of time after the first dose of mRNA-1273. Very limited information regarding these events has been provided at this time. Based on temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Definitive causal association is confounded by age and medical history of diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia.

DECREASED APPETITE **COVID19 (COVID19 (MODERNA)) (1201)**

Resident expired on january 21, 2021 No prior vaccinations for this event.

DECREASED APPETITE **COVID19 (COVID19 (MODERNA)) (1201)**

Per granddaughter's report, pt became very weak within hours of receiving the first dose of the Moderna COVID-19 vaccine and could not get out of bed the next morning without assistance, reported difficulty seeing, and did not recognize some family members. By Sunday, 1/31, pt was unable to be awakened, would not eat, and had low urinary output. Granddaughter reports that the morning of 2/1 he was awake and ate a small amount and seemed to be improving although still weak and unable to get out of bed. Granddaughter reported he died 2/1 around 10am in the morning. No prior vaccinations for this event.

DECREASED APPETITE **COVID19 (COVID19**

(MODERNA)) (1201)

Resident received the vaccine on 1-22-21 and she was diagnosed with COVID-19 during routine testing on 1-28-21. She didn't have any symptoms except feeling weak and she had a decrease in her appetite. She already had a poor appetite prior. She died on 2-2-21.

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (MODERNA)) (1201)

Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021and felt poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM CHLORIDE 1000 MG ONCE

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (MODERNA)) (1201)

1-2 days after vaccine, pt developed weakness, fatigue, body aches, nausea, headache and poor appetite. Pt was admitted to the hospital on 2/5/21 and death occured on 2/6/21

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (MODERNA)) (1201)

"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (MODERNA)) (1201)

Patient had the first Moderna Covid vaccine on Thursday 1/21/2021. She had a bit of sore arm on that day and the day after. On Saturday 1/23/2021, she had a fever of 100.5 F (11AM), nausea, light headache and chills. The temperature went down after she took ibuprofen. Patient's husband enrolled her to V-Safe to report all the adverse effects she experienced. On Sunday 1/24/2021, her temperature was 98.3F. She still had nausea and no appetite. She and her husband watched a football game in their bedroom upstairs. Husband noticed that his wife was pacing around the room many times. At 7Pm, Husband went downstairs for dinner but she refused to come down to eat. He went upstairs around 8pm, TV was still on. He turned off TV and went down stairs again thinking his wife felt as sleep while watching TV. He went back upstairs for bed around 10:30 PM. Husband said his wife had a deviated septum so she would snore very loudly when asleep. He didn?t hear her snoring so he went to check on her and found her not responsive. Husband called emergency services. Paramedic came at 10:45 and said patient was passed. Husband sent many texts to V-safe after that to report the incident. No response was received from V-safe. Patient?s doctor told her husband that she died due to cardiac arrest.

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (MODERNA)) (1201)

Patient experienced loss of taste and lack of appetite. Passed away on 1/23/21. No prior vaccinations for this event.

DECREASED APPETITE	**COVID19 (COVID19 (MODERNA)) (1201)**	
2/10: Fever, fatigue, tylenol 2/11 @ 1300: pt made DNR, hospice consulted 2/11 @ 1800 decreased LOC, increased RR, fever, chills - 1/5L NS bolus IV, rectal tylenol. Refusing to eat/drink, PO morphine 2/12 @ 16:30, deceased at facility **resident was not doing well prior to vaccination		No prior vaccinations for this event.
DECREASED APPETITE	**COVID19 (COVID19 (MODERNA)) (1201)**	
On monitoring for declining in condition, loss of appetite and generalized body weakness on2/1/2021. Was confirmed COVID-19 positive 4/23/2020.		No prior vaccinations for this event.
DECREASED APPETITE	**COVID19 (COVID19 (MODERNA)) (1201)**	
"86yo female alert, stable with ankle abrasion eating 100% prior to vaccine in assisted living facility. On 2/1/2021, received Moderna vaccine. Starting thereafter, eating 50% on 2/2/21. Temperature was 98 tympanic. On 2/3, the leg abrasion started having moderate bleeding. On 2/4, the caregiver noted patient ""not looking good, unable to talk, arms moving aimlessly, grasping"". BP 95/41, temperature 98, oxygen on room air 92-93%. POA did not want hospital transfer. 2/5 Hospice started, oxygen given, morphine given. 2/5-2/8 comfort care given, patient responsive to tactile stimuli, resting, not taking oral medications or food. 2/8/2021 patient expired."		No prior vaccinations for this event.
DECREASED APPETITE	**COVID19 (COVID19 (MODERNA)) (1201)**	
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever,		No prior vaccinations for this event.

and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

DECREASED APPETITE

COVID19 (COVID19 (MODERNA)) (1201)

Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (MODERNA)) (1201)

Started feeling unwell; Headaches; Body aches; Chest pain; Didn't had wishes to eat; Diarrhea; COVID-19 pneumonia; A spontaneous report was received from a consumer concerning a 69-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced COVID-19 pneumonia, feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea The patient's medical history high blood pressure which was controlled with medication. Concomitant product use included nifedipine and fenofibrate. On 20-JAN-2021, approximately a week and a half or two prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number 030L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. A week and a half or two later the patient stated feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea for which patient was hospitalized on 06-FEB-2021. Since everything seemed to be fine the patient was discharged on an unknown date in FEB-2021 however, patient's family was not notified that it was a late reaction to the vaccine's first dose. Later, due to shortness of breath he was hospitalized again on 08-FEB-2021 and was diagnosed for pneumonia and was intubated on the same day. Due to COVID-19 situation patient's family could not be in the facilities and that there wasn't any follow up of the patient given to the family, so family did not have much information. During the first hospitalization(06-FEB-2021) the patient had a blood test which showed a normal result and was tested for COVID-19 and Influenza, both were negative. During second hospitalization (08-FEB-2021) the hospital said that the patient was stable. The patient's family did not know the results of the tests conducted at the time. The action taken with the vaccine in response to the events is not applicable. The outcome of COVID-19 pneumonia was fatal. The patient died on 14 Feb 2021 The cause of death was reported as COVID-19 related pneumonia. The autopsy was not done.; Reporter's Comments: Very limited information regarding this event has been provided at this time. The cause of death was reported as COVID-19 related pneumonia. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the events are assessed as unlikely related. Further information has been requested.; Reported Cause(s) of Death: COVID-19 pneumonia	No prior vaccinations for this event.	
DECREASED APPETITE		**COVID19 (COVID19 (MODERNA)) (1201)**

Patient was transferred from hospital for further evaluation and care by pulmonologist. He started having symptoms a week before with fatigue, emesis, decreased p.o. intake, shortness of breath, vomiting and diarrhea. The two previous takes before death required increasing oxygen and family wanted everything done including intubation. He was transferred to ICU.	No prior vaccinations for this event.
DECREASED APPETITE	**COVID19 (COVID19 (MODERNA)) (1201)**
Hx dementia, CVA, CAD. 2-3 year history of only consuming 25% of 1-2 meals daily. All meds d/c early 2020 because of refusing to eat or drink anything. Suddenly began drinking april/may, gained weight back. Vaccinated on 1/7/21 & 2/4/21. On 2/22/21 had significant changes in respiratory status. Passed away 2/23/21.	No prior vaccinations for this event.
DECREASED APPETITE	**COVID19 (COVID19 (MODERNA)) (1201)**
Beginning in the evening 2/19/21, fever/chills/fatigue; worsening of symptoms 2/20/21 with lethargy/lack of appetite/weakness; unable to arouse on 2/21/21 then breathing stopped, patient's spouse called 911 performed CPR, EMS continued for 15 min then while in ambulance to hospital where he was pronounced dead. Official time of death 2:20pm	No prior vaccinations for this event.
DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration,	No prior vaccinations for this event.

on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was okay, but he was very agitated; reported as not like this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away

DECREASED APPETITE

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Hospice Resident received first Covid 19 vaccine dose on 1/6/21. 1/7/21 resident had decreased appetite noted in am but ate 100% of meal at dinner. 1/9/21 resident had decreased appetite with emesis x 2, loose BM x 2. Call placed to hospice. 1/10/21 5:44 am resident able to take HS meds, ingest 2 cups of shake. No emesis or loose stool noted. 12PM nurse noted resident not eating meals but ingesting milkshake and medications without any problems. Hospice contacted for change in condition. 1:00 pm hospice ordered Phenergan 12.5 mg Q 6 hrs PRN. Labs to be drawn 1/11/21. Hospice notified POA. 1/11/21 12:24am Resident had blood in stool. Resident denies any pain, on 2L of O2 for comfort.	No prior vaccinations for this event.
DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.	Influenza Virus Vaccines - Unknown date/type or brand
DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No reactions immediately after vaccine was given. Resident has dementia, has had multiple hospitalizations related to a renal stone recently. Had a tooth that was bothering her, went to see her dentist and it was extracted on 1/6/21. On 1/10 they noted feet and ankles are dark purple with white splotches appears to be mottling. Minimally responsive to voice and touch. Not eating. Compassionate visit	No prior vaccinations for this event.

with family. Family did not want hospice, did not feel it was needed, said, what more could they do for her than you're already doing? On 1/11 at 1950 was determined to be deceased.

	DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Admitted 1/14/21: Patient is an elderly 93-year-old female with multiple medical problems including chronic combined CHF, P 80, diabetes mellitus, HTN, hyperlipidemia, CKD stage 3, has been complaining of generalized weakness, fatigue, decreased appetite for the past few days. She had an outpatient COVID-19 vaccine earlier today. Within 2 hr of admitting the patient to the hospital, condition clinically deteriorated. Patient elected to be DNR/DNI while in the ED. Patient was pronounced dead at 10:30 p.m. earlier today. Preliminary cause of death: Hypoglycemia induced lactic acidosis.		No prior vaccinations for this event.
	DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness; respiratory distress Narrative: Patient tolerated his 1st dose of the COVID-19 vaccine well, on 12/16/2020, and received his 2nd dose on 1/6/2021. Patient had some mild clinical decline the past few days prior to 2nd vaccination, with a decreased appetite and some increased fatigue per nursing report, but no significant changes. He experienced nausea on the evening of 1/6/21, which was effectively managed, but by early morning he spiked a fever of 102.9 with a sat of 86.1%. He continued to deteriorate from that point on and died 1/7/21 @13:20. Clinically, the presentation was most consistent with an aspiration pneumonia.		No prior vaccinations for this event.
	DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient developed fever to 102 within 24 hours with decreased mentation. Stopped eating/drinking despite aggressively treating fever. Was DNR B status. Family agreed to a trial of IV fluids on 1/21 but was not successfully started until 1/22 after several attempts. Family wanted only comfort measures with no transfer to hospital. Patient continued to have fevers to 102-103 range. Patient passed on 1/23 . Patient did test positive for COVID in early September without significant illness. She was in usual state of health prior to vaccination.

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient stated he wasn't feeling well on January 25, 2021, wasn't eating and complained of abdominal pain. Patient noted to have indigestion and was constipated. Meds provided and labs ordered. On morning of January 26, 2021, patient became weak, lethargic and hypoxic and was sent to emergency department around 0700 hours on January 26, 2021. At approximately 1100 hours, emergency physician notified this writer that patient was not going to overcome his illness and would be placed on comfort care. At approximately 1130 hours, this writer was notified that patient had passed away from multi-organ failure.	No prior vaccinations for this event.
DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic #1. Patient tested positive for COVID-19 by rapid testing on 1/6/21. She demonstrated poor appetite and fluid/food intake and an IV of Normal Saline was initiated on 1/7/21. Oxygen saturation was initiated on 1/12/21 at 4L per nasal cannula. for shortness of breath. On 1/22/21 at 0310 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.	No prior vaccinations for this event.
DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began to demonstrate a cough the evening of 1/5/2021, after receiving the COVID-19 vaccine earlier in the afternoon. A rapid COVID-19 test was performed and was positive. She began to demonstrate shortness of breath with exertion on 1/7/21, and lethargy on 1/12/21. Appetite and oral intake began to decline on 1/12/21, and Oxygen saturation dropped on 1/16/21 to 82%, and oxygen was initiated at 3L per nasal cannula. On 1/19/21 at 0414 patient was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.	No prior vaccinations for this event.

	DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
she was injected, sh stopped eating and talking, the doctor watched her for 2 days. had her transported to the hospital. i was told she had tested positive for COVID 2 times once at the home and once at the hospital. with in 2 DAYS at the hospital she wa on a ventilator 2 days later she died. i talked with the rehab center and confirmed she tested negative for COVID on Dec 27th 2020 and was given the Vaccine on the 29th Dec 202 was in the hospital 4 day later, was on a ventilator 4 days after that then died a few day later as her heart stopped beating. all the while i had POA and was not contacted by Hospital staff until after they had made the next step.		No prior vaccinations for this event.
	DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
According to medical report, Pt presented to the ED on 1/14/21 w/ cc of SOB for 1 day. She received her COVID-19 vaccine on 1/9/21. Pt stated that she developed a dry hacking cough 2 days prior to the vaccine on 1/7/21. Over the last few days prior to admission, she developed generalized weakness, SOB, loss of sense of taste and smell w/ associated decreased appetite and nausea ultimately SOB in the24 hours prior to admission. Final Diagnosis- acute hypoxic respiratory failure secondary to COVID-19 pneumonia. Pt died on 2/3/21. See Medical report for more information.		No prior vaccinations for this event.
	DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because		No prior vaccinations for

I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21

this event.

DECREASED APPETITE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient with failure to thrive symptoms prior to 2nd dose, not eating, not taking medications.

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Early in the shift on January 31 resident was noticed to be more tired than usual and was not eating well. Lung sounds were crackly and resident was found to be hypotensive. He was evaluated in emergency department. He was diagnosed with pneumonia. Received a loading dose of antibiotic and returned to facility.

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

7 days after receiving the vaccine, patient suffered excessive diarrhea and slight coughing. 9 days after vaccine, patient was tested for Covid 19, and received positive results. Patient was transported to hospital via ambulance but hospital returned her to the nursing home since chest was clear, no respiratory issues, and no fever. 10 days after receiving the vaccine, patient was turned over to hospice care but still in the nursing home. Hospice was called in to provide better physician advice and access 24/7. 14 days after receiving vaccine, patient began experiencing excruciating body aches, coughing, low oxygen levels, and no appetite. 18 days after vaccine, patient died.

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

pt became lethargic, stopped eating. No fever; no nausea No prior vaccinations for this event.

DECREASED APPETITE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident had slight/slow decline in health prior to vaccine but continued to be able to walk around with walker at community. The day of the vaccine she had a fever. 2 days after vaccine resident did not get out of bed all day and refused to eat. She had small amounts of orange juice as her blood sugar level was low due to not eating. Resident was diagnosed with a UTI and began an oral antibiotic. 3 days after and on day 5 after vaccine resident began feeling weak and had a fall on each day. The following day again resident spent the day in bed. The next day she was quite restless, was on the edge of her bed attempting to self transfer often throughout the day. Resident continued to be restless on the 10th of Feb, had further decline on the 11th of Feb. Resident passed away early the AM of Feb. 12th.

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"The day after the 2nd shot, patient developed blisters on his lips and mouth. The care facility said that he had a nut allergy -- but he had never been allergic to nuts. He stopped eating and drinking and his BP had dropped to 60/40. By Jan 16th they called to say he was dying and he passed away on 1/18/21. Patient had COVID19 from Oct 29th - early November. By Nov 21st he had lost 40 lbs. He was 6'3"" and had gone from 189lbs to 149 lbs with COVID. By Nov 21st when we could visit, he had recovered from COVID, but was very thin and weak. He could not bathroom alone and kept falling. He didn't seem to have a bad reaction to the 1st COVID shot, But he immediately reacted to the 2nd shot and passed away within 6 days."	Shingles - Glaxo 8/22/2020, resulted in hospitalization and LTC.
DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/23 - Mild injection site discomfort. Appetite loss compared to previous day. Beginning loss of mental acuity compared to previous day. 1/24 - Continued loss of appetite. Near complete loss of ability to move. Continued decline of mental acuity. Very little speaking. 1/25 - Stopped speaking completely. Loss of bowel control in the evening and continued until death. Complete loss of appetite. 1/26 - Near complete loss of ability to swallow. Moved to hospice 4:00pm. 1/27 - Died 4:00am	No prior vaccinations for this event.
DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin	No prior vaccinations for this event.

placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.

	DECREASED APPETITE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21- N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.		No prior vaccinations for this event.
	DECREASED APPETITE	**COVID19 (COVID19**

(PFIZER-BIONTECH))
(1200)

Pale, not eating, no urine output After 1st covid vaccine

DECREASED APPETITE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient had declining health for the past 6 months, dementia and unable to walk. Patient had decreased appetite starting 1/1/21. After 1st vaccine shot patient appetite decreased further. After 2nd vaccine shot patient fatigue increased to the point where she could not get out of bed and had minimal appetite. Patient passed away 10 days after receiving 2nd shot on 2/22/21. Patient did not go to ED and was not hospitalized.

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Possible Stroke per Medical examiner but Reported symptoms after covid vaccine 2/11 therefore being considered poss Covid vaccine related also. No hospitalization prior to death. (Symptoms reported to office 2/17) Fatigue, decreased appetite-

No prior vaccinations for this event.

DECREASED APPETITE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1. Fatigue ? day 1 - Tuesday 2. Loss of appetite ? day 1 Tuesday 3. Fever 102.0 ? day 2 - Wednesday 4. Chills ? day 2 - - Wednesday 5. Weak ? day 2 - - Wednesday 6. Non-ambulatory (unusual) ? day 2 - - Wednesday 7. Two emergency service ambulance assessment ? day 2 - - Wednesday 8. Symptoms improved ? day 3 - Thursday 9. Ambulatory - day 3 - Thursday 10. Symptoms worsened ? day 4 - Friday

No prior vaccinations for this event.

11. Chills ? day 4 - Friday 12. Non-ambulatory again ? day 4 - Friday 13. Fever 102.0 ? day 4 - Friday 14. Left side flank pain ? day 4 - Friday 15. CPR and declared decease at home by paramedics - day 5 - Saturday morning @ 1:32am

DECUBITUS ULCER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Death Narrative: Patient received first dose of COVID vaccine on 1/30/21. Reported by his wife to agency that he passed away at an outside hospital on 2/14/21. By report of his wife: ""due to sepsis (related to bed sores) and aspiration pneumonia"""	No prior vaccinations for this event.
DEEP VEIN THROMBOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Pt he reports he developed chills SOB body aches the same night as receiving the COVID vaccine on 1.26.2021-pt is currently reporting CheSt tightness and SOB Admitted to hosp: ICU with Bilateral Pulmonary Emboli, LLE DVT, NSTEMI, Arrhythmia.	No prior vaccinations for this event.
DEHYDRATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of	No prior vaccinations for this event.

severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.

DEHYDRATION	COVID19 (COVID19 (MODERNA)) (1201)
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration	No prior vaccinations for this event.

DEHYDRATION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was	No prior vaccinations for this event.

okay, but he was very agitated; reported as not like this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away	
DELIRIUM	**COVID19 (COVID19 (MODERNA)) (1201)**
Client unexpectedly collapsed and passed away on 1/13/21 from suspected sudden cardiac death. Prior to her death, she was in skilled care for rehabilitation following hospitalization from 12/21-12/31/20 for an acute lower GI bleed. Her hospitalization and skilled care stay were complicated by delirium and she was being treated for delirium with olanzapine (Zyprexa) at time of death.	No prior vaccinations for this event.
DEMENTIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident in our long term care facility who received first dose of Moderna COVID-19 Vaccine on 12/22/2020, only documented side effect was mild fatigue after receiving. She passed away on 12/27/2020 of natural	No prior vaccinations for this event.

causes per report. Has previously been in & out of hospice care, resided in nursing home for 9+ years, elderly with dementia. Due to proximity of vaccination we felt we should report the death, even though it is not believed to be related.

	DEMENTIA	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient was tested positive for Covid-19 on 12/9/20. Patient received Covid Vaccine on 1/21/21. Patient was observing for 15 minutes in treatment room by Nursing staff. Patient denied any signs/symptoms adverse effect: headache, dizziness & weakness, difficulty breathing, muscle pain, chills, nausea and vomiting, and fever . Patient seated on treatment table appeared to be relaxed, respiration even and unlabored. Health teaching provided. Patient educated to report any changes in condition to staff immediately. Patient verbalized understanding and able to verbalize signs and symptoms and adverse effects to be aware of related vaccine. On 1/22/21: patient was seen by medical provider for ""altered behavior"". Per medical provider's documentation: ""Patient was fallen on 1/2/21 and was sent out to outside hospital on 1/4/21. CT head: no intracranial abnormality, age-related changes. Patient had labs (B12, RPR, folate) were within normal limit"". We did MMSE today: 22/30 score ""mild dementia"" On 1/23/20: ""Patient was inside his cell. He was walking towards cell door to obtain his breakfast, when custody witnessed him collapse and activated the alarm. Nursing staff arrived at cell front at 06:34 am and found the patient pulseless and unresponsive, and CPR was immediately initiated. AED was attached at 06:35 am and no shock advised. AMR then arrived and patient did not have ROSC, and was pronounced dead at 06:54 am.""""		No prior vaccinations for this event.

	DEMENTIA	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient fell the day after receiving the Moderna COVID-19 vaccine. She broke her hip in this fall. During surgery to correct the broken hip, she went in to sudden and unexpected cardiac arrest. The anesthetist did not notice any ST changes or A fib; dysrhythmia was very unexpected. The patient had a DNR. She died at		No prior vaccinations for this event.

13:00 on 02/07/2021. Causes of death are listed as 1. Cardiac Arrest 2. Recent hip fracture with hip placement 3. History of Breast Cancer 4. Hypothyroid and 5. Dementia

DEMENTIA **COVID19 (COVID19 (MODERNA)) (1201)**

Patient with severe dementia in Hospice Care No prior vaccinations for this event.

DEMENTIA **COVID19 (COVID19 (MODERNA)) (1201)**

Resident had severe CAD, DM type 2, and hx of RBKA and left 5 digits on foot amputation. Hx of osteomyelitis post surgical. After last surgery, resident did not have a good appetite, more restless, increased confusion with dementia. Significant other passed away on 12/30/20, resident began refusing meals, decreased eating. Vaccinated on 1/13/21. On 1/25/21 Resident labs showed kidney failure. Dr. spoke with family and transitioned to Comfort care, on 2/5/21 went hospice. Patient passed away on 2/13/2021. No prior vaccinations for this event.

DEMENTIA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death occurred 3 days after vaccine receipt; attributed to complications of her chronic advanced dementia with aspiration at age 87. No evidence of acute vaccine reaction. No prior vaccinations for this event.

DEMENTIA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by No prior vaccinations for

ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.	this event.
DEMYELINATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.	No prior vaccinations for this event.
DENTAL DISCOMFORT	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient went home around 11 am on 1-31-21 after her vaccine and 15 minute observation period. She was eating breakfast after at home and complained to a neighbor that her teeth hurt and she was nauseated after eating. In the afternoon, she felt dizzy and had diarrhea accompanied with blood. Close to 9 PM, her son went to check on her. The patient was found on the floor--she was unresponsive and had purple lips. Her son called an ambulance and started chest compressions. The patient passed away at the	No prior vaccinations for this event.

hospital. The doctor has ordered an autopsy, and the results are pending.

DEPENDENCE ON RESPIRATOR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
she was injected, sh stopped eating and talking, the doctor watched her for 2 days. had her transported to the hospital. i was told she had tested positive for COVID 2 times once at the home and once at the hospital. with in 2 DAYS at the hospital she wa on a ventilator 2 days later she died. i talked with the rehab center and confirmed she tested negative for COVID on Dec 27th 2020 and was given the Vaccine on the 29th Dec 202 was in the hospital 4 day later, was on a ventilator 4 days after that then died a few day later as her heart stopped beating. all the while i had POA and was not contacted by Hospital staff until after they had made the next step.	No prior vaccinations for this event.
DEPRESSED LEVEL OF CONSCIOUSNESS	**COVID19 (COVID19 (MODERNA)) (1201)**
resident had a pressure ulcer to RT hip, was getting treatment on. Was scheduled to have wound debrided and wound vac applied on 1-19-2021. Appetite was poor, not wanting to get out of bed, and decline in alertness. Passed away on 1-16-2021	No prior vaccinations for this event.
DEPRESSED LEVEL OF CONSCIOUSNESS	**COVID19 (COVID19 (MODERNA)) (1201)**
2/10: Fever, fatigue, tylenol 2/11 @ 1300: pt made DNR, hospice consulted 2/11 @ 1800 decreased LOC, increased RR, fever, chills - 1/5L NS bolus IV, rectal tylenol. Refusing to eat/drink, PO morphine 2/12 @ 16:30, deceased at facility **resident was not doing well prior to vaccination	No prior vaccinations for this event.

DEPRESSED LEVEL OF CONSCIOUSNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
Beginning in the evening 2/19/21, fever/chills/fatigue; worsening of symptoms 2/20/21 with lethargy/lack of appetite/weakness; unable to arouse on 2/21/21 then breathing stopped, patient's spouse called 911 performed CPR, EMS continued for 15 min then while in ambulance to hospital where he was pronounced dead. Official time of death 2:20pm		No prior vaccinations for this event.
DEPRESSED LEVEL OF CONSCIOUSNESS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.		No prior vaccinations for this event.
DEPRESSION		**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors.		No prior vaccinations for this event.

Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse		
	DERMATITIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Presented from clinic with 3-4 days of extensive rash. There were multiple areas of skin sloughing on bilateral upper extremities and abdominal wall.		No prior vaccinations for this event.
	DIABETES MELLITUS	**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccination at 14:20 2/26/21. Was observed until discharged at 15:15. Discharged per wheel chair to lobby in alert/stable condition, to wait on bus to take him home. At 18:00 his neighbor heard him fall, could not get patient to answer phone, found him unresponsive. Neighbor called 9-1-1, ambulance personnel could not revive patient. Coroner's office ruled his death as Natural Causes due to Hypertension, Cardiac disease, Diabetes, ESRD. There were no indication of anaphylactic reaction noted when I questioned the coroner's office. The Coroner's office/EMS were aware the patient had received the Moderna COVID 19 vaccination that day.		No prior vaccinations for this event.
	DIALYSIS	**COVID19 (COVID19 (MODERNA)) (1201)**

Patient received COVID19 vaccine at clinic at 11:52 am, discharge post treatment stable. Got home around 2:30 pm went to bed. He usually got tired post dialysis. He did not wake up at 6 pm. His wife went check on him. found patient cold and unresponsive. 911 pulseless PEA. ER Medical hospital. Pronounced death at 7:40 pm	No prior vaccinations for this event.

DIALYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.	No prior vaccinations for this event.

DIALYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.	No prior vaccinations for this event.

DIAPHRAGMATIC SPASM

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

No symptoms or signs on the day 1st dose of vaccine was received (2/11/2021). 3 days later, (2/14/2021) patient experienced chills for approximately 6 hours, followed by severe (visible) chest spasms, and then cardiac arrest. 911 was called upon witnessing chest spasms, but cardiac arrest/death occurred before patient could be transported to the hospital.

No prior vaccinations for this event.

DIARRHOEA

COVID19 (COVID19 (MODERNA)) (1201)

ON 1/21/2020 RESIDENT WAS EXPERINCING CHILLS AND LOOSE STOOLS. FOLLOWING THIS EPISODE BECAME UNRESPONSIVE, PALE, DIAPHORETIC AND BRADYCARDIC. PALLIATIVE CARE WAS PROVIDED. RESIDENT PASSED AWAY APPROX. 10 HOURS LATER.

No prior vaccinations for this event.

DIARRHOEA

COVID19 (COVID19 (MODERNA)) (1201)

on 1/13/2021 at 3:40am Cliff called for assistance. He lost his balance and had fallen. Cliff refused vitals, refused emergency department, denied hitting his head. As the day progressed patient developed a headache, diarrhea, and vomiting. He again declined the offer for the emergency room. At supper time wife and staff found Cliff unresponsive, 911 was called and he was taken to the emergency department. The ER did a CT scan and found an acute subdural hematoma. Patient was placed on comfort cares and expired at 3pm on 01/14/2021. Cliff did not have a history of falls.

Influenza vaccine 10/06/2020, age 88, fever, chills, vomiting, malaise

DIARRHOEA

COVID19 (COVID19 (MODERNA)) (1201)

On 2/1/2021, the patients daughter, who claims is a nurse, reported this incident to me. She stated that the evening after the patient received the vaccine, she felt some mild injection site pain. The morning after, the patient reported severe abdominal pain, diarrhea and vomiting. The patients daughter then called her physician to report these symptoms and attributed them as an adverse reaction to the vaccine at that time. These symptoms were intermittent for one week and no other adverse reactions were noted. In the early morning hours of 1/27/2021, the patient was toileting and had expired while doing so. An ambulance was called and cause of death was not found. An autopsy was not performed.	No prior vaccinations for this event.
DIARRHOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Toileting and had expired while doing so; Severe abdominal pain; Diarrhea; Vomiting; Mild injection site pain; A spontaneous report was received from a healthcare professional concerning an 88-year-old , female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced the events, toileting and had expired while doing so (death), mild injection site pain, severe abdominal pain, diarrhea, and vomiting. The patient's medical history was not provided. No relevant concomitant medications were reported. On 20 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 029L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 20 Jan 2021, the patient felt mild pain at the injection site after receiving the vaccine. On 21 Jan 2021, the patient reported severe abdominal pain, diarrhea and vomiting. These symptoms were intermittent for a week and no other adverse events were noted. On 27 Jan 2021, the patient passed away while toileting. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 27 Jan 2021. The cause of death was unknown. An autopsy was not performed.; Reporter's Comments: The gastrointestinal events were consistent with increased risk associate with elderly age of patient. The cause of death was unknown. Autopsy was not performed. Very limited information regarding the events is available at this time. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Reported Cause(s) of Death: unknown cause of death	No prior vaccinations for this event.

DIARRHOEA	COVID19 (COVID19 (MODERNA)) (1201)
Individual developed severe body aches, severe shoulder discomfort, high fevers (documented max temp. 103.7 F). Daughter reported that she became non-responsive with high fevers, and when the fevers decreased she was more lucid. Her condition rapidly progressed to nausea vomiting, diarrhea and patient died on 2/9/2021.	No prior vaccinations for this event.

DIARRHOEA	COVID19 (COVID19 (MODERNA)) (1201)
Started feeling unwell; Headaches; Body aches; Chest pain; Didn't had wishes to eat; Diarrhea; COVID-19 pneumonia; A spontaneous report was received from a consumer concerning a 69-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced COVID-19 pneumonia, feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea The patient's medical history high blood pressure which was controlled with medication. Concomitant product use included nifedipine and fenofibrate. On 20-JAN-2021, approximately a week and a half or two prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number 030L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. A week and a half or two later the patient stated feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea for which patient was hospitalized on 06-FEB-2021. Since everything seemed to be fine the patient was discharged on an unknown date in FEB-2021 however, patient's family was not notified that it was a late reaction to the vaccine's first dose. Later, due to shortness of breath he was hospitalized again on 08-FEB-2021 and was diagnosed for pneumonia and was intubated on the same day. Due to COVID-19 situation patient's family could not be in the facilities and that there wasn't any follow up of the patient given to the family, so family did not have much information. During the first hospitalization(06-FEB-2021) the patient had a blood test which showed a normal result and was tested for COVID-19 and Influenza, both were negative. During second hospitalization (08-FEB-2021) the hospital said that the patient was stable. The patient's family did not know the results of the tests conducted at	No prior vaccinations for this event.

the time. The action taken with the vaccine in response to the events is not applicable. The outcome of COVID-19 pneumonia was fatal. The patient died on 14 Feb 2021 The cause of death was reported as COVID-19 related pneumonia. The autopsy was not done.; Reporter's Comments: Very limited information regarding this event has been provided at this time. The cause of death was reported as COVID-19 related pneumonia. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the events are assessed as unlikely related. Further information has been requested.; Reported Cause(s) of Death: COVID-19 pneumonia

DIARRHOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was transferred from hospital for further evaluation and care by pulmonologist. He started having symptoms a week before with fatigue, emesis, decreased p.o. intake, shortness of breath, vomiting and diarrhea. The two previous takes before death required increasing oxygen and family wanted everything done including intubation. He was transferred to ICU.	No prior vaccinations for this event.

DIARRHOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Diarrhea followed by death 24 hrs after vaccination No prior vaccinations for this event.

DIARRHOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospice Resident received first Covid 19 vaccine dose on 1/6/21. 1/7/21 resident had decreased appetite noted in am but ate 100% of meal at dinner. 1/9/21 resident had decreased appetite with emesis x 2, loose BM x 2. Call placed to hospice. 1/10/21 5:44 am resident able to take HS meds, ingest 2 cups of shake. No emesis or loose stool noted. 12PM nurse noted resident not eating meals but ingesting milkshake and medications without any problems. Hospice contacted for change in condition. 1:00 pm hospice ordered	No prior vaccinations for this event.

Phenergan 12.5 mg Q 6 hrs PRN. Labs to be drawn 1/11/21. Hospice notified POA. 1/11/21 12:24am Resident had blood in stool. Resident denies any pain, on 2L of O2 for comfort.

	DIARRHOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Symptoms of fever (Tmax 102.9), diarrhea, and altered mental status started ~ 24 hours after vaccination. No evidence of septicemia with negative blood cultures Minimal improvement over 3 days, transferred to tertiary care center for MRI brain after which LP was recommended. However family declined as intubation would have been required and was not consistent with patient's goals of care.		No prior vaccinations for this event.
	DIARRHOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic. Client tested positive for COVID-19 by rapid testing on 1/21/21, with c/o hurting all over and loose stools. She became non-verbal on 1/23/21 with poor intake. On 1/24/21 at 0537 Client was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.		No prior vaccinations for this event.
	DIARRHOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
emesis bright yellow in color, liquid BM, increased respirations No prior vaccinations for this event.		

DIARRHOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Began with vomiting and diarrhea. C/O chest pain. Bradycardia. Hypotension. 2 seizures in 45 minutes after not having one in years. We gave fluids. Gave Zofran. Comfort measures. Pt passed at midnight. Was completely fine one day before. Had minimal issues with COVID though did have a pneumonia that was treated w ATB early on and resolved.	No prior vaccinations for this event.	
DIARRHOEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21	No prior vaccinations for this event.	
DIARRHOEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began feeling nauseated on 1/18/21 around 6pm, and had uncontrolled diarrhea, reported that she did not feel right. Staff reported to this writer, that her skin tone was gray in tone and she just didn't look good. She was transferred to the HOSPITAL ER VIA AMBULANCE.	No prior vaccinations for this event.	
DIARRHOEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Received Pfizer Covid Vaccine in the AM on 2/9/21. Arrived to emergency department later the same day complaining of nausea, weakness, fatigue, Vomiting, Diarrhea. Post operative diagnosis, Ischemic colon/toxic megacolon.	No prior vaccinations for this event.	
DIARRHOEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
7 days after receiving the vaccine, patient suffered excessive diarrhea and slight coughing. 9 days after vaccine, patient was tested for Covid 19, and received positive results. Patient was transported to hospital via ambulance but hospital returned her to the nursing home since chest was clear, no respiratory issues, and no fever. 10 days after receiving the vaccine, patient was turned over to hospice care but still in the nursing home. Hospice was called in to provide better physician advice and access 24/7. 14 days after receiving vaccine, patient began experiencing excruciating body aches, coughing, low oxygen levels, and no appetite. 18 days after vaccine, patient died.	No prior vaccinations for this event.	
DIARRHOEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative.	No prior vaccinations for this event.	

Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

DIARRHOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Diarrhea , fatigue on 2/10 Fall 2/12 out to hospital Resident Expired 2/14 No prior vaccinations for this event.

DIARRHOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was	No prior vaccinations for this event.

diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her

husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

	DIARRHOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient was not vaccinated at hospital. Caregiver reports that patient was vaccinated with second dose on Monday 2/15/21. Tuesday patient experienced n/v/d. Went to an ED on Wednesday and was cleared and sent home. Thursday reported shortness of breath to her caregiver and then collapsed. Patient was brought to as PEA arrest and ultimately died.		No prior vaccinations for this event.
	DIARRHOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.		No prior vaccinations for this event.
	DIARRHOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose		No prior vaccinations for this event.

of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice, memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200 mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation: tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed, metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol

sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral patchy opacities

DIARRHOEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Pfizer-BioNTech COVID- 19 Vaccine EUA Patient received COVID-19 Vaccine dose #2 on February 24, 2021. On February 25th at 10:36 AM,Patient's son called physician to report some side effects to second dose of Covid vaccine. She had diarrhea when she came home yesterday. Son has been up all night with her as patient has had a ""hacking cough,feels terrible, and now has had diarrhea x2"". Patient has taken Advil and will be taking tylenol periodically through out the day for her side effects. Patients son notified physician at 09:55 AM on February 26 that the patient has expired."

No prior vaccinations for this event.

DIARRHOEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)

No prior vaccinations for this event.

DIARRHOEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On date on second dose, 2/27/2021, the pt began have fatigue and diarrhea at around 10:30 am. This continued to the following day. On 2/28/2021, the patient was last seen around 4:20 pm by his wife in their residence. She found him unresponsive at 5:30 pm in their bedroom. EMS was called and the decedent was declared deceased. The pt had his first dose on 2/9/2021. Both doses were given at the hospital. Per family, the pt had no adverse affects following the first dose.

No prior vaccinations for this event.

DIARRHOEA

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Minor arm pain on 2nd day of each vaccine Diarrhea 3 days after 2nd vaccine Massive heart attack (left ventricle) 8 days (2/24/21) after vaccine Home hospice 3:30pm 2/24/21 Stopped breathing 5:45 am, pronounced dead at 8:22 am on 2/25/21	No prior vaccinations for this event.
DIARRHOEA HAEMORRHAGIC	**COVID19 (COVID19 (MODERNA)) (1201)**
6 days after vaccine developed bloody diarrhea. Thought to have ischemic colitis but negative evaluation. became hypotensive bradycardic placed on ventilator. Subsequently was poorly responsive and eventually coded once more and succumbed	No prior vaccinations for this event.
DIARRHOEA HAEMORRHAGIC	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient went home around 11 am on 1-31-21 after her vaccine and 15 minute observation period. She was eating breakfast after at home and complained to a neighbor that her teeth hurt and she was nauseated after eating. In the afternoon, she felt dizzy and had diarrhea accompanied with blood. Close to 9 PM, her son went to check on her. The patient was found on the floor--she was unresponsive and had purple lips. Her son called an ambulance and started chest compressions. The patient passed away at the hospital. The doctor has ordered an autopsy, and the results are pending.	No prior vaccinations for this event.
DIASTOLIC DYSFUNCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia	No prior vaccinations

was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.		for this event.
	DIET REFUSAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.		No prior vaccinations for this event.
	DIET REFUSAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient became nauseated about 10 minutes after vaccine administered, this subsided but returned several hours after the vaccine was given. She continued with intractable nausea and vomiting for about 24 hours. This patient was enrolled in hospice and she continued to decline and refused to eat or drink. She was taking Ibuprofen due to intractable back pain. Her emesis was coffee ground color. After this her condition continued to decline until her death		No prior vaccinations for this event.
	DIET REFUSAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was a Resident on our LTC wing. Per the LTC Manager: Resident had hx of CVA with deficits in speech and extremities. Hx of decreased circulation to BLE's which resulted in wounds to bilateral feet on and		No prior vaccinations

off that needed treatment. Average meal consumption 25-50% of meals, started refusing more often in December and January. Would consume small amounts 60-120mL of fluids here or there. Vaccinated on 1/7/21. Stopped eating 1/18/21. Attempted bolus NS fluid 1/25/21. Resident refused all treatment afterwards. Went hospice on 2/3/21 and passed away on 2/7/21.

for this event.

DIET REFUSAL

COVID19 (COVID19 (MODERNA)) (1201)

Resident had severe CAD, DM type 2, and hx of RBKA and left 5 digits on foot amputation. Hx of osteomyelitis post surgical. After last surgery, resident did not have a good appetite, more restless, increased confusion with dementia. Significant other passed away on 12/30/20, resident began refusing meals, decreased eating. Vaccinated on 1/13/21. On 1/25/21 Resident labs showed kidney failure. Dr. spoke with family and transitioned to Comfort care, on 2/5/21 went hospice. Patient passed away on 2/13/2021.

No prior vaccinations for this event.

DIET REFUSAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

My mom received the Covid 19 vaccine on Jan 5, 2021 and became very about a week later. I was informed that she tested positive for Covid 19 on January 14th. One January 17th she became very tired and weak and would not eat. Hospice called me and told me that she was in a decline state. I saw her on January 25 and 26 and she was just sleeping and could not open her eyes. Her vitals were good and she seemed to understand when I talked to her - she would squeeze my hand and moan but she could not talk or open her eyes. My mom passed away on January 27, 2021 just 22 days after receiving the Covid 19 vaccine. She was very think to begin with and being to weak and tired to eat resulted in her losing even more weight. Some of the other residents were given fluids to help and they recovered. My mom was not given fluids. I believe there were 20 deaths in her care home for the month of January when they

No prior vaccinations for this event.

vaccinated. This was an alarming number of deaths for the home. The facility had very few Covid deaths in 2019 and 2020. I asked every week if they had any Covid and or Covid deaths and this amount was shocking to me and the workers there.

DIET REFUSAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
pt became lethargic, stopped eating. No fever; no nausea No prior vaccinations for this event.	
DIFFERENTIAL WHITE BLOOD CELL COUNT	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
DIFFERENTIAL WHITE BLOOD CELL COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.	No prior vaccinations for this event.

DIFFERENTIAL WHITE BLOOD CELL COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.	No prior vaccinations for this event.
DIFFERENTIAL WHITE BLOOD CELL COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition:

No prior vaccinations for this event.

Deceased

DIFFERENTIAL WHITE BLOOD CELL COUNT ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the

No prior vaccinations for this event.

decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

DIFFERENTIAL WHITE BLOOD CELL COUNT ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
DIFFERENTIAL WHITE BLOOD CELL COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	No prior vaccinations for this event.
DIFFERENTIAL WHITE BLOOD CELL COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
DIFFERENTIAL WHITE BLOOD CELL COUNT NORMAL	**COVID19 (COVID19 (PFIZER-**

BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression

No prior vaccinations for this event.

By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

DISABILITY	**COVID19 (COVID19 (MODERNA)) (1201)**
2-24-21 patient with development of cough, fatigue, increasing on chronic disability worsening debility and falls. scheduled for office visit 2-25.21 0900 call from spouse 0210 am patient was not breathing and lvad alarming low flow alarm on arrival of ems confirm asystolic not breathing and dead	No prior vaccinations for this event.

DISCOLOURED VOMIT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
He started vomiting 2 days later. we suspect he was having stool issues as well. he vomited blood at some point over the weekend. there was black vomit right before he passed. from 2am-6am he was wheezing and rattling and then he passed at approximately 6am 3/1/2021 at home. EMS did come and try to revive him and were unsuccessful.	No prior vaccinations for this event.

	DISCOMFORT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1-12-21 Resident is complaining of heart pain. Resident blood pressure is 228/105. 1-22-21 Dx UTI 1-13-21 His nurse called MD at approximately 0645, reported to him that it was reported to this nurse that resident has not slept in 2 days and night, has an increased blood pressure, reports severe pain in lower back, and appears to be uncomfortable Resident is able to verbalize his pain and where it is at, but is unable to explain the quality of the pain or give a number on the 0/10 pain scale.		No prior vaccinations for this event.

	DISCOMFORT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's		No prior vaccinations for this event.

via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

	DISORIENTATION	**COVID19 (COVID19 (MODERNA)) (1201)**

itchy skin, swelling, disorientation that led to a fall No prior vaccinations for this event.

DISORIENTATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	

"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."

No prior vaccinations for this event.

	DISSEMINATED INTRAVASCULAR COAGULATION	**COVID19 (COVID19 (MODERNA)) (1201)**

covid shot 2/2; feel bad 2/5; covid positive diagnosis - 2/8 s/s cough, fever, shortness of breath , hypertension, afib (in er) - admitted went into DIC per intensivist 2/11 patient died

No prior vaccinations for this event.

DISSEMINATED INTRAVASCULAR COAGULATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver failure, pneumonia, and DIC>"		No prior vaccinations for this event.
DISSEMINATED INTRAVASCULAR COAGULATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.		No prior vaccinations for this event.
DIVERTICULITIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Client was being treated with antibiotics by her PCP for diverticulitis flare up. It had not been resolved on the date of her death which occurred 01/27/21, She was found unresponsive by staff, 911 contacted, and paramedics pronounced her deceased at 7:48 AM. After consultation with PCP manner of death was noted		No prior vaccinations for this event.

as cardiac arrest. PCP was to sign off on death certificate.

DIZZINESS		**COVID19 (COVID19 (MODERNA)) (1201)**
"1-2-2021 10:30 PM Complained Right arm/back hurt - took Tylenol 1-3-2021 Complained Right arm hurt, dizzy 1-4-2021 Felt better - did laundry, daughter found her deceased at 3:30 pm. Dr. at hospital said it was ""cardiac event"" according to death certificate."		No prior vaccinations for this event.
DIZZINESS		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient recieved vaccine 1 of covid 19 i 1/19/2021. She felt poorly on 1/20/2021. She felt dizzy and fell at 3 AM on 1/23/2021. She felt poorly and did not know her son's name which was not normal. She went to ER on 1/24. She was assessed as not having fractures. She was going to be transferred to a skilled nursing facility. She was not having respiratory complaints. She was awaiting transfer when her O2 levels started dropping substantially. She declined aggressive intervention and she died within a few hours.		No prior vaccinations for this event.
DIZZINESS		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was feeling dizzy and under the weather after the vaccination. The following day he died in his sleep during a nap.		No prior vaccinations for this event.
DIZZINESS		**COVID19 (COVID19 (MODERNA)) (1201)**
The patient went home around 11 am on 1-31-21 after her vaccine and 15 minute observation period. She was eating breakfast after at home and complained to a neighbor that her teeth hurt and she was nauseated		No prior vaccinations

after eating. In the afternoon, she felt dizzy and had diarrhea accompanied with blood. Close to 9 PM, her son went to check on her. The patient was found on the floor--she was unresponsive and had purple lips. Her son called an ambulance and started chest compressions. The patient passed away at the hospital. The doctor has ordered an autopsy, and the results are pending.

for this event.

DIZZINESS

COVID19 (COVID19 (MODERNA)) (1201)

Moderna Vaccine Lot 029K20A Patient received second dose of vaccine on 2/2/21. Within 30 minutes patient had a near syncopal episode. She felt lightheaded and shortly after had episode of nonbloody vomiting. Hypotensive 81/69 and started on levophed. Alert and orientated. Lungs clear, abdomen benign on admission. Patient had no reaction when received first dose of the vaccine. Patient developed worsening shortness of breath, tachypnea, Afib with RVR, hypotension and required intubation and multiple pressors.

No prior vaccinations for this event.

DIZZINESS

COVID19 (COVID19 (MODERNA)) (1201)

Patient previously had dizzy spills, but about a week after receiving the vaccine her dizzy spills began to get worse. The whole prior she kept saying I am just not right. On the 2/7/21 she a COVID test done, a nurse came to her house and preformed. On the morning of the 8th patient was on the phone with someone else and patient asked this person to call me and go check on her. Within 5 minutes I was over at her house, and I found her on the floor, she on her belly facedown. It looked like she was on the toilet, and it looked like she fall getting her off, she was still wet, she still felt warm. I called the ambulance and immediately began CPR. When EMS arrived they took over the CPR and transported her to the Hospital. The EMS was there for about 40 minutes and used an machine to preform the compressions. She was pronounced deceased at the hospital. No autopsy was done.

No prior vaccinations for this event.

DIZZINESS

COVID19 (COVID19

	(MODERNA)) (1201)
Patient felt fine on Friday afternoon and evening after shot. Felt fine on Saturday until the afternoon when she started feeling fatigued and chilled. Decided to take a warm bath at about 6pm. Was found dead in bathtub at approximately 7pm with blisters on arms, legs, and face.	No prior vaccinations for this event.
DIZZINESS	**COVID19 (COVID19 (MODERNA)) (1201)**
"Possible heart attack on 2/5/21. Complaint: "" On Feb 5th I believe I experienced a mild hear attack"" (Comment: He said he felt ""clammy, sweaty, excruciating pain on my left side - including his left arm, and left leg, dizzy, exhausted."" This happened after work, and after taking a shower. He said that was the first time he's experienced it, and that it has not happened since then. He said he has constant headaches, ""It just went away yesterday.""""	No prior vaccinations for this event.
DIZZINESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had sudden death 1 week after 2nd COVID vaccine. Had complained of dizziness throughout the week leading up to it.	No prior vaccinations for this event.
DIZZINESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Within 10 minutes following the second vaccination, patient reported dizziness and nausea, had an episode of vomiting but recovered within 30 minutes. It was reported to our clinic that the patient was found deceased on March 1, 2021 at approximately 10 pm. Cause of death is not determined at this time.	No prior vaccinations for this event.

	DIZZINESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.		No prior vaccinations for this event.
	DIZZINESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/7-21 - Received second dose of pfizer covid-19 vaccine 1/8/21 - Fever, dizziness, headache 1/10/21 0250 was found not breathing. EMS performed CPR and patient deceased		No prior vaccinations for this event.
	DIZZINESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
little bit of a reaction light headed after 5 minutes. vitals were low, so observed for 30 minutes after being light headed. Patient was found unresponsive and pronounced dead later that day.		No prior vaccinations for this event.
	DIZZINESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test		Influenza Virus Vaccines - Unknown date/type or

performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.	brand	
DIZZINESS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient's wife called this morning stating that her husband has passed away last night. After receiving first dose of Pfizer COVID-19 vaccine at around 0830, patient remained in the Immunizations Department for the 15-minute monitoring period. Per wife, patient's only complaint was pain at the injection site. At 1300, wife states that patient complaint of dizziness which ""dissipated after a few minutes"" followed by a headache which ""dissipated after a few minutes"" as well. Then patient complained of nausea, no vomiting and ""couldn't relax."" Per wife, from around 1400/1500, patient stayed on his recliner while still having a conversation with her--""he didn't get up to eat."" Last conversation they had was around 2000/2100. Per wife, at around 2100/2200, patient was quiet and when she checked on him, ""he wasn't responding anymore."" Wife then called 911, ""but they couldn't revive him.""""	No prior vaccinations for this event.	
DIZZINESS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
REC'D CALL FROM PT'S DAUGHTER, HER FATHER WAS VACCINATED ON 1/22/21, WOKE UP 1/23/21 WAS SHORT OF BREATH AND DIZZY. PT PRESENTED TO ED OF LOCAL HOSPITAL AND WAS ADMITTED, PT PASSED ON 1/25/21. DAUGHTER STATES THAT FAMILY AND DOCTORS AGREE THAT THE VACCINE DID NOT CONTRIBUTE TOWARDS PT'S DEATH, BUT FELT IT NEEDED TO BE REPORTED. PT'S DAUGHTER CONTACTED THIS RN AT LOCAL HEALTH DEPARTMENT TO	No prior vaccinations for this event.	

REPORT TO VAERS.

DIZZINESS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated

No prior vaccinations for this event.

ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

DIZZINESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
New onset dizziness with hypotension, tachycardia, and vomiting blood. Sent to ER - told he went into cardiac arrest and died.	No prior vaccinations for this event.
DIZZINESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Complained of dizziness on January 18,th seen by MD this date. Passed away on 22nd.

No prior vaccinations for this event.

DIZZINESS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Few minutes post vaccination, after moving to observation area via wheelchair, the patient complained of dizziness. She took glucose tabs she had brought with her. Staff wheeled her to Triage # 1. Her eyes rolled back in her head and she lost consciousness. Staff (paramedics on site) transferred her to gurney and started compressions. AED placed, V- Fib was rhythm, Shock # 1 given, CPR resumed. Shocked again. Fire truck and additional EMT arrived on site and took over care. Epinephrine was given 3 times via intra-osseous route, Amiodarone given intra-osseous route. Additional defibrillation with on site AED for a total of 6-7 times. Patient had good chest rise with ambu-bag, no airway obstruction or peri-oral edema noted. Code called at 12:40 PM.

No prior vaccinations for this event.

DIZZINESS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Light headedness, fatigue, nausea No prior vaccinations for this event.

DIZZINESS **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"Patient felt achy, tired starting the day after the vaccine. Per his wife, he was very tired and ""losing stamina"". On 2/13/21, he woke up feeling dizzy and weak. His wife asked him if he wanted to go to the doctor and he declined. He ate breakfast and went to rest in his easy chair. He passed away an hour later."

No prior vaccinations for this event.

DIZZINESS

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Patient received the vaccine around 11 am. He hadn't been feeling well (headache, dizziness) per report and initially called in to work. He then decided to come to work and was found down in a patient bathroom during his shift on our Facility while taking care of a patient (he was a nurse aid). Patient was coded and the team and was transferred to our Facility ED. He expired 3/3 2112	No prior vaccinations for this event.
DIZZINESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The same day that the person was vaccinated he started feeling dizzy and had difficulty breathing. He was hospitalized from February 5 to February 23. Patient died in the hospital on February 23, 2021	No prior vaccinations for this event.
DRUG INEFFECTIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed/died on 09Feb2021 from respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed/died on 09Feb2021 from respiratory failure from COVID19; This is a spontaneous report from a contactable physician. An 89-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in 10Jan2021 at 12:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had no COVID prior to vaccination. The patient received one dose of Pfizer vaccine on 10Jan2021. The patient was presented to the ER with COVID symptoms and was diagnosed on 27Jan2021. Patient subsequently died on 09Feb2021 from respiratory failure from COVID19. It was unknown if autopsy was done. The patient was tested for COVID post vaccination via nasal swab: covid-19 virus test positive on 27Jan2021. The events resulted in emergency room/department or urgent care, hospitalization, and patient died. No follow-up attempts are possible, information about batch number	No prior vaccinations for this event.

cannot be obtained. No further information is expected.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported COVID post vaccination and respiratory failure with fatal outcome, and the administration of COVID 19 vaccine, BNT162B2, based on the reasonable temporal association. More information on the underlying medical condition in this 89-year-old male patient is required for the Company to make a more meaningful causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: presented to the ER with COVID symptoms and was diagnosed on 27Jan. Patient subsequently died on 09Feb from respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed on 27Jan. Patient subsequently died on 09Feb from

DRUG SCREEN NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency

No prior vaccinations for this event.

room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

DRUG SCREEN POSITIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death within thirty days of vaccine. Multiple co-morbidities and placed on hospice 12/28/20.

No prior vaccinations for this event.

DRY MOUTH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21

No prior vaccinations for this event.

DRY SKIN

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

view 2/5/2021 09:23 e Progress Note Note Text: Patient passed away in the facility this morning. view 2/5/2021 08:39 Orders - Administration Note Note Text: Resident passed. view 2/5/2021 08:33 Nurses Note Note Text: Body released to funeral home at this time. Personal effects sent with resident include: 1 pair of glasses, 1 yellow wedding band, 1silver spoon ring, 1 ring with black and clear stones. Resident has own teeth view 2/5/2021 08:32 Nurses Note Note Text: cause of death per CRNP failure to thrive. view 2/5/2021 07:44 Orders - Administration Note Note Text: Take and document temp & PO2 every 4 hours for MONITORING Resident passed. view 2/5/2021 06:49 Nurses Note Note Text: Son returned call and was updated of resident's passing this am view 2/5/2021 06:33 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Unknown Resident expired @ 0604 [linked] view 2/5/2021 06:06 Nurses Note Note Text: Res found without pulse or respirations. Pronounced at 0604. Updated. N/o's for RN to pronounce, release body to funeral home, dispose of medications per facility policy. Daughter updated. Funeral Home called to release body. view 2/5/2021 05:26 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Pulse ox 60% on O2 @ 5L/min via mask. Resps 44 per minute. view 2/5/2021 01:57 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/5/2021 00:52 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Residents resps are 40 per minute, pulse ox 76% on O2 @ 5L/min via mask. Resps are labored, shallow and rapid. view 2/5/2021 00:48 Nurses Note Note Text: Nonresponsive to verbal and tactile stimulation. Appears comfortable. view 2/4/2021 22:01 Nurses Note Note Text: Resident resting comfortably, breathing becoming increasingly shallow, wearing O2 via mask at 5L via mask, no dyspnea noted, feet are mottled, oral and peri care provided Q2H. No s/s of pain or discomfort. view 2/4/2021 21:40 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective [linked] view 2/4/2021 19:32 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger medicated for air hunger, RR 28 to 32/ min view 2/4/2021 19:22 Nurses Note Note Text: Daughter updated on

No prior vaccinations for this event.

N/O to increase Morphine Sulfate 20mg/mL 0.25mL to Q2H prn from Q6H prn. view 2/4/2021 18:06 Nurses Note Note Text: POA Daughter and daughter aware of residents current condition. view 2/4/2021 11:58 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/4/2021 11:13 Nurses Note Note Text: Pt. noted to be lethargic at this time. Does respond to verbal and tactile stimuli by opening her eyes but non verbal currently. Skin warm and dry. No mottling or apnea observed at this time. O2 sat 88% with O2 at 2 LPM via n/c. On increased to 3 LPM via mask as pt. noted to be mouth breathing. Respirations 28. F/U O2 sat 93%. HOB elevated. Pt. medicated with morphine by LPN. Daughter updated on pt.'s condition. Does not want pt. sent out to hospital and would like comfort measures to continue. Daughter also in agreement with delay in d/c d/t pt.'s condition.CRNP updated on pt.'s condition, delay in d/c and daughter's wishes. No n/o's at this time. view 2/4/2021 10:56 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB Resident showing s/s of discomfort. SOB at this time and high respirations. Repositioned, changed for incontinence care and mouth care provided. view 2/4/2021 10:34 Progress Note Note Text: Spoke with RN regarding change in condition. Updated Sr Living regarding change. Recommendation to cancel d/c/transfer for today, see how resident does through the weekend and re-evaluate on Monday. Daughter updated on cancellation of d/c today. view 2/4/2021 10:04 Nurses Note Note Text: Daughter aware that resident's O2 sat was 88% on room air on 3-11 shift and that oxygen was applied via nasal cannula. view 2/4/2021 10:03 Nurses Note Note Text: N/O: Discharge 2/4/21 with scripts to Sr. Living. Daughter aware. view 2/4/2021 09:53 Nurses Note Note Text: Pt. to be d/c'd to another facility this am as per MD order. Pt. alert and responsive. Skin assessment done as per facility policy. No pressure areas noted at this time. No s/sx of pain or discomfort observed at this time. V.S. 97.0 67 20 O2 sat 95% with O2 at 2 LPM via n/c. view 2/4/2021 07:45 Nurses Note Note Text: Resident seen by Dr. for discharge. Orders pending at this time. view 2/4/2021 07:36 Nurses Note Note Text: CRNP and Dr. updated on O2 sat 88% on RA with f/u of 93% with O2 on at 2 LPM as well as rest of VS, 3-11 shift 2/3/21. No n/o's at this time. view 2/3/2021 21:17 Nurses Note Note Text: Resident Sp02 88% on RA. Pulse 124. Respirations 40. PRN morphine given and O2 applied via NC at 2L/min. After recheck pulse ox up to 93%, pulse 100, and respirations 22. Resident appears comfortable at this time. view 2/3/2021 20:05 Orders - Administration Note

Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective [linked] view 2/3/2021 19:48 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN given for SOB after elevation of HOB not effective. view 2/3/2021 11:51 Nurses Note Note Text: CRNP updated rapid COVID test done for d/c tomorrow was negative. No n/o's at this time. view 2/3/2021 11:44 Nurses Note Note Text: Daughter notified of rapid covid swab being negative. view 2/3/2021 09:50 Orders - Administration Note Note Text: Obtain Rapid Covid test on 2/3/2021 for discharge. Please give copy of results to Social Worker every day shift for covid testing for 1 Day Completed and negative. view 2/3/2021 08:45 Skilled Nursing Note Reason for skilled service: Therapy describe skilled service: Nursing, therapy assessment: V.S. 97.8 79 18 138/84 Orientation: Oriented to self only. Oxygen: O2 sat 94% on RA Edema: Trace edema noted BLE. Pedal pulses present. Pain: Denies pain or discomfort at this time. Nursing note: Pt. alert and responsive. Skin warm and dry. Lung sounds diminished. No respiratory distress observed at this time. Abdomen soft. BS+ in all 4 quads. Continent/Incontinent of B&B. 1 assist with ambulation, transfers. 1 assist with ADL's. Working with therapy on gait training, therapeutic exercise, therapeutic activities & neuromuscular reeducation. view 2/2/2021 14:37 Progress Note Note Text: Per health professional at Sr Living, prepared to accept patient to their Memory Care Unit 2/4. Transportation arranged for 11 AM per family request. Daughter (POA) updated on d/c time on 2/4/21. Facility requesting rapid COVID test completed prior to d/c and results sent to them. All other information sent for continuity of care.

DYSARTHRIA

COVID19 (COVID19 (MODERNA)) (1201)

1/13/21 pt came into clinic for vaccine. Had difficulty remembering age. Called me Mon. 1/18/21 stating she was sick. When asked what her sx were, she stated fatigue. She was well the night of the shot, Thur. and Fri. but became tired on Sat. and Sun. I went through other sx with her such as h/a, fever, n/v, muscle aches, weakness and she said she experienced none of those. I questioned her about eating and drinking and she said she ate and drank water. She seemed fine so I told her to call her doctor if she was worse or the fatigue persisted or call 911. She agreed. Two staff from clinic called her Mon. and Tues, (1/18 and

No prior vaccinations for this event.

1/19). On Tues. she may have had sl slurred speech. She was found deceased on

	DYSARTHRIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Adverse reaction to the vaccine started with variable weakness beginning 1/29/2021. On 1/30/21 around 8:30pm, he needed assistance in the bathroom related to weakness and had what was later identified as a stroke with left side weakness and slurred speech. In accordance with his wishes, he had care at home. Due to his advanced age and frailty, a CT scan was not pursued. The 325 mg of aspirin that he was previously taking daily was discontinued. After the stroke, he needed total care. Hospice was established at home. Nursing assistant care was delivered by daughter. Death followed 9 days later (2/9/2021).		No prior vaccinations for this event.
	DYSARTHRIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Decedent had unwitnessed fall out of wheelchair 1/25/21 around 9:43am, denied head strike, pain, discomfort. Around 10:02pm, 1/25/21, decedent noted to have slurred speech and fluctuating HR, transported to Hospital and made cmo.		No prior vaccinations for this event.
	DYSARTHRIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Extreme Fatigue, slurring speech, unable to stand, eat. Death on 2/5/21		No prior vaccinations for this event.
	DYSARTHRIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Developed acute facial droop and slurred speech 2h after 1st dose of the vaccine on 2/17, found with R MCA stroke. Then became unresponsive on 2/27 and was found with an acute L MCA stroke. Was transferred from another hospital, was not a candidate for intervention, and was made comfort and died on 2/28	No prior vaccinations for this event.
DYSARTHRIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.	No prior vaccinations for this event.
DYSKINESIA	**COVID19 (COVID19 (MODERNA)) (1201)**
"86yo female alert, stable with ankle abrasion eating 100% prior to vaccine in assisted living facility. On 2/1/2021, received Moderna vaccine. Starting thereafter, eating 50% on 2/2/21. Temperature was 98 tympanic. On 2/3, the leg abrasion started having moderate bleeding. On 2/4, the caregiver noted patient ""not looking good, unable to talk, arms moving aimlessly, grasping"". BP 95/41, temperature 98, oxygen on room air 92-93%. POA did not want hospital transfer. 2/5 Hospice started, oxygen given, morphine given. 2/5-2/8 comfort care given, patient responsive to tactile stimuli, resting, not taking oral medications or food. 2/8/2021 patient expired."	No prior vaccinations for this event.

	DYSKINESIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021		No prior vaccinations for this event.
	DYSKINESIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 10 minutes after receiving the COVID- 19 vaccine resident displayed seizure activity, staring straight ahead and strong allover muscle jerking of both the up and lower extremities, color became gray, activity lasted approximately 3 minutes, resident then became relaxed, color returned to normal, BP-140/80, 97.8, 60, 16, sleeping the remainder of the shift,. Resident continued to decline until resident CTB on 1/19/21		No prior vaccinations for this event.
	DYSLIPIDAEMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.		No prior vaccinations for this event.
	DYSPEPSIA	**COVID19 (COVID19 (MODERNA)) (1201)**

Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021and felt poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM CHLORIDE 1000 MG ONCE	No prior vaccinations for this event.

DYSPEPSIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient stated he wasn't feeling well on January 25, 2021, wasn't eating and complained of abdominal pain. Patient noted to have indigestion and was constipated. Meds provided and labs ordered. On morning of January 26, 2021, patient became weak, lethargic and hypoxic and was sent to emergency department around 0700 hours on January 26, 2021. At approximately 1100 hours, emergency physician notified this writer that patient was not going to overcome his illness and would be placed on comfort care. At approximately 1130 hours, this writer was notified that patient had passed away from multi-organ failure.	No prior vaccinations for this event.

DYSPEPSIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/28/2021- Seen by FNP for indigestion, chest pressure and palpitations. EKG reviewed and referral made to Cardiology. 1/29/2021-1800 Presented to ED in cardiac arrest-onset PTA. Patient was found unresponsive by	No prior vaccinations for this event.

his wife at their home. The last known well was at 1530 when she called him on the phone. The patient was pronounced at ~1850.

	DYSPHAGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received vaccine on 1/4/2021. He was in Hospice for CHF and renal failure, but was able to get up in his wheelchair and eat and take medications and talk. On 1/5/2021 am, he was noted to be very lethargic an could only mumble, could not swallow. No localizing neurologic findings. He was too lethargic to get up in chair.		No prior vaccinations for this event.
	DYSPHAGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident getting rehab therapy in the facility and has a long history of Parkinson's Disease. On 01/29/21, he received the COVID vaccine on left deltoid, resident was recently hospitalized due to Pneumonia and was on antibiotic IV and was recently placed on GT feeding due to severe dysphagia from his Parkinson's disease. On 01/31/21, started having increased congestion. On 02/02/21, started having increased temperature and WBC went up >20,000 on 02/03/21, started on Vancomycin IV on 02/04/21 but was transferred to the hospital. Facility was notified today (02/18/21) that resident expired in the hospital.		No prior vaccinations for this event.
	DYSPHAGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
He developed a fever on 1/8, become unable to swallow and bedbound. He was already end of life and Hospice care at the time of the vaccine.		No prior vaccinations for this event.
	DYSPHAGIA	**COVID19 (COVID19**

	(MODERNA)) (1201)
approximately 24 hours post vaccine Patient developed a low grade fever of 99.5 and had increased fatigue. 48 hours later she had decreased neurological functioning. 02/23 she had difficulty swallowing. 02/23 She was admitted to hospice services. 02/26 she passed just before 10 am.	No prior vaccinations for this event.
DYSPHAGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Has underlying dementia and often with difficulty eating. 1 week after immunization she developed a stroke with left sided weakness and difficulty swallowing. Comfort measures instituted. Not sure if this is related to the vaccine, but thought I should report	No prior vaccinations for this event.
DYSPHAGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Heart stopped; Could not swallow; This is a spontaneous report from a contactable nurse (patient's wife). An 85-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 21Jan2021 at a single dose for COVID-19 immunization. Medical history included blood pressure abnormal (verbatim: blood pressure) from an unknown date and unknown if ongoing, neuropathy from an unknown date and unknown if ongoing, weight issue from an unknown date and unknown if ongoing, diabetes from an unknown date and unknown if ongoing, walker user from an unknown date and unknown if ongoing. Concomitant medications included insulin aspart (NOVOLOG) taken for diabetes from an unspecified date to an unspecified date; and he was taking a long acting one as well. The patient previously received the influenza vaccine (MANUFACTURER UNKNOWN) for immunization on unknown dates (""had flu shots before with no reactions and everything, nothing before""). On 24Jan2021, the patient's heart stopped (death, medically significant), and could not	No prior vaccinations for this event.

swallow (medically significant). The clinical course was reported as follows: The patient's wife stated the patient was taking insulin aspart (NOVOLOG) and he was taking a long acting one as well. The reporter, the patient's wife and a retired registered nurse (RN) stated, her husband (patient) just died and she thought he died from the COVID vaccine (later clarified the reason of death was-heart stopped). The patient had the vaccine on 21Jan2021, which was on a Thursday, and he was fine. On the following Sunday around 1:30 (on 24Jan2021), the patient was feeling a little weak, however, the patient's wife thought maybe his blood sugar was low. The patient's wife checked, and the patient's blood sugar was 91. The patient's wife went to get some yogurt to feed him in order to get his blood sugar up a little; ""which was a normal thing for him, it was not that low for him."" Then, suddenly, the patient fell, and the patient's wife could not get a pulse or anything. The patient's wife called an unspecified number and she started compressions; however, he was dead. The patient's wife stated the patient just had his heart test, a three hour long one, and it was ""perfect three weeks ago."" The patient had just gone to the doctor the other day and his blood pressure was ""fine and everything."" The patient's wife stated that other than his diabetes, ""which he had for (sentence incomplete)."" Regarding lab tests, the patient's wife stated, ""No, he had it before but not in the last two weeks. He was going for one because we just went to the doctor last week and he was going to call yesterday to make the appointment request to get his blood work done. Blood work has been good except his A1C was always high, but other than that everything was good"" (as reported). Regarding causality, the patient's wife stated, ""I do, because he was fine until about half an hour before he died. He said to me, I feel a little weak today and then I was talking to him that your upper body strength is really good and then I said, we just have to work on your weight a little more because he did have neuropathy. And then, I went out of the room and all of a sudden I just heard him fall and that is when I just went in to check his blood sugar and it was 91 and I got him yogurt and he started eating that and then that was it, he started spitting it out and he said, I could not swallow and that was it, he just died."" The patient's wife further added, ""I just wanted other people to know that things like this happen and I am sure it was from that because he was healthy as could be. He was walking with his walker, the day before outside and he felt fine."" The clinical outcome of the event, heart stopped, was fatal. The clinical outcome of the event, could not swallow, was unknown. The patient died on 24Jan2021 due to ""heart stopped."" An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and

will be requested during follow up.; Reported Cause(s) of Death: Heart stopped"

	DYSPHAGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.		No prior vaccinations for this event.

	DYSPHAGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had no energy in the first 24 hours and then began a steady decline that started with vomiting after 48 hours, then an inability to swallow and ultimately the patients death on 2/5/21.		No prior vaccinations for this event.

	DYSPHAGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.		No prior vaccinations for this event.

	DYSPHAGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/23 - Mild injection site discomfort. Appetite loss compared to previous day. Beginning loss of mental		No prior vaccinations for

acuity compared to previous day. 1/24 - Continued loss of appetite. Near complete loss of ability to move. Continued decline of mental acuity. Very little speaking. 1/25 - Stopped speaking completely. Loss of bowel control in the evening and continued until death. Complete loss of appetite. 1/26 - Near complete loss of ability to swallow. Moved to hospice 4:00pm. 1/27 - Died 4:00am		this event.
	DYSPHAGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21- N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm		No prior vaccinations for this event.

and noted she was not breathing. Supervisor called and pronounced resident deceased.		
	DYSPHAGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.		No prior vaccinations for this event.
	DYSPHAGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient, age 101, was having a period of declining health prior to vaccine administration. This continued after the vaccine to include increased pain, inability to swallow and ultimately Patient passed away on 1/9/2021. The physician does not believe this is due to vaccine administration, however family asked that this information be reported for record keeping.		No prior vaccinations for this event.
	DYSPHONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches;		No prior vaccinations

Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday for this event.

morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An

autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death		
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg		No prior vaccinations

STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.

for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

hypoxia, secretions,cough, dyspnea Narrative: ALS patient on hospice with ongoing history of aspiration pna, receiving tube feeds. Developed incr in secretions, hypoxeia, temp and with recently noted clogged feeding tube.

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

The patient had severe shortness of breath resulting in cardiac arrest on the 5th day after the vaccine. Shortness of breath started 12 hours after injection. On the 5th day, the patient was discovered to also have a rash throughout his body, but it is unknown when this rash started.

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

Started with cough, mild shortness of breath and feeling terrible in evening of 1/19. No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

Pt received second dose of COVID vaccine on 01/20/2021 at 1430. At 1600 Pt developed a wet productive cough with coarse crackles. Pt ate dinner at 5 pm cough persisted. At 18:30 the nurse went to Pt's room to give him his medications. Pt still had a cough, denied shortness of breath. Pt was in a good mood and joking

No prior vaccinations for this event.

with staff. Pt asked to be shaved. At 19:45 Pt was sitting in the lounge and a CNA noticed that Pt was pale/white in color and clammy. 02 Sat was 85%. Respirations were labored. Pt was placed on 4 L of 02. Increased to 5 L via face mask and 02 sat was 89-90%. Ambulance was called at unknown time. Pt arrived at Medical Center at 2120 and was pronounced dead at 2127.

DYSPNOEA **COVID19 (COVID19 (MODERNA)) (1201)**

Patient had increased SOB while at home. EMS was called. Patient coded in the squad No prior vaccinations for this event.

DYSPNOEA **COVID19 (COVID19 (MODERNA)) (1201)**

Patient obtained initial dose of Moderna vaccine on Thurday, Jan 14. No adverse effects reported during initial 15 minute post vaccine waiting period. Saturday morning (Jan 16), patient developed severe cough, labored breathing, and fever. Additionally patient mental status changed suddenly, became non-communicative (unable to speak, but would scream if she was touched). O2 status was irregular, dropping to 78. Sunday morning, EMT and then hospice was hospice called. Monday morning, after hospice emergency kit was initiated, patient passed away.

No prior vaccinations for this event.

DYSPNOEA **COVID19 (COVID19 (MODERNA)) (1201)**

Fever Feeling tired short of breath all night and morning after the vaccine My grandma had to be intubated and then passed away to a heart distress we think it was the vaccine because she was fine even with dialysis. When she got the vaccine it took hours and her health conditions changed.

No prior vaccinations for this event.

DYSPNOEA **COVID19 (COVID19 (MODERNA)) (1201)**

Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.	No prior vaccinations for this event.	
DYSPNOEA		**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.	No prior vaccinations for this event.	
DYSPNOEA		**COVID19 (COVID19 (MODERNA)) (1201)**
CARDIAC ARREST THAT LEAD TO DEATH - IT WAS REPORTED BY EMS THAT THE PT HAD RECEIVED THE VACCINE ABOUT 30 MINS PRIOR. HE ARRIVED HOME, BECAME SHORT OF BREATH & COLLAPSED. 911 WAS CALLED AND HE WAS TRANSPORTED VIA EMS TO HOSPITAL (16:17) WHERE HE LATER EXPIRED (23:01).	No prior vaccinations for this event.	
DYSPNOEA		**COVID19 (COVID19 (MODERNA)) (1201)**

about 20+ hours after vaccination resident was having hard time breathing, 911 was called. Resident coded multiple times at the facility after CPR she was taken to ICU. She coded again and was placed on life support. Due to her choice to not be on life support she passed on 11/26/2021.

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

Patient developed SOB but reported good O2Sats. Instructed on going to ER if worsening symptoms. Patient eventually expired on 1/22/21

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

Pt started complaining of chest heaviness and shortness of breath on the afternoon of 1/21/21. EMS was called to the patients home and she was found to have an O2 sat in the 70's. She was admitted to hospital and found to have a proBNP of 5000. She tested negative for Covid-19. She was determined to be in acute-on-chronic heart failure and was referred for hospice care. She passed away on the evening of 1/24/21.

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19

(MODERNA)) (1201)

Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face, increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
got up in the night and stated that she couldn't breath, ambulance was called, pt expired in route to hospital. *relayed to me by Facility staff RN.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Congestion, Hypoxia, SOB, Tachycardia, Weakness. Started on O2 @ 3L, HOB elevated, Tylenol supp		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Shortness of Breath, decreased oxygen saturation, irregular heart rhythm, hypertension, Positive for COVID, bilateral pneumonia		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient's wife called the physician's office with increasing SOB. MD advised that the patient go to the ED. While dressing, the patient became unresponsive, 911 called. Patient expired in ED.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Got vaccine on 1/15/21. He was tired right away, bedridden the next 3 days. He couldn't breathe so he was taken by ambulance on 1/18/21. He was in hospital for several days. put on remdesivir cocktail for 10 days.		No prior vaccinations for

Slowly getting worse and died in hospital on 1/30/21.		this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021and felt poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM CHLORIDE 1000 MG ONCE		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had no symptoms or adverse events until the next evening after shot (1/29/21) where daughter reported her having heart palpitations. Family told her to rest and did not seek medical attention. Saturday afternoon (1/30/2021), patient started experiencing labored breathing. Daughter called 911 and before the ambulance arrived, the patient's breathing became more and more shallow. Patient was taken to the local hospital and passed away Saturday evening around 5:30 pm.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Moderna Vaccine Lot 029K20A Patient received second dose of vaccine on 2/2/21. Within 30 minutes patient		No prior vaccinations

had a near syncopal episode. She felt lightheaded and shortly after had episode of nonbloody vomiting. Hypotensive 81/69 and started on levophed. Alert and orientated. Lungs clear, abdomen benign on admission. Patient had no reaction when received first dose of the vaccine. Patient developed worsening shortness of breath, tachypnea, Afib with RVR, hypotension and required intubation and multiple pressors.	for this event.
DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient, who was a pharmacist, developed fatigue and shortness of breath hours after receiving vaccine. Two days later, on 01/28/2021, the patient went to local urgent care for worsening shortness of breath and was referred to Hospital for worsening dyspnea and hypoxia. The patient was admitted to the hospital We was found to have bilateral pulmonary infiltrates and treated for pneumonia with Rocephin and azithromycin. He was tested for COVID-19 multiple times, but each of the results were negative. Despite the negative results, there was high clinical suspicion for COVID-19 and the patient was started on Remdesivir and Decadron. The patient's oxygen requirements continued to worsen and the patient was transferred to another facility for higher level of care. There his hypoxia worsened and he required mechanical ventilation. Patient then developed hypotension and required vasopressors for blood pressure support. Furthermore, patient developed acute renal failure requiring hemodialysis. Despite mechanical ventilation with FiO2 100%, and for vasopressors, patient clinically deteriorated and family decided to palliatively extubate on 02/05/2021.	No prior vaccinations for this event.
DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort	No prior vaccinations for this event.

care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.

	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
EARLY SUNDAY MORNING THE PATIENT BEGAN VOMITTING AND SHORT OF BREATH AND CHEST AND BACK PAIN. SHE CODED WHEN SHE GOT IN THE ER AND LATER PASSED AWAY THE MONDAY. DIAGNOSIS WAS PNEUMONIA AND HEART FAILURE PER STEP DAUGHTER.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Brain aneurysm; Anaphylactic reaction; Collapsed; BP sky rocketed; Shortness of breath; A spontaneous report was received from a consumer concerning a 69-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced blood pressure skyrocketed, shortness of breath, loss of consciousness, massive anaphylactic reaction, and brain aneurysm. The patient's medical history, as provided by the reporter, included high blood pressure and arthritis. Products known to have been used by the patient, within two weeks prior to the event, included an antihypertensive. On 04 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. Twenty-two minutes later she had a massive anaphylactic reaction. She experienced shortness of breath, blood pressure skyrocketed, and loss of consciousness. She was taken to the emergency room. The patient had a brain aneurysm and never recovered. No treatment information was provided. The patient died on 04 Jan 2021. The cause of death was reported as brain aneurysm. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns a 69-year-old, female patient with a medical history of hypertension, who experienced fatal, serious, unexpected events of Anaphylactic reaction, hypertension, dyspnea, loss of consciousness and brain aneurysm. The events occurred 22 minutes after the first dose of mRNA-1273 was administered. No treatment information was provided. The patient never recovered and died. The cause of death was reported as brain aneurysm. Very limited information regarding		No prior vaccinations for this event.

this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Additional information has been requested.; Reported Cause(s) of Death: Brain aneurysm

	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Within a few days, my mother started reporting profound fatigue and shortness of breath while conducting routine household activities. She no longer had to energy for her daily exercise walks and became increasingly lethargic. She died in her sleep while taking an afternoon nap on Thursday, February 4th. I am highly concerned this could be a vaccine related.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received his second dose of Moderna COVID vaccine on 2/6 at 12:40PM. Patient was observed for 15 minutes post-vaccination with no adverse events. On the evening of 2/6 (time unknown) the patient began to develop dry cough and fatigue. He was checked by a physician at that time (who was a family member). Patient continued to feel unwell into Sunday. His lungs were clear when checked Sunday afternoon (time unknown). At approximately 5:30pm on 2/7 the patient began experiencing sudden onset shortness of breath. A pulse ox was conducted at that time and it was 92%, and again shortly thereafter and it was 90% (as reported by family member). 9-1-1 was contacted at this time. CPR was initiated when he arrived at the emergency department, pulse ox was 60% (as reported by family member). The patient passed away shortly thereafter on 2/8/2021.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was hospitalized on 31 Jan for COVID pneumonia after 3 days of increasing baseline		No prior vaccinations for this

supplemental O2 requirements and dyspnea and ultimately died on comfort care on 3 Feb 2021. event.

	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
ON 02/08/2021 AROUND 0600 RESIDENTCOMPLAINED OF MOUTH PAIN AND RECEIVED OXYCODONE. DURING THE COURSE OF THE MORNING, RESIDENT EXHIBITED A FEW EPISODES OF LABORED/SHALLOW BREATHING AND SOB AT RESTING. 0XYGEN SATURATION RATE WAS 93-98% ON ROOM AIR, LUNG SOUNDS CLEAR IN ALL LOBES AND PULSE AND TEMPERATURE WITHIN NORMAL RANGE. AS THE DAY PROGRESSED, VITAL SIGNS REMAINED STABLE BUT RESIDENT CONTINUED TO HAVE PERIODS OF SOB/LABORED BREATHING.FAMILY AND NURSE PRACTIONER UPDATED AND THE ORDER WAS RECEIVED TO SEND PATIENT TO MEDICAL CENTER ER FOR EVALUATION PER AMBULANCE. RESIDENT TRANSPORTED AT 1425. RESIDENT RETURNED FROM THE ER AT 1830 ON HOSPICE CARE WITH THE DIAGNOSIS OF: ACURE RESPIRATORY FAILURE WITH HYPOXIA AND END OF LIFE DECISION MAKING. RESIDENT WAS MADE COMFORTABLE AND MONITORED DURING THE NIGHT AND EXPIRED AT 0630 ON 02/09/2021.		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
pt received vaccine on 2/3. early on 2/4 developed chest pain, dyspnea, and was seen in ED and diagnosed with acute exacerbation of CHF and NSTEMI type 2, and anemia. on 2/5 transfusion was started and pt developed worsening dyspnea and then PEA arrest. Pt achieved ROSC and was transferred to the cardiac intensive care unit where he required vasopressor support. he subsequently declined and died on 2/7		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Received Moderna covid vaccination 1/14/2021. 1/16/2021 received report of cough and difficulty breathing. Proceeded to hospital and was diagnosed Covid+ on testing. Continued to decline, died 1/31/2021.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Received Moderna #1 on 1/12/2021. 1/15/2021 developed worsening shortness of breath. Went to hospital and diagnosed with anemia, 4 negative fecal tests, neg EGD and colonoscopy. Discharged and readmitted (circumstances unknown for this episode) then readmitted a third time 1/20/2021 for shortness of breath. Diagnosed covid + at third hospitalization and continued to get worse. He died 1/23/2021.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient sent to the ED or sudden onset of shortness of breath on 02/02/2021. Per documentation by the MD, the patient had COVID19 ""several weeks ago"" and the nursing facility felt like he had recovered. A rapid test done in the ED was negative. When the patient worsened and seemed to be following the same path as other		No prior vaccinations for this event.

COVID patients, a send out PCR test was done, which was positive. The patient worsened and passed away that same day (02/05/2021) I was not made aware that the patient had the vaccine on 01/21/2021 until Monday 02/08/2021."

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

Death; kidney failure (unable to urinate); shortness of breath; required oxygen; A spontaneous report was received from consumer concerning an 87-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced shortness of breath, kidney failure and death. The patient's medical history included advanced kidney and heart disease. No relevant concomitant medications were reported. On 06 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 17 Jan 2021, the husband reported that the patient experienced adverse events. Symptoms included shortness of breath and kidney failure (unable to urinate). The patient was admitted to the hospital and discharged to hospice. Oxygen was administrated for shortness of breath. Action taken with mRNA-1273 in response to the events was not applicable. On 20 Jan 2021, the patient died. The cause of death was unknown. Autopsy details were unknown.; Reporter's Comments: This case concerns a 87-year-old, female patient with the medical history of advanced kidney and heart disease, who experienced fatal unexpected event of dyspnea, renal failure and death. The events of dyspnea and renal failure occurred 12 days and the event of death occurred 15 days after the first dose of mRNA-1273 (Lot: unknown). The patient was admitted to the hospital and discharged to hospice. Oxygen was administrated for shortness of breath. The cause of death was unknown. Autopsy details were unknown. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, the history of advanced kidney and heart disease may remain as confounder. Additional information has been requested.; Reported Cause(s) of Death: Unknown cause of death

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19

(MODERNA)) (1201)

"The decedent experienced severe chest pain and dyspnea approximately nine days following the first series of the vaccine. He reported to family members that he was having a ""severe reaction"" to the vaccine and believed it was acute pericarditis due to the same symptoms he experienced prior. He reported that on 2/1/21 around 0300 hours, the symptoms were the most severe and he was going to seek medical attention, but did not. He waited till the convenient store opened and purchased OTC Tylenol for relief of symptoms. He continued to have dyspnea and chest pain up until 2/9/21, when he called 911 complaining of chest pain and was found to have a STEMI; subsequently died at Hospital in the ER."

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

patient tested positive for covid on 1/29/21. was hospitalized on 2/8/21 for shortness of breath, generalized weakness, nausea.

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

covid shot 2/2; feel bad 2/5; covid positive diagnosis - 2/8 s/s cough, fever, shortness of breath , hypertension, afib (in er) - admitted went into DIC per intensivist 2/11 patient died

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

Developed severe shortness of breath. No prior vaccinations for this event.

DYSPNOEA **COVID19 (COVID19 (MODERNA)) (1201)**

Resident has shortness of breath on 1/19/2021 and was transferred to Hospital 1/20/2021 No prior vaccinations for this event.

DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Two days later passed away; difficulty breathing, shortness of breath; difficulty breathing, gurgling; Not feeling well; Achiness; Severe fever; Chills; A spontaneous report was received from a physician concerning a 56-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed fever, chills, achiness, shortness of breath, gurgling and unresponsive. The patient's medical history was not provided. Concomitant product use was not provided. On 19 Jan 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Lot 042L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. After receiving the vaccine on 19 Jan 2021, the patient experienced fever, chills, shortness of breath, gurgling and achiness. On 21 Jan 2021, the patient was found unresponsive. Emergency medical services were called to perform life saving measures however, they were unsuccessful. No further treatment information was provided. The patient died on 21 Jan 2021. The cause of death was reported as unknown. An autopsy was planned.; Reporter's Comments: This case concerns a 56-year-old, female, who experienced a serious event of death, with many other events after receiving second dose of mRNA-1273 (Lot# 042L20A). Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death	No prior vaccinations for this event.

DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Fever by the next day, difficulty breathing, pneumonia, and then DEATH within a few days. (Died 02/01/2021)	No prior vaccinations for this event.

DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away; tired; nonresponsive; cold; difficulty breathing; swelling; sore arm; feeling weird and funny; A	No prior vaccinations

spontaneous report (United States) was received from a consumer concerning a 63 year old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and the patient experienced limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal and the patient passed away . Medical history included treatment for tuberculosis and dialysis. Concomitant medication included calcium acetate, Renvela, glipizide, omeprazole, aspirin, vitamin D, losartan, furosemide, rifampin, and Sensipar. On 14 Jan 2021, the patient received the first of their first planned doses of mRNA-1273 (lot number 030L20A) for prophylaxis of COVID-19 infection. On 13 Jan2021, the patient tested negative for COVID-19). On 16 Jan 2021, the patient experienced a sore arm, and feeling weird/funny. On 17Jan2021, the patient experienced difficulty breathing and swelling. On 18 Jan 2021, the patient declined dialysis, was tired and wanted to lay down. At 8 am, the patient was found nonresponsive and cold and is believed to have passed away around 4 am. The coroner tested the deceased for COVID-19 and the test was positive. No autopsy was reported. No death certificate was issued at the time of the report but the reporter believes it will list cause of death as COVID complications. Action taken with the mRNA-1273 was not applicable. The outcome of the events of limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal, was fatal. On 18 Jan 2021, the patient was died. Cause of death was COVID-19. Autopsy details were not provided.; Reporter's Comments: The events developed on four days after first dose of mRNA-1372. Dyspnea, unresponsive to stimuli, and death were consistent with infection in pandemic set up confounded by age of patient and refusal of dialysis Cause of death was reported as COVID-19. Autopsy details were not provided. Based on reporter's causality the events are assessed as unlikely related to mRNA-1273.; Reported Cause(s) of Death: COVID-19

for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

Per EMS/Hospital report patient had difficulty breathing and cardiac arrest with prolonged CPR (greater than 45 mins in the ER) who was resuscitated. Family subsequently arrived including son and daughter and all family members were in the ER room are in agreement that patient would not want further aggressive cares given her extremely poor prognosis in light of chronic debilitation with numerous medical issues and now a

No prior vaccinations for this event.

very long period of CPR. Hospital Course After updating family they stated patient would not want further aggressive cares given her grim prognosis and chronic severe and debilitating medical issues. She continued to have myoclonic jerking. She was extubated to comfort cares in the ER and did not pass immediately therefore brought to a room. She received comfort cares and passed away at 0450 with family present.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

911 called to patients house for trouble breathing and abdominal pain. Patient coded, wife presented DNR paperwork. Patient presented to Hospital DOA at 0958.

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19

	(MODERNA)) (1201)
Approximately 2 weeks after the first COVID vaccine she developed shortness of breath that was much more significant than she had previously. This was the first time she had expressed this symptom to me as being something she was concerned about and difficult for her to manage (we have spoken almost daily for many years). Within 24 hours of the second dose of the mRNA vaccine, they called an ambulance to get her and she was taken to the hospital and diagnosed with bacterial pneumonia. The doctors said it was unrelated, but I found a study with a different vaccine (LAIV) that also seemed to increase the incidence of bacterial pneumonia. They hypothesized through diverting the immune system. So while I don't think the vaccine gave her the bacteria, I do think it may have caused her immune system to be temporarily compromised allowing the bacteria to grow out of control. I feel this is important to report to look for these types of patterns as perhaps it can help others avoid the death spiral that happened to my mother. There were also intervening events between her hospitalization and her death including two successful surgeries (one for a broken hip and another to put in stents in her leg). So to summarize, the first vaccine was within about 2 weeks of the onset of her breathing problems. Within 24 hours of the second vaccine she was hospitalized and diagnosed with bacterial pneumonia. As she was battling bacterial pneumonia in the hospital she broke her hip and was found to have reduced peripheral circulation and had 2 surgeries to correct those. They were successful according to the surgeons, however she died within a week or so of the surgeries. She had other comorbidities as well which I'm sure predisposed her such as diabetes, hypertension and cancer for many years.	Breathing issues ~2 weeks after first dose of mRNA vaccine in the series but were not nearly as acute or severe as they were fol
DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
This is a hospice patient under the care of Hospice at an affiliated nursing home. Pt received the vaccination around noon on 2-16-21 by a representative from Pharmacy. The following afternoon 2-17-21 at 14:45 the pt	No prior vaccinations for this event.

started to experience severe SOB resp rate 36, audible wheezing and use of respiratory accessory muscles. BP180/80, 113 pulse temp 98. Pt was given morphine and ativan. The respiratory distress was eased however pt never returned to baseline and died 2-22-21 around 4am.

	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
On January 1, 2021, patient was admitted to Medical Center with COVID. Tested positive on January 2, 2021. Spent 10 days in hospital. Once recovered from pneumonia and fever gone, on January 10, 2021, she was transferred to Rehabilitation Center for continued treatment. She spent 16 days there. She developed UTI and CDIF infections and was on/off oxygen. She started physical therapy. She was scheduled to be released to go home on January 27, 2021. On January 26, 2021, the day before going home, Rehabilitation Center gave her the Moderna vaccine. On January 27, the day she went home, she started feeling very weak and couldn't walk. My dad tried lifting her and they both fell to the ground. My dad called 911 and she was taken to Medical Center, with high fever and possible stroke symptoms (which later was negative). Two days later, she had difficulty breathing and was put on a ventilator. She was on a ventilator for about three days. They took it off and she slowly started recovering. The doctors did all kinds of tests (blood clot in lung, heart, etc.) and all was negative. The only thing they could trace it to was an adverse reaction to the vaccine. After spending 11 days at hospital and treating her for various infections, her heart stopped and she passed away suddenly.		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
"My grandpa had a stroke on the 15th of February. He claimed he had been feeling ""off"" for a few days, but didn't say anything. A blood clot had formed in his brain. He was doing better and about to go to rehab to strength his right side of his body. On the 22nd he took a turn for the worst. He was having trouble breathing and they sedated and partially paralyzed him to put a tube in his mouth. I believe another blood clot had formed and oxygen wasn't properly going through his body. They could not stabilize him, and he passed		No prior vaccinations for this event.

away the same day."

	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
	High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death	No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
	Patient was transferred from hospital for further evaluation and care by pulmonologist. He started having symptoms a week before with fatigue, emesis, decreased p.o. intake, shortness of breath, vomiting and	No prior vaccinations for this event.

diarrhea. The two previous takes before death required increasing oxygen and family wanted everything done including intubation. He was transferred to ICU.

DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
30 hours after the first Covid vaccination, the resident was lethargic, non responsive with shortness of breathe.	No prior vaccinations for this event.
DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from	No prior vaccinations for this event.

which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

DYSPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

Died at home; Gasping for air/difficulty breathing; Soreness; A spontaneous report was received from a physician concerning a 45 years-old, female patient who experienced soreness/MedDRA PT: pain, gasping for air/difficulty breathing/MedDRA PT: dyspnoea and subsequently died/MedDRA PT: death. The patient's medical history included blood pressure (disorder not specified), thyroid disorder, depression and anxiety. Concomitant product use included blood pressure medication, thyroid medication and possibly depression and anxiety medication. On 28 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot #007M20A) (route of administration and injection site not provided) for prophylaxis of COVID-19 infection. On 28 Jan 2021, following the vaccination, the patient was fine but had experienced some soreness. Per patient's coworker, the patient did not take any medication as it made the patient sick. The physician was not aware of any complaints from the vaccine. On 13 Feb 2021 at 3:31am, the patient called 911. Per the 911 call, the patient was gasping for air on the call and having difficulty breathing. The patient subsequently died on 13 Feb 2021 at home. The physician inquired whether Moderna gets involved with the autopsy and logistics of the death of patients and wanted to know the time frame for reporting a death of a patient who received the vaccine. The physician did not know who administered the patient's vaccine. Action taken with

No prior vaccinations for this event.

mRNA-1273 in response to the events was not applicable as the patient deceased. The event died was fatal. The outcome for the events soreness and gasping for air/difficulty breathing was unknown. The patient died on 13 Feb 2021. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter's Comments: Very limited information regarding the event of dyspnea and death has been provided at this time. Further information has been requested. Patient's medical history of blood pressure is considered a risk factor. Based on the current available information and temporal association between the use of the product and the onset of the pain, a causal relationship cannot be excluded.; Reported Cause(s) of Death: Died at home

	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received dose 1 of Moderna Vaccine on 1/14/21 administered by pharmacy. Patient was hospitalized on 1/31/21 due to shortness of breath and diminished O2 sats down to 88%. Patient was in atrial fibrillation. Patient discharged from hospital on 2/25/21 to home. Patient received dose 2 of Moderna Vaccine on 2/25/21 prior to discharge from hospital. Last hospital note stated that patient was pleasant and cooperative with good motivation. Patient passed away after discharge from the hospital on 2/26/21. Patient's son called the hospital to report his passing.		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
1-25-2021- Phone call: pt had cold and cough prior to vaccine. cough worsened 1-28-2021 Phone call: pt requesting provider visit, cough is same and taking tessalon pearls 1-29-2021 Provider in office visit: pt complain of cough and SOB for 6 days. Getting worse. Temp 101.2, pulse ox 87%, BP 128/70. level of distress- leaning forward to breath. appeared ill. diffuse rales throughout both lung fields, more at bases. Diagnosis Pneumonia due to COVID 19 virus. Sent to ER		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
pt received vaccine at covid clinic on 12/30 at approximately 3:30, pt vomited 4 minutes after receiving shot--dark brown vomit, staff reported pt had vomited night before. Per staff report pt became short of breath between 6 and 7 pm that night. Pt had DNR on file. pt passed away at approximately 10pm. Staff reported pt was 14 + days post covid		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident became SOB, congested and hypoxic requiring oxygen, respiratory treatments and suctioning. Stabilized after treatment and for the next 72 hours with oxygen saturations in the 90s. On 1/3/2021 was found without pulse and respirations. Resident was a DNR on Hospice.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received Covid Vaccine, noted after 30 mins with labored breathing BP 161/77, HR 116, R 38, T 101.4,		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash,		No prior vaccinations for

nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.		this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fever, shortness of breath and chest pain that resulted in a heart attack a few hours after vaccination		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a		No prior vaccinations for

spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient this event. received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was okay, but he was very agitated; reported as not like this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away

DYSPNOEA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Difficulty breathing, death. No prior vaccinations for this event.

DYSPNOEA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

No adverse effects from vaccination seen on 1/2/21. On 1/6/21 resident was seen by Dr and her baclofen pump was refilled with 20 ml Baclofen 4,000mcg/ml. ITB Rate increased by 6% to 455.5 mcg/day simple continuous rate over 3 days. On 1/8/21 at 0615 resident was shaking, lower extremities mottled, Sa02 70%, pulse 45. Oxygen started at 2 L/m per NC. At 0715 her primary physician was notified as well as her daughter. Oxygen increased to 4 L/min, sats at 83%. SOA noted, reported all over pain. At 0850 when they attempted to reposition the resident, she was not responsive. Licensed nurse assessed her and no heartbeat heard or pulse found.

No prior vaccinations for this event.

DYSPNOEA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.

Influenza Virus Vaccines - Unknown date/type or brand

DYSPNOEA **COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.	No prior vaccinations for this event.
DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The day following the vaccine, the patient complained of throat issues and anxiety. This was not new... however . That evening he reported difficulty breathing and was placed on oxygen; a COVID test was performed and was negative. On 12/30/2020, patient complained of sternal pressure and was transferred to the hospital. The patient died 12/31/2020 and records obtained from the hospital indicated the patient died from a massive myocardial infarction.	No prior vaccinations for this event.
DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was	No prior vaccinations for this event.

extubated and put on comfort measures and passed away

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt called son to let him know he couldn't breath around 2 AM. Pts son showed up at his house 10 minutes later and ambulance arrived with in 20 minutes at 2:15		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
At approximately 12:15 pm the resident had a brief unresponsive episode that resolved quickly. Her Vital signs were stable and her mentation was at baseline. Later that evening approximately 10 pm she had labored respirations, shortness of breath, lethargy with bilateral crackles, Oxygen desaturated to 76% on room air, tachycardia and hypotension. She expired at 6:30 a.m. the following day.		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new		No prior vaccinations for this event.

periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on

admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
decedent had shortness of breath and hypoxia, cardiac arrested in front of the EMS crew, ACLS initiated, arrived in the Hospital ED asystole and pronounced dead		No prior vaccinations for this event.

DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

See initial report No prior vaccinations for this event.

DYSPNOEA COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"CC:full arrest HPI:HPI and ROS limited due to patient's condition. History is via EMS, medical record, and son. Per Son patient had Covid vaccine on Saturday morning. Slept all day Sunday. Woke up Sunday night a bit ""like coming out of a deep sleep per son, around 10 pm. Shortly after that patient was having a hard time breathing. Emergency called. Arrested around the time EMS arrived. King airway, I/O and CPR initiated. Patient has been in v fib. Was shocked multiple times, given 4 rounds of epi, bicarb and amiodarone. ACLS continued on arrival. Multiple rounds of epi, and attempted defib. Patient given epi, bicarb. Rhythms included fine v fib, asystole, and PEA. Unrecoverable with no cardiac motion. Time of death 11:50 pm."	No prior vaccinations for this event.

DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line	No prior vaccinations for this event.

placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.

DYSPNOEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient arrived at ER with complaints of CPR in progress. Per EMS, patient became short of breath while performing yard work on 1/26/2021. At arrival, patient was in fine v fib with a total of 6 shocks delivered along with 300 mg amiodarone followed by 150 mg amiodarone, 1 amp epinephrine and 2 epinephrine drips adminstered en route to ED. CPR initiated at 1755 and EMS reports asystole at 1829. TOD 1909 pronounced by ED DO Dx: Cardiac arrest

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt began experiencing shortness of breath 3 days after vaccine and expired later that day.

No prior vaccinations for this event.

DYSPNOEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient has been under Hospice services for almost a year. She began to demonstrate a large amount of oral secretions on 1/10/21 at 2130. She was suctioned and a Rapid COVID-19 test was performed, which was negative. The COVID-19 Rapid test was repeated on 1/11/21 and was positive. Oxygen saturation was noted to be 78% on 1/12/21, and oxygen was initiated at 1133 at 3L per nasal cannula. Oxygen was increased to 4L at 1635 d/t shortness of breath. On 1/15/21 @ 0645 patient was unresponsive and without

No prior vaccinations for this event.

vital signs. Orders were for DNR and CPR was not initiated.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic #1. Patient tested positive for COVID-19 by rapid testing on 1/6/21. She demonstrated poor appetite and fluid/food intake and an IV of Normal Saline was initiated on 1/7/21. Oxygen saturation was initiated on 1/12/21 at 4L per nasal cannula. for shortness of breath. On 1/22/21 at 0310 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
family states seemed short of breath since after the covid vaccine. Staff said beginning on 1/22/21 the patient seemed sluggish, more tired, and nausea noted. She stayed in her room more after the vaccine because worried about giving/getting COVID to others. was talking on the phone at 11:30 PM on 1/26/21 to staff person about temperature of room. at 12:15 AM on 1/27/21 staff noted not breathing, started CPR and called EMS. When EMS arrived they stopped the code because she was too long deceased.		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Legs started swelling and shortness of breath Thursday January 21 2021 Was rushed to hospital with kidney failure and fluid build up around lungs and entire body Blood pressure dropped and had multiple		No prior vaccinations for this event.

organ failure

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
REC'D CALL FROM PT'S DAUGHTER, HER FATHER WAS VACCINATED ON 1/22/21, WOKE UP 1/23/21 WAS SHORT OF BREATH AND DIZZY. PT PRESENTED TO ED OF LOCAL HOSPITAL AND WAS ADMITTED, PT PASSED ON 1/25/21. DAUGHTER STATES THAT FAMILY AND DOCTORS AGREE THAT THE VACCINE DID NOT CONTRIBUTE TOWARDS PT'S DEATH, BUT FELT IT NEEDED TO BE REPORTED. PT'S DAUGHTER CONTACTED THIS RN AT LOCAL HEALTH DEPARTMENT TO REPORT TO VAERS.		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After being observed for approximately 20 minutes and patient walked to her car without assistance I was called to assess the patient in the parking lot for troubles breathing. EMS was called as I made my way outside. Upon my arrival patient was leaning out of the car and stating that she could not breath. She was able to tell me that she was allergic to penicillin. Oxygen was immediately placed on the patient with minimal relief. Lung sounds were coarse throughout. She then began to vomit about every 20-30 seconds. Epipen was administered in the right leg with no relief. Patient continued to complain of troubles breathing and vomiting. A second epipen was administered in the patients right arm again with no relief. A few minutes later patient was given racemic epinephrine through the oxygen mask. There appeared to be mild improvement in her breathing as she appeared more comfortable, but still complaining of shortness of breath and vomiting. When EMS arrived patient was unable to transport herself to the stretcher. When EMS and clinical staff transferred patient to the stretcher she became unresponsive. She appeared to still be breathing. She did not respond to verbal stimuli. Per ED report large amount of fluid was suctioned from the		No prior vaccinations for this event.

patients lungs following intubation in the ambulance. When patient arrived to the ED she was extubated and re-intubated without difficulty and further fluid was suctioned. At that time patient was found to be in PEA, shock was delivered. Shortly thereafter no cardiac activity was found and patient pronounced dead.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of the COVID-19 Moderna vaccine on 1/19/2021 at an outside facility (no lot #, route, or site available to me in electronic charting). Pt began having hypoxia, SOB, and a dusky appearance of extremities on 1/29/2021 and was brought by EMS to our hospital. PT is a DNR and family had been looking into a hospice sign up due to dementia and general decline in the weeks prior to hospitalization. Pt tested positive on admission for COVID-19 via PCR test on 1/29/2021. Pt continued to have respiratory decline, was put on comfort care per wishes of family/advanced directives, and he passed away the evening of 1/30.		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
According to medical report, Pt presented to the ED on 1/14/21 w/ cc of SOB for 1 day. She received her COVID-19 vaccine on 1/9/21. Pt stated that she developed a dry hacking cough 2 days prior to the vaccine on 1/7/21. Over the last few days prior to admission, she developed generalized weakness, SOB, loss of sense of taste and smell w/ associated decreased appetite and nausea ultimately SOB in the24 hours prior to admission. Final Diagnosis- acute hypoxic respiratory failure secondary to COVID-19 pneumonia. Pt died on 2/3/21. See Medical report for more information.		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH))**

view 2/5/2021 09:23 e Progress Note Note Text: Patient passed away in the facility this morning. view 2/5/2021 08:39 Orders - Administration Note Note Text: Resident passed. view 2/5/2021 08:33 Nurses Note Note Text: Body released to funeral home at this time. Personal effects sent with resident include: 1 pair of glasses, 1 yellow wedding band, 1silver spoon ring, 1 ring with black and clear stones. Resident has own teeth view 2/5/2021 08:32 Nurses Note Note Text: cause of death per CRNP failure to thrive. view 2/5/2021 07:44 Orders - Administration Note Note Text: Take and document temp & PO2 every 4 hours for MONITORING Resident passed. view 2/5/2021 06:49 Nurses Note Note Text: Son returned call and was updated of resident's passing this am view 2/5/2021 06:33 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Unknown Resident expired @ 0604 [linked] view 2/5/2021 06:06 Nurses Note Note Text: Res found without pulse or respirations. Pronounced at 0604. Updated. N/o's for RN to pronounce, release body to funeral home, dispose of medications per facility policy. Daughter updated. Funeral Home called to release body. view 2/5/2021 05:26 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Pulse ox 60% on O2 @ 5L/min via mask. Resps 44 per minute. view 2/5/2021 01:57 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/5/2021 00:52 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Residents resps are 40 per minute, pulse ox 76% on O2 @ 5L/min via mask. Resps are labored, shallow and rapid. view 2/5/2021 00:48 Nurses Note Note Text: Nonresponsive to verbal and tactile stimulation. Appears comfortable. view 2/4/2021 22:01 Nurses Note Note Text: Resident resting comfortably, breathing becoming increasingly shallow, wearing O2 via mask at 5L via mask, no dyspnea noted, feet are mottled, oral and peri care provided Q2H. No s/s of pain or discomfort. view 2/4/2021 21:40 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective [linked] view 2/4/2021 19:32 Orders -

No prior vaccinations for this event.

Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger medicated for air hunger, RR 28 to 32/ min view 2/4/2021 19:22 Nurses Note Note Text: Daughter updated on N/O to increase Morphine Sulfate 20mg/mL 0.25mL to Q2H prn from Q6H prn. view 2/4/2021 18:06 Nurses Note Note Text: POA Daughter and daughter aware of residents current condition. view 2/4/2021 11:58 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/4/2021 11:13 Nurses Note Note Text: Pt. noted to be lethargic at this time. Does respond to verbal and tactile stimuli by opening her eyes but non verbal currently. Skin warm and dry. No mottling or apnea observed at this time. O2 sat 88% with O2 at 2 LPM via n/c. On increased to 3 LPM via mask as pt. noted to be mouth breathing. Respirations 28. F/U O2 sat 93%. HOB elevated. Pt. medicated with morphine by LPN. Daughter updated on pt.'s condition. Does not want pt. sent out to hospital and would like comfort measures to continue. Daughter also in agreement with delay in d/c d/t pt.'s condition.CRNP updated on pt.'s condition, delay in d/c and daughter's wishes. No n/o's at this time. view 2/4/2021 10:56 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB Resident showing s/s of discomfort. SOB at this time and high respirations. Repositioned, changed for incontinence care and mouth care provided. view 2/4/2021 10:34 Progress Note Note Text: Spoke with RN regarding change in condition. Updated Sr Living regarding change. Recommendation to cancel d/c/transfer for today, see how resident does through the weekend and re-evaluate on Monday. Daughter updated on cancellation of d/c today. view 2/4/2021 10:04 Nurses Note Note Text: Daughter aware that resident's O2 sat was 88% on room air on 3-11 shift and that oxygen was applied via nasal cannula. view 2/4/2021 10:03 Nurses Note Note Text: N/O: Discharge 2/4/21 with scripts to Sr. Living. Daughter aware. view 2/4/2021 09:53 Nurses Note Note Text: Pt. to be d/c'd to another facility this am as per MD order. Pt. alert and responsive. Skin assessment done as per facility policy. No pressure areas noted at this time. No s/sx of pain or discomfort observed at this time. V.S. 97.0 67 20 O2 sat 95% with O2 at 2 LPM via n/c. view 2/4/2021 07:45 Nurses Note Note Text: Resident seen by Dr. for discharge. Orders pending at this time. view 2/4/2021 07:36 Nurses Note Note Text: CRNP and Dr. updated on O2 sat 88% on RA with f/u of 93% with O2 on at 2 LPM as well as rest of VS, 3-11 shift 2/3/21. No n/o's at this time. view 2/3/2021 21:17 Nurses Note Note Text:

Resident Sp02 88% on RA. Pulse 124. Respirations 40. PRN morphine given and O2 applied via NC at 2L/min. After recheck pulse ox up to 93%, pulse 100, and respirations 22. Resident appears comfortable at this time. view 2/3/2021 20:05 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective [linked] view 2/3/2021 19:48 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN given for SOB after elevation of HOB not effective. view 2/3/2021 11:51 Nurses Note Note Text: CRNP updated rapid COVID test done for d/c tomorrow was negative. No n/o's at this time. view 2/3/2021 11:44 Nurses Note Note Text: Daughter notified of rapid covid swab being negative. view 2/3/2021 09:50 Orders - Administration Note Note Text: Obtain Rapid Covid test on 2/3/2021 for discharge. Please give copy of results to Social Worker every day shift for covid testing for 1 Day Completed and negative. view 2/3/2021 08:45 Skilled Nursing Note Reason for skilled service: Therapy describe skilled service: Nursing, therapy assessment: V.S. 97.8 79 18 138/84 Orientation: Oriented to self only. Oxygen: O2 sat 94% on RA Edema: Trace edema noted BLE. Pedal pulses present. Pain: Denies pain or discomfort at this time. Nursing note: Pt. alert and responsive. Skin warm and dry. Lung sounds diminished. No respiratory distress observed at this time. Abdomen soft. BS+ in all 4 quads. Continent/Incontinent of B&B. 1 assist with ambulation, transfers. 1 assist with ADL's. Working with therapy on gait training, therapeutic exercise, therapeutic activities & neuromuscular reeducation. view 2/2/2021 14:37 Progress Note Note Text: Per health professional at Sr Living, prepared to accept patient to their Memory Care Unit 2/4. Transportation arranged for 11 AM per family request. Daughter (POA) updated on d/c time on 2/4/21. Facility requesting rapid COVID test completed prior to d/c and results sent to them. All other information sent for continuity of care.

DYSPNOEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Narrative: Patient with history advanced vascular dementia, hypertensive cerebrovascular disease and stroke, T2DM. Received her second dose of Pfizer COVID-19 vaccine at approximately 14:00 and was

No prior vaccinations for

reported to have expired at home at 20:55. Dr. (Medical Director) spoke with patient's son/caregiver 2/4/21. Son reports that patient was in her usual health yesterday morning, deemed well enough by son to travel for vaccination. He reports she had no bothersome symptoms after either first or second vaccinations. Specifically denied rash, wheeze, and difficulty breathing. Son was with patient throughout the day. In the evening, when preparing for bed, he noted she became suddenly unresponsive in a similar fashion as she has done several times in past years. While in all previous such episodes she recovered within minutes, last evening she did not regain consciousness, experiences a brief period of labored breathing, and died. Patient's son called 911 and the patient's body was brought to the medical examiners. The medical examiner declined to proceed with autopsy. Patient's son is not interested in autopsy. Patient's son reports confidence that his mother's underlying hypertensive/diabetic cardiovascular disease is the natural cause of her death. Other Relevant Hx: Symptoms: & Death Treatment:	this event.
DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The	No prior vaccinations for this event.

following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom only had site soreness after her covid vaccine on 1/21 which resolved within a couple days. However, she died in the early morning hours of 1/25, she was fine the day before, no sign of injury. We found her collapsed on the ground and although we tried cpr she was already dead. She had gone to the hospital on 12/28 for shortness of breath, angina and symptomatic anemia, her ekg was unchanged and blood work normal except for anemia. The cardiologist did not think a cardiac cath was needed. Her shortness of breath improved with a blood transfusion and a dose of lasix (no heart failure).		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client was administered the vaccine while symptomatic (01/25/21) although client did not know he was symptomatic for COVID-19. He had been exposed to a family member who had tested positive and should have been in quarantine but wasn't either because it was not felt he was considered a close contact by his family opinion or his family member never notified public health of this close contact...?. Clinet had presented to the ED following day after vaccination for shortness of breath and fatigue and an antigen test		No prior vaccinations for this event.

showed he was positive for COVID-19. He was sent home that same day 01/26/21. He was back in ED on 01/28/21 for worsening symptoms and admitted to hospital and later placed on ventilator. He passed away on 02/09/2021 (date of death was per his wife).

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is	No prior vaccinations for this event.

now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
For the two days prior to presentation the patient had been complaining of chest pain, his breathing seemed to be labored Monday. He and the family thought the pain was due to shingles as he carried this diagnosis from a month ago. Patient had also received the COVID vaccine 2 days prior to presentation and assumed	No prior vaccinations for this event.

he was feeling unwell due to the vaccine. Family wanted to take him to the hospital yesterday and earlier today but he refused. She left him in his home earlier this afternoon prior to presentation and returned to check on him finding him unresponsive and apneic at which time EMS was activated. #cardiac arrest -- suspect primary cardiac given collateral from family at home, consider hypoxemia which was corrected with advanced airway and 100% FiO2, patient clinically euvolemic and with soft brown stool in diaper not suggestive of GI hemorrhage, attempt to address acidosis with CPR and bicarbonate, not hypoglycemia, on bedside ultrasound FAST neg and no pericardial effusion suggestive of tamponade and +lung sliding bil not spontaneous pneumothorax Assessment/Diagnosis: -cardiac arrest, cause unspecified		
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The individual received the vaccine around 12:00pm on 02/11/21. Around 9pm the individual went to lay down on the couch at home and started to have difficulty breathing. Within 30 minutes the individual became week and unresponsive. She was transported to the hospital where she was pronounced deceased at 11:44 pm on 02/11/21.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was given the Pfizer vaccine on January 22, 2021, nausea and shortness of breath was taken to the Hospital on the 23rd of January and passed on the 24, 2021		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
She started having breathing problems/heart attack appearance. on 1/22/21 and went to the ER. Upon		No prior vaccinations for

admittance was told it was an anaphylactic shock from the Covid shot. They kept her in ICU and released her 1/23/21. At 12:45 am on 1/24/21 she passed out and we called the ambulance. Hospital admitted her and worked through multiple organ failure issues and thought her numbers were under control. She was released on 1/27/21 and was driving on 1/28/21 around 4:15 pm and appears to have had heart failure and had a wreck. She passed away that day.	this event.	
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer 1/22/2021. RNA+ 2/4/2021. S/S SOB, cough, confusion. COVID assoc. resp. failure, stage 4 lung cancer, COPD, HTN, former smoker. patient in hospice and died 2/10/2021.	No prior vaccinations for this event.	
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.	No prior vaccinations for this event.	
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Associate developed SOB on 2/12/21. Taken to Hospital on 2/13/21. Reported deceased 2/14/21.	No prior vaccinations for this event.
DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.	No prior vaccinations for this event.
DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation	No prior vaccinations for this event.

candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

SOB, DOE, oxygen desaturation, nausea. Ems transport to ER for eval No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Daughter of decedent reported that he quickly declined within 2 weeks of receiving vaccine and developed shortness of breath. Decedent received vaccine 1/30/2021 and died 2/15/2021. Only received first dose of series.	No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient received first dose of covid vaccine on 1/22/2021. Patient had no immediate reaction. Patient presented to the Emergency Department on 1/26/2021 c/o shortness of breath and chest pain. ECG showed a ST elevation myocardial infarction. Patient was treated and transferred to a cath lab where he died. Patient had significant coronary artery disease.	No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Grandmother had trouble breathing the night she got the vaccine. She went to the hospital. They found	No prior vaccinations for this

pneumonia and a partial bowel obstruction. The obstruction cleared but she died from the pneumonia on 2/16/21. event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches,	No prior vaccinations for this event.

diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on

10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death		
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient was not vaccinated at hospital. Caregiver reports that patient was vaccinated with second dose on Monday 2/15/21. Tuesday patient experienced n/v/d. Went to an ED on Wednesday and was cleared and sent home. Thursday reported shortness of breath to her caregiver and then collapsed. Patient was brought to as PEA arrest and ultimately died.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received the 2nd dose of the Covid vaccine approximately around 1105 by pharmacy through the		No prior vaccinations for

pharmacy LTC partnership vaccination program. Resident had no adverse effects until around 8:00 pm she began complaining of body aches, and chills, Tylenol was given at this time. Around 9:30pm resident was sleeping in bed. Around 12:00 am the CNA called nurse into room to assess resident as the resident stated she did not feel good. Temperature at that time was 102.2, and vomiting. RN came to assess @ 1220 am She was noted to be vomiting, diaphoretic, pale and having trouble breathing. Temp was 97.3 after vomting, Pulse 53, Resp 20, o2 sats were 40-45%, unable to obtain Blood pressure, Applied 5 L of oxygen at this time and had LPN call 911 immediately. Resident was repsonsive and able to follow staff members instructions but was only answering yes or no simple questions at the time time of assessment. Paramedics arrived at 0040 and resident was sent to Hospital. @ 0130 ER nurse called to nursing facility to notify resident had coded in the ER and passed away @ 0110.	this event.
DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had sore arm on the day of vaccination. Per patient's nephew , the next morning patient experienced body pains, aches, headache . Onn Tuesday patient had fever. Patient's condition progressively got worse. He had difficulty breathing by Wednesday night. He had low oxygen levels at 80 per pulse ox reading. Patient was coughing up blood. Family took him to hospital on Thursday morning due to breathing difficulty and patient died 2.18.21 at 10 am	No prior vaccinations for this event.
DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1)	No prior vaccinations for this event.

Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.

DYSPNOEA	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21- N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm	No prior vaccinations for this event.

and noted she was not breathing. Supervisor called and pronounced resident deceased.

DYSPNOEA	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.	No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
02/07/21 through 2/13/21 slightly fatiqued, took all his prescribed medications, ate breakfast, lunch and dinner was drinking eight 10 oz bottles of water. On 02/14/21 was very tired had a difficult time breathing after taking the normal meds. He took a breathing treatment with his prescribed Ipratropium Bromide and Albuterol Sulfate via home nebulizer. This did not improve his breathing. He was very weak and breathing was labored. 911 was called by wife. 911EMTchecked pulse and breathing. Informed him they would give him a breathing treatment.He started to go limp. EMT's got him to Ambulance and to Medical Center to the ER. Heroics done. He died. Pulmonary and Cardiac Arrest		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident is a Hospice patient. On 1-23-2021 am shift resident was observed by nursing have chest congestion and had a emesis times 1 with SOB, Zofran 4 mg was given. HOB (02 sats 88%) was elevated resident on 02 via nasal canula with 02 sat now @ 90% . no respiratory distress noted. MD was called with response pending for orders. @ 1400 resident with no signs of life. vs 90%-24-97/71-97.6. Hospice on site and time of death 1436		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist		No prior vaccinations for this event.

and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice, memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200 mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation: tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed, metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of

breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral patchy opacities

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Extreme difficulty breathing upon exertion, collapsed shortly after walking started, loss of conciousness, and death		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Elevated heart rate, flushing of the face and ears, vomiting, trouble breathing, pulmonary edema		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Shortness of breath - related to chronic comorbidities		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient reported to emergency room on 2/20 with increasing of shortness of breath, quantitated		No prior vaccinations for this

unable to walk from room to room in his house. Patient was admitted.		event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pale, Short of Breath, Hypoxic, Lethargic within minutes became unresponsive and died.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.		No prior vaccinations for this event.
	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197,		No prior vaccinations for this event.

creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

DYSPNOEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on

No prior vaccinations for this event.

2/19/21.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On the evening of 2/23/221 at 9:00 pm, resident reported feeling SOB, BP 80/44, Pulse 53, O2Sat 95% on 3L oxygen, hands cold, pulse weak. Temp 92.5F MD notified. EMS activated. EMS arrival and HR 20. Family refused transport to ER. Resident expired at 2:40 am on 2/24/21 Meds continued: duloextine, VITd2,hydralazine, synthroid, lisinopril, mag ox, folplex, pantoprazole, potassium chloride, ellipta, ensure, hydrocortisone cream, boost, deprox, xanax, morphine, lorazepam, tylenol, albuterol inhlation, ventolin inh.		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/21 - Resident complained of SOB. SPO2 66% on RA, vs 105/66-96-20 T98.2 O2 administered Pox 97% Binax test revealed (+) COVID results. Resident transferred to COVID wing. Family (HCP) updated and declined transfer to hospital Resident continued with fever, hypoxia and lethargy. Family elected CMO and Hospice notified. Resident died on 1/16/2021 @ 930AM.		No prior vaccinations for this event.

	DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per Patients Wife - Same day - Flu like symptoms, Nausea, Headache. Restless that night. Next day - Weak, shortness of breath. Wife called squad to get him out of his wheelchair but patient refused hospital as it gets him agitated. Patient passed away around 11 AM the day after vaccination.		No prior vaccinations for this event.

DYSPNOEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.	
DYSPNOEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt received 2nd Pfizer BioNTech Covid 19 EUA vaccine @1:50 pm; Pt released from Observation @2:09 pm. Approximately 2:18 pm RN called to parking lot and observed pt having difficulties. Called for EMS & crash cart. Vitals taken 2:20 BP 83/55, no respirations noted, pt unresponsive. AED attached. EMS arrived 2:22 and took over care of pt. and transported @2:40 pm to Hospital. Per wife, pt has history of PE in Oct. 2020, HTN, diabetes with insulin pump, obesity, gastroparesis, home oxygen and uses motorized scooter. Wife also said pt had allergy to iodine not previously reported, and MD had stopped Zarelto subsequent to 1st Pfizer vaccine 2/8/21 ""due to breathing difficulty"". Patient was unable to be resuscitated. Time of death 14:59."	No prior vaccinations for this event.	
DYSPNOEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated approx 9a. Later that evening, patient was having trouble breathing so they called son who lives down the road to come, 20 mins after the call the patient has passed. Per medical examiner, pt died due to possible PE, MI, or his aortic aneurysm ruptured.	No prior vaccinations for this event.	
DYSPNOEA		**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
within 24 hours after her second injection she developed chills, had a syncopal episode and had, difficulty breathing. this progressed over the next day when she had a second syncopal episode and her dyspnea and confusion worsened EMT was called and she was brought to the hospital. she was in flash pulmonary edema and with her history of severe aortic stenosis she was admitted to the cardiac icu. she had no prior history up to that time of pulmonary edema and was functioning without distress in her home. she had a history of covid in early april, manifesting primarily as severe confusion, from which she recovered.	No prior vaccinations for this event.
DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Presented to ED via EMS c/o increasing shortness of breath, O2 sat mid to high 80s on 4L. When EMS arrived , pt was in distress, intubated by EMS and transported to ED. Pt had a PEA arrest en route but resuscitated w/ return of spontaneous circulation after receiving a dose of epinephrine and chest compressions. Pt was hypotensive on arrival to ED. He was started on sepsis protocol , volume resuscitation and empiric antibiotics. Once stabilized, he was admitted to icu at hospital. Removed from respirator 2/22/21	No prior vaccinations for this event.
DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Pt he reports he developed chills SOB body aches the same night as receiving the COVID vaccine on 1.26.2021-pt is currently reporting CheSt tightness and SOB Admitted to hosp: ICU with Bilateral Pulmonary Emboli, LLE DVT, NSTEMI, Arrhythmia.	No prior vaccinations for this event.

DYSPNOEA	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent	No prior vaccinations for this event.

plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

DYSPNOEA

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Patient hospitalized with shortness of breath and pneumonia (from 2/15/2021 to 2/21/2021) and patient died at another facility on 3/2/2021.	No prior vaccinations for this event.
DYSPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The same day that the person was vaccinated he started feeling dizzy and had difficulty breathing. He was hospitalized from February 5 to February 23. Patient died in the hospital on February 23, 2021	No prior vaccinations for this event.
DYSPNOEA	**COVID19 (COVID19 (UNKNOWN)) (1202)**
Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2 diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated) then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and was intubated. Transported to hospital. SARS CoV-2 and influenza negative.	No prior vaccinations for this event.
DYSPNOEA	**COVID19 (COVID19 (UNKNOWN)) (1202)**
Received first SARS-CoV2 vaccination yesterday at local store Experienced new symptoms of chills, nausea as well as worsening from baseline dyspnea at night. Wife states he had rough morning breathing and had sudden loss of consciousness and unresponsiveness and failed to respond to bystander CPR. He expired at	No prior vaccinations for this event.

his home.

	DYSPNOEA AT REST	**COVID19 (COVID19 (MODERNA)) (1201)**
ON 02/08/2021 AROUND 0600 RESIDENTCOMPLAINED OF MOUTH PAIN AND RECEIVED OXYCODONE. DURING THE COURSE OF THE MORNING, RESIDENT EXHIBITED A FEW EPISODES OF LABORED/SHALLOW BREATHING AND SOB AT RESTING. 0XYGEN SATURATION RATE WAS 93-98% ON ROOM AIR, LUNG SOUNDS CLEAR IN ALL LOBES AND PULSE AND TEMPERATURE WITHIN NORMAL RANGE. AS THE DAY PROGRESSED, VITAL SIGNS REMAINED STABLE BUT RESIDENT CONTINUED TO HAVE PERIODS OF SOB/LABORED BREATHING.FAMILY AND NURSE PRACTIONER UPDATED AND THE ORDER WAS RECEIVED TO SEND PATIENT TO MEDICAL CENTER ER FOR EVALUATION PER AMBULANCE. RESIDENT TRANSPORTED AT 1425. RESIDENT RETURNED FROM THE ER AT 1830 ON HOSPICE CARE WITH THE DIAGNOSIS OF: ACURE RESPIRATORY FAILURE WITH HYPOXIA AND END OF LIFE DECISION MAKING. RESIDENT WAS MADE COMFORTABLE AND MONITORED DURING THE NIGHT AND EXPIRED AT 0630 ON 02/09/2021.		No prior vaccinations for this event.
	DYSPNOEA EXERTIONAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Within a few days, my mother started reporting profound fatigue and shortness of breath while conducting routine household activities. She no longer had to energy for her daily exercise walks and became increasingly lethargic. She died in her sleep while taking an afternoon nap on Thursday, February 4th. I am highly concerned this could be a vaccine related.		No prior vaccinations for this event.
	DYSPNOEA EXERTIONAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Admitted to hospital with sob upon exertion that started prior to vaccine. Hx COPD, HTN, CKD,		No prior vaccinations for

hyperlipidemia, bladder cancer in remission. Stated he has been taking Eliquis and Xarelto between renal doctor and cardiologist Dr. Anticipating going home 2/5/21 but then turned blue and stopped breathing under a DNR. COVID test negative. Labs show acute on chronic renal failure with an elevated troponin likely from demand ischemia.		this event.
	DYSPNOEA EXERTIONAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began to demonstrate a cough the evening of 1/5/2021, after receiving the COVID-19 vaccine earlier in the afternoon. A rapid COVID-19 test was performed and was positive. She began to demonstrate shortness of breath with exertion on 1/7/21, and lethargy on 1/12/21. Appetite and oral intake began to decline on 1/12/21, and Oxygen saturation dropped on 1/16/21 to 82%, and oxygen was initiated at 3L per nasal cannula. On 1/19/21 at 0414 patient was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.		No prior vaccinations for this event.
	DYSPNOEA EXERTIONAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21		No prior vaccinations for this event.

DYSPNOEA EXERTIONAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

SOB, DOE, oxygen desaturation, nausea. Ems transport to ER for eval No prior vaccinations for this event.

DYSSTASIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

The vaccine was given on Monday. Tuesday afternoon he developed weakness in both legs and could not stand up. This was a new development; he had neuropathy in one leg but he had been able to stand up and walk three hours before. He was helped to the bathroom. He said he felt better and might want to stand up again. He was helped to bed. He was found dead around 5:30 Wednesday morning. He was 94 years old and had a lot of medical conditions. No one has indicated his death had anything to do with the vaccine. I'm sure it's just a coincidence that he died so soon after receiving the vaccine

No prior vaccinations for this event.

DYSSTASIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Extreme Fatigue, slurring speech, unable to stand, eat. Death on 2/5/21 No prior vaccinations for this event.

DYSURIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and

No prior vaccinations for this event.

targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of

the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

EAR HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
EATING DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient with failure to thrive symptoms prior to 2nd dose, not eating, not taking medications.	No prior vaccinations for this event.
ECCHYMOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident returned to the memory support unit at 1500. Resident was than toileted and transferred in to bed per his request. At 1515 resident was observed face down beside bed, resident sustained a 1inX1in eccyhmotic/hematoma to the forehead. Neuro Checks with in normal limes Vital signs: 100/52, 100, 97.2, 28. Resident sent to ED for further medical evaluation via EMS.	No prior vaccinations for this event.
ECHOCARDIOGRAM	**COVID19 (COVID19 (MODERNA)) (1201)**

"Possible heart attack on 2/5/21. Complaint: "" On Feb 5th I believe I experienced a mild hear attack"" (Comment: He said he felt ""clammy, sweaty, excruciating pain on my left side - including his left arm, and left leg, dizzy, exhausted."" This happened after work, and after taking a shower. He said that was the first time he's experienced it, and that it has not happened since then. He said he has constant headaches, ""It just went away yesterday.""""	No prior vaccinations for this event.
ECHOCARDIOGRAM	**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation	No prior vaccinations for this event.
ECHOCARDIOGRAM	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note	No prior vaccinations for this event.

second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse

ECHOCARDIOGRAM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient woke up on the morning of 2/6 with symptoms of a stroke. Rushed to hospital where clot found in brain. Recovered from initial stroke but then had another major stroke on 2/8 and never recovered.	No prior vaccinations for this event.

ECHOCARDIOGRAM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
within 24 hours after her second injection she developed chills, had a syncopal episode and had, difficulty breathing. this progressed over the next day when she had a second syncopal episode and her dyspnea and confusion worsened EMT was called and she was brought to the hospital. she was in flash pulmonary edema and with her history of severe aortic stenosis she was admitted to the cardiac icu. she had no prior history up to that time of pulmonary edema and was functioning without distress in her home. she had a history of covid in early april, manifesting primarily as severe confusion, from which she recovered.	No prior vaccinations for this event.

ECHOCARDIOGRAM ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar	No prior vaccinations for this event.

level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.

ECHOCARDIOGRAM ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
ECHOCARDIOGRAM ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	No prior vaccinations for this event.
ECHOCARDIOGRAM ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
This is a 94-year-old male who is brought in by ambulance after being found on the floor with unknown	No prior vaccinations for

downtime. He was in asystole upon EMS arrival. He remains in asystole. No advanced airway is in place. The patient is getting compressions from Lucas device upon arrival. It was reported that he was last talked to by family at 2 PM. The patient got his SARS-CoV-2 vaccination this morning. The patient is evaluated emergently. CPR was ongoing with 3 rounds of epinephrine given. The patient remains in asystole. He has rigor mortis. The patient's pupils are fixed and dilated. The patient has compressions paused and ultrasound is used to evaluate for cardiac activity. None is detected. The patient has no electrical activity on monitor. The patient's time of death is 2113.	this event.
ECHOCARDIOGRAM ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.	No prior vaccinations for this event.
EGFR GENE MUTATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.	
EJECTION FRACTION DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.	No prior vaccinations for this event.	
EJECTION FRACTION DECREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	No prior vaccinations for this event.	

EJECTION FRACTION DECREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.		No prior vaccinations for this event.
ELECTROCARDIOGRAM		**COVID19 (COVID19 (MODERNA)) (1201)**
Presented to Urgent Care for weakness and confusion, transferred to ED, patient had a cardiac arrest and was unable to be resuscitated		No prior vaccinations for this event.
ELECTROCARDIOGRAM		**COVID19 (COVID19 (MODERNA)) (1201)**
"Was given vaccine around 1:30Pm on 2-11-2021. He and his wife waited in the building for 15 minutes and then left. he denied complaint. (He was waiting to have both Covid shots before he went to cardiologist Re: CAD.) He had an alarm going off in his house, was going to basement to check it out. Police officer heard alarm, came into house, & heard a thud when Doc fell. He was in PEA (Pulseless Electrical Activity) when		No prior vaccinations for this event.

brought into ER. Given 5 ""rounds of Epinephrine with no response."		
	ELECTROCARDIOGRAM	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).		No prior vaccinations for this event.
	ELECTROCARDIOGRAM	**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation		No prior vaccinations for this event.
	ELECTROCARDIOGRAM	**COVID19 (COVID19 (MODERNA)) (1201)**
Blood pressure went down until he died; Couldn't hear his heartbeat; neck was sweating; He was cold; Couldn't get up; Death; Sick; immediately very tired; he was tired; Hands were shaking; Slept for too long; A		No prior vaccinations for

spontaneous report was received on 18 Feb 2021 from a consumer concerning a 81-years-old, male patient who received Moderna's COVID-19 vaccine and developed immediately very tired, hands were shaking, neck was sweating, was cold, sick, couldn't get up, couldn't hear his heartbeat and blood pressure went down until he died. Patients' medical history, as provided by patient's spouse, was emergency room(ER) admission in November 2020 because he had a congested chest (he had fluid around his heart). At that time, they gave him pills for kidney function. Other concomitant medication reported was Coumadin, blood thinner. Two weeks before receiving the vaccine, patient's EKG was normal. On 11 Feb 2021, in the morning, patient received their first of two planned doses of mRNA-1273(BATCH/LOT # 007M20A) probably in the right arm for the prophylaxis of COVID-19 infection. On 11 Feb 2021, approximately after 15 minutes of receiving vaccine, they left and patient was immediately very tired, his hands were shaking. So, patient's spouse made them down sleep for too long. On Friday, 12 Feb 2021 she tried to pick him up, but he was tired, exhausted, and sick. On Saturday, 13 Feb 2021, she brought him a coffee and he couldn't hold it because his hands were shaking, so she gave him the coffee and then made him pee on the bed because he couldn't get up. At lunch time she made him eat something and he fell sleep again. His wife was hanging around him all day and around 7:30pm she realized that he was cold, and his neck was sweating, she couldn't hear his heartbeat. So, she called emergency services and when they arrived, her husband's blood pressure went down until he died. Treatment for the events were not provided. Action taken with mRNA-1273 was not applicable. Patient was pronounced dead on 13 Feb 2021 20:00. The cause of death was not provided. The plans for an autopsy were not provided. The events of blood pressure went down until he died and couldn't hear his heartbeat were fatal. The outcome for the remaining events were unknown.; Reporter's Comments: This case concerns an 81 year old, male patient, who experienced a serious event of death among others, 2 days after receiving mRNA- 1273 (Lot# 007M20A). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death this event.

ELECTROCARDIOGRAM

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
1/28/2021- Seen by FNP for indigestion, chest pressure and palpitations. EKG reviewed and referral made to Cardiology. 1/29/2021-1800 Presented to ED in cardiac arrest-onset PTA. Patient was found unresponsive by his wife at their home. The last known well was at 1530 when she called him on the phone. The patient was pronounced at ~1850.	No prior vaccinations for this event.
ELECTROCARDIOGRAM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom only had site soreness after her covid vaccine on 1/21 which resolved within a couple days. However, she died in the early morning hours of 1/25, she was fine the day before, no sign of injury. We found her collapsed on the ground and although we tried cpr she was already dead. She had gone to the hospital on 12/28 for shortness of breath, angina and symptomatic anemia, her ekg was unchanged and blood work normal except for anemia. The cardiologist did not think a cardiac cath was needed. Her shortness of breath improved with a blood transfusion and a dose of lasix (no heart failure).	No prior vaccinations for this event.
ELECTROCARDIOGRAM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from	No prior vaccinations for this event.

nursing home staff report.

	ELECTROCARDIOGRAM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.		No prior vaccinations for this event.
	ELECTROCARDIOGRAM	**COVID19 (COVID19**

(PFIZER-BIONTECH))
(1200)

1. Fatigue ? day 1 - Tuesday 2. Loss of appetite ? day 1 Tuesday 3. Fever 102.0 ? day 2 - Wednesday 4. Chills ? day 2 - - Wednesday 5. Weak ? day 2 - - Wednesday 6. Non-ambulatory (unusual) ? day 2 - - Wednesday 7. Two emergency service ambulance assessment ? day 2 - - Wednesday 8. Symptoms improved ? day 3 - Thursday 9. Ambulatory - day 3 - Thursday 10. Symptoms worsened ? day 4 - Friday 11. Chills ? day 4 - Friday 12. Non-ambulatory again ? day 4 - Friday 13. Fever 102.0 ? day 4 - Friday 14. Left side flank pain ? day 4 - Friday 15. CPR and declared decease at home by paramedics - day 5 - Saturday morning @ 1:32am

No prior vaccinations for this event.

ELECTROCARDIOGRAM ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Found dead at home slumped on the floor; Loss of appetite; Body aches; Feverish; A spontaneous report was received from a physician, concerning a 65-years-old male patient, who received Moderna's COVID-19 Vaccine and experienced feverish, body aches, loss of appetite, and death. The patient's medical history, as provided by the reporter, included diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia. Concomitant medications reported included metformin, glimepiride, lisinopril, atorvastatin, aspirin, methimazole, propranolol, and cilostazol. On 05 Jan 2021, prior to the onset of events, the patient received the first of two planned doses of mRNA-1273 (lot number 037k20a) for COVID-19 infection prophylaxis. On an unknown date in Jan 2021, some time after receiving the vaccine, the patient was feeling feverish with body aches and loss of appetite. On 09 Jan 2021 at approximately 21:30, the patient was found dead at home slumped on the floor. According to the paramedics, the patient was dead longer than when his wife found him, and no resuscitation was performed. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events, feverish, body aches, loss of appetite, was considered resolved. The patient died on 09 Jan 2021. The cause of death was not reported. The reporter assessed the event, death, as not related to Moderna's COVID-19 Vaccine. The reporter did not provide assessment for the events, feverish and body aches, in relation to

No prior vaccinations for this event.

Moderna's COVID-19 Vaccine.; Reporter's Comments: This case concerns a 65 year old male patient with medical history of diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia, who experienced the serious unexpected event of death, non-serious unexpected event of loss of appetite, and non-serious expected events of fever and body pain. The event of death occurred 5 days after the first dose of mRNA-1273. The events of fever, body pain and loss of appetite occurred an unspecified period of time after the first dose of mRNA-1273. Very limited information regarding these events has been provided at this time. Based on temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Definitive causal association is confounded by age and medical history of diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia.	
ELECTROCARDIOGRAM ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29	No prior vaccinations for this event.
ELECTROCARDIOGRAM ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at	No prior vaccinations for this event.

bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

ELECTROCARDIOGRAM ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

No prior vaccinations for this event.

ELECTROCARDIOGRAM ABNORMAL

COVID19 (COVID19

	(PFIZER-BIONTECH)) (1200)
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.	No prior vaccinations for this event.
ELECTROCARDIOGRAM ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia	No prior vaccinations for this event.
ELECTROCARDIOGRAM ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)

No prior vaccinations for this event.

ELECTROCARDIOGRAM ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2

No prior vaccinations for this event.

remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

ELECTROCARDIOGRAM CHANGE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."	No prior vaccinations for this event.

ELECTROCARDIOGRAM NORMAL	COVID19 (COVID19 (MODERNA)) (1201)
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.

	ELECTROCARDIOGRAM NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation		No prior vaccinations for this event.
	ELECTROCARDIOGRAM NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.		No prior vaccinations for this event.
	ELECTROCARDIOGRAM NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had		No prior vaccinations for this event.

a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days

prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

ELECTROCARDIOGRAM QRS COMPLEX ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 1/9/2021 observed with elevated respirations of 38-42 per minute, BP manually 72/50. pulse is jumping rapidly between 110-16 bpm. oxygen sat 76% RA, resident refusing oxygen at first attempt, allowed oxygen to be placed, is now 84% on 4L. resident shaking head yes that he is hurting, and yes that he would take medication for pain. Dr. notified, branch block. Received order for morphine 2mg per hr as needed for elevated respirations and pain. Dr. also gave orders to D/C Tamsulosin and finasteride. Resident continue with decreased O2 sats and elevated respirations. Absence of vital signs on 1/10/21 at 826PM.

No prior vaccinations for this event.

ELECTROCARDIOGRAM QT PROLONGED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

No prior vaccinations for this event.

ELECTROCARDIOGRAM ST SEGMENT ELEVATION

COVID19 (COVID19 (MODERNA)) (1201)

CARDIAC ARREST, DEATH Narrative: The patient presents to the emergency department in cardiopulmonary arrest. CPR was continued upon arrival. The Combi tube was removed and an endotracheal tube was placed without complications. ROSC was obtained multiple times but the patient continued to go into PEA. The patient was seen in the emergency department by both critical care and Cardiology. EKG shows ST elevations, but the patient was unstable to go to catheterization. The patient had

No prior vaccinations for this event.

1 episode of asystole. Despite best efforts and multiple attempts we were unable to resuscitate the patient. Time of death 1253 on 1/24/21.		
	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of covid vaccine on 1/22/2021. Patient had no immediate reaction. Patient presented to the Emergency Department on 1/26/2021 c/o shortness of breath and chest pain. ECG showed a ST elevation myocardial infarction. Patient was treated and transferred to a cath lab where he died. Patient had significant coronary artery disease.		No prior vaccinations for this event.
	ELECTROENCEPHALOGRAM ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."		No prior vaccinations for this event.
	ELECTROMYOGRAM ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first		No prior vaccinations for

COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.

this event.

ELECTROMYOGRAM ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.

Influenza Vaccine

EMBOLIC CEREBELLAR INFARCTION

COVID19 (COVID19 (MODERNA)) (1201)

"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with

No prior vaccinations for this event.

the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

EMBOLIC CEREBRAL INFARCTION

COVID19 (COVID19 (MODERNA)) (1201)

"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal

No prior vaccinations for this event.

abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

EMOTIONAL DISTRESS		**COVID19 (COVID19 (MODERNA)) (1201)**
1-25-2021- Phone call: pt had cold and cough prior to vaccine. cough worsened 1-28-2021 Phone call: pt requesting provider visit, cough is same and taking tessalon pearls 1-29-2021 Provider in office visit: pt complain of cough and SOB for 6 days. Getting worse. Temp 101.2, pulse ox 87%, BP 128/70. level of distress- leaning forward to breath. appeared ill. diffuse rales throughout both lung fields, more at bases. Diagnosis Pneumonia due to COVID 19 virus. Sent to ER		No prior vaccinations for this event.
EMPHYSEMA		**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.
EMPHYSEMA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt		No prior vaccinations for

was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.		this event.
	EMPHYSEMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise.		No prior vaccinations for this event.

Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

ENCEPHALITIS	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	No prior vaccinations for this event.
ENCEPHALOPATHY	**COVID19 (COVID19 (MODERNA)) (1201)**
Sudden death 2/7/21 @ 0309 Started acute encephalopathy & required intubation Soon after intubation went into cardiac arrest Likely severe acidosis.	No prior vaccinations for this event.
END STAGE RENAL DISEASE	**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccination at 14:20 2/26/21. Was observed until discharged at 15:15. Discharged per wheel chair to lobby in alert/stable condition, to wait on bus to take him home. At 18:00 his neighbor heard him fall, could not get patient to answer phone, found him unresponsive. Neighbor called 9-1-1, ambulance	No prior vaccinations for this event.

personnel could not revive patient. Coroner's office ruled his death as Natural Causes due to Hypertension, Cardiac disease, Diabetes, ESRD. There were no indication of anaphylactic reaction noted when I questioned the coroner's office. The Coroner's office/EMS were aware the patient had received the Moderna COVID 19 vaccination that day.		
	END STAGE RENAL DISEASE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident did not exhibit any side effects from the vaccine. Staff spoke with him in his room at approximately 7:20am and returned to his room just a few minutes later and he was unresponsive. When the RN got to the room he had CTB. Physician documented heart failure and end stage kidney disease on the death certificate.		No prior vaccinations for this event.
	ENDOSCOPY UPPER GASTROINTESTINAL TRACT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death ""cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its components or a severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed. MDs recommending		No prior vaccinations for this event.

hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative status. 1/29 Pt passed away."

ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient vaccinated on 12/28. Approximately one day later, develops cough and on azithromycin x 1 week. On 1/3, patient develops left-sided weakness and aphasia. Taken to the hospital, tested COVID+, required intubation -- acute hypoxic respiratory failure secondary to COVID - on H&P. Patient died on 1/4/21 at 7:20am.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Fever Feeling tired short of breath all night and morning after the vaccine My grandma had to be intubated and then passed away to a heart distress we think it was the vaccine because she was fine even with dialysis. When she got the vaccine it took hours and her health conditions changed.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram	No prior vaccinations for this event.

positive cocci in clusters growing after 9 hours.

ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to the Emergency Department complaining of chest pain, pale, cool diaphoretic, and hypotensive. The patient was discovered to have a large saddle pulmonary embolism, went into cardiac arrest and expired. Of note, the patient received her second Moderna COVID vaccine on 1/23, which would place her first one approximately 12/25 if she received them at the appropriate interval. This information is from the patient's daughter and the ED record, the information is not available in CAIR. Per the daughter, the patient started feeling ill on 1/21, improved on 1/25, and then acutely worsened on 1/27, resulting in the ED visit.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
36 hours after vaccination, the patient had increased respiratory distress. He was placed on high flow nasal cannula oxygen with mild improvement. He then continued to be hypotensive requiring IV fluids and subsequently IV vasopressors. Patient's BP was stabilized with vasopresor, however he continued to deteriorate clinically with altered mental status and lethargy, concerned for bowel peroration based on physical exam by MD. He was then emergency intubated and placed on mechanical ventilation. He was then transferred to acute care hospital near by.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presented to ER via EMS at 1556 3 days after receiving vaccine. pt was breathing approximately 50 times a minutes and o2 sats in the 70's upon arrival. NP decided to intubate, Rocuronium and Versed given. Pt became bradycardic and 1 amp of Atropine was given without improvement. No pulse felt, CPR started per ACLS protocol. 7 Epi's given. Time of death- 1632. After TOD pt was swabbed for COVID-19 and the results	No prior vaccinations for this event.

were positive.

	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.
	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident c/o nausea evening of 1/29 (nausea common for her post dialysis), had a large emesis at approx 2220, 0030 (unusual for resident to vomit)- received Zofran per order. Skin cool and damp, Blood sugar 147 (checked due to h/o diabetes and poor intake). At approx 230am Blood pressured checked and noted to be 52/29. Resident transferred to ER, intubated and transferred to higher level of care where she passed away on 1/30 at 736pm. Resident's medical notes indicated likely shock, cardiogenic in nature, sepsis (source unknown) along with a multitude of other co-morbidities that resident has.		No prior vaccinations for this event.
	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident passed away unexpectedly on 01/19/21 after developing acute hypoxic respiratory failure on morning of 01/19/21. She was transferred to hospital via EMS where she was intubated, coded, and ultimately expired with uncertain underlying cause, potentially ACS.		No prior vaccinations for this event.

ENDOTRACHEAL INTUBATION		**COVID19 (COVID19 (MODERNA)) (1201)**
CARDIAC ARREST, DEATH Narrative: The patient presents to the emergency department in cardiopulmonary arrest. CPR was continued upon arrival. The Combi tube was removed and an endotracheal tube was placed without complications. ROSC was obtained multiple times but the patient continued to go into PEA. The patient was seen in the emergency department by both critical care and Cardiology. EKG shows ST elevations, but the patient was unstable to go to catheterization. The patient had 1 episode of asystole. Despite best efforts and multiple attempts we were unable to resuscitate the patient. Time of death 1253 on 1/24/21.		No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Moderna Vaccine Lot 029K20A Patient received second dose of vaccine on 2/2/21. Within 30 minutes patient had a near syncopal episode. She felt lightheaded and shortly after had episode of nonbloody vomiting. Hypotensive 81/69 and started on levophed. Alert and orientated. Lungs clear, abdomen benign on admission. Patient had no reaction when received first dose of the vaccine. Patient developed worsening shortness of breath, tachypnea, Afib with RVR, hypotension and required intubation and multiple pressors.		No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Sudden death 2/7/21 @ 0309 Started acute encephalopathy & required intubation Soon after intubation went into cardiac arrest Likely severe acidosis.		No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION		**COVID19 (COVID19 (MODERNA)) (1201)**

Patient was vaccinated on 1/14/2021. On 1/22/2021, patient tested positive for COVID-19 and admitted to the hospital for acute hypoxemic respiratory failure, COVID-19 pneumonia, and severe ARDS. Patient was intubated on 1/23/2021 and later died on 2/10/2021 after being extubated and placed on comfort measures.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine given in clinic per protocol - patient monitored for 15 minutes, no adverse reactions noted at the time. Patient stated he felt fine following 15 minute monitoring time. Patient left facility- it was later reported that pt had a fall at home. Upon review of pt's medical record - Pt's wife had to initiate CPR and call EMS for transportation and life saving measures enroute to the Emergency Room. Pt was intubated as pt was in asystole upon arrival to the ER, ACLS was continued, pt was noted to have a traumatic brain injury from his fall at home, and pt was pronounced dead at 1620.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient passed away on 2/2/21 after being admitted on 1/31/21 after receiving COVID19 Moderna Vaccine on 1/26/21. On initial report to the hospital patient reported having a cough for over 2 weeks (starting approx. 1/17/21). He had a postive COVID19 PCR on 1/31/21. Intubated on 1/31/21 and passed away on 2/2/21	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Per EMS/Hospital report patient had difficulty breathing and cardiac arrest with prolonged CPR (greater than 45 mins in the ER) who was resuscitated. Family subsequently arrived including son and daughter and all family members were in the ER room are in agreement that patient would not want further aggressive cares given her extremely poor prognosis in light of chronic debilitation with numerous medical issues and now a very long period of CPR. Hospital Course After updating family they stated patient would not want further	No prior vaccinations for this event.

aggressive cares given her grim prognosis and chronic severe and debilitating medical issues. She continued to have myoclonic jerking. She was extubated to comfort cares in the ER and did not pass immediately therefore brought to a room. She received comfort cares and passed away at 0450 with family present.

	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.		No prior vaccinations for this event.

	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient experienced an episode of emesis and loss of consciousness several hours after vaccine on 2/16/21. He was taken by EMS to the hospital and was noted to be hypoxic and hypotensive. He was admitted to the hospital and subsequently intubated. He was also found to have a small bowel obstruction and a nasogastric tube was placed to decompress the bowel. He required pressor support as well. He expired on 2/17/21.		No prior vaccinations for this event.

	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
"My grandpa had a stroke on the 15th of February. He claimed he had been feeling ""off"" for a few days, but didn't say anything. A blood clot had formed in his brain. He was doing better and about to go to rehab to		No prior vaccinations

strength his right side of his body. On the 22nd he took a turn for the worst. He was having trouble breathing and they sedated and partially paralyzed him to put a tube in his mouth. I believe another blood clot had formed and oxygen wasn't properly going through his body. They could not stabilize him, and he passed away the same day."	for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was transferred from hospital for further evaluation and care by pulmonologist. He started having symptoms a week before with fatigue, emesis, decreased p.o. intake, shortness of breath, vomiting and diarrhea. The two previous takes before death required increasing oxygen and family wanted everything done including intubation. He was transferred to ICU.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
92 yo female who received her first dose of Moderna vaccine on 1/11/2021 with no known adverse effects. Admitted to the hospital on 1/17/21 with a spine compression fracture. Discharged and readmitted on 1/19 /21 with nausea and vomiting. Found to have new atrial flutter and elevated troponin attributed to NSTEMI. Discharge on Aspirin and Plavix. No cath. Second dose of Moderna vaccine 2/25/21. No immediate reaction. One hour later began to feel progressively weak. EMS called shortly after getting home. Intubated in the field. Died at 0658 on 2/26/21 s/p PEA arrest without ROSC.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Death Narrative: Family was able to be present at bedside shortly after patient was extubated. Fentanyl bolus given 10-15 minutes prior. Patient passed away soon after endotracheal tube removed. Time of	No prior vaccinations for this event.

death 10:14am.

	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.		No prior vaccinations for this event.

	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - anuerism lead to death approximately 14 hours after initial symptoms.		No prior vaccinations for this event.

	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On day due for 2nd dose, Patient was found unresponsive at work in the hospital. Patient pupils were fixed and dilated. Full ACLS was initiated for 55 minutes with multiple rounds of bicarb, calcium chloride, magnesium, and epinephrine. Patient was intubated. Patient continued into V. Fib arrest and was shocked multiple times.		No prior vaccinations for this event.

	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any	No prior vaccinations for this event.

symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.

ENDOTRACHEAL INTUBATION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

After being observed for approximately 20 minutes and patient walked to her car without assistance I was called to assess the patient in the parking lot for troubles breathing. EMS was called as I made my way outside. Upon my arrival patient was leaning out of the car and stating that she could not breath. She was able to tell me that she was allergic to penicillin. Oxygen was immediately placed on the patient with minimal relief. Lung sounds were coarse throughout. She then began to vomit about every 20-30 seconds. Epipen was administered in the right leg with no relief. Patient continued to complain of troubles breathing and vomiting. A second epipen was administered in the patients right arm again with no relief. A few minutes later patient was given racemic epinephrine through the oxygen mask. There appeared to be mild improvement in her breathing as she appeared more comfortable, but still complaining of shortness of breath and vomiting. When EMS arrived patient was unable to transport herself to the stretcher. When EMS and clinical staff transferred patient to the stretcher she became unresponsive. She appeared to still be breathing. She did not respond to verbal stimuli. Per ED report large amount of fluid was suctioned from the patients lungs following intubation in the ambulance. When patient arrived to the ED she was extubated and re-intubated without difficulty and further fluid was suctioned. At that time patient was found to be in PEA,

No prior vaccinations for this event.

shock was delivered. Shortly thereafter no cardiac activity was found and patient pronounced dead.

	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/28/2021- Seen by FNP for indigestion, chest pressure and palpitations. EKG reviewed and referral made to Cardiology. 1/29/2021-1800 Presented to ED in cardiac arrest-onset PTA. Patient was found unresponsive by his wife at their home. The last known well was at 1530 when she called him on the phone. The patient was pronounced at ~1850.		No prior vaccinations for this event.
	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient expired. Per Emergency MD note: ""This is a 72-year-old male with what sounds like diabetes, atrial fibrillation, and hypertension who presents via EMS in cardiac arrest. It sounds like he received his Covid vaccine last week. Initially he had some mild effects from it. However over the last day or so he has felt very unwell. He apparently called his wife today and told her that he was not feeling well and so she returned home. Shortly thereafter he attempted to get up from his chair. He then collapsed and fell forward onto his face. Sounds like his wife had some difficulty rolling him over to perform CPR. When EMS arrived they found him in PEA. He received a total of 5 rounds of epinephrine. At some point they did have return of spontaneous circulation. However just prior to arriving in the emergency department they lost pulses again. The patient was intubated with an 8 oh endotracheal tube prior to arrival."""		No prior vaccinations for this event.
	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt had 2nd vaccine, went home and started having ""cramping"" in all of her muscles. It became bad enough that she was taken to local ED where she then started coughing up blood, required intubation and about 6 hrs later, died."	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
73-year-old man s/p first dose of Pfizer at 10:20 AM Ambulated comfortably to exit after 20 minutes in observation but 10:45 collapsed while exiting the building 10:47 CPR initiated 10:49 medical team/EMS found no pulse, agonal respirations, ventricular fibrillation Paramedics and team performed ACLS; of note patient was intubated 7.5 ETT with bilateral breath sounds on ventilation; paramedic reported easy intubation with no apparent throat swelling; 11:02 transported to Emergency Department 11:30 Pronounced dead at Emergency Department	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Day after receiving the vaccine, the patient complained of abdominal pain which worsened over the day. She went to the ED and was hospitalized. Abdominal pain complaints increased and continued, she decompensated rapidly, was intubated and subsequently died 3 days later. Imaging results showed, progressive ovarian cancer in the bowels. Blood culture revealed that she had E.Coli in her blood. It is thought that this is NOT related to the vaccine.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and	No prior vaccinations for this event.

targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of

the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and ACLS guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and ACLS guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.	No prior vaccinations for this event.

ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

For the two days prior to presentation the patient had been complaining of chest pain, his breathing seemed to be labored Monday. He and the family thought the pain was due to shingles as he carried this diagnosis from a month ago. Patient had also received the COVID vaccine 2 days prior to presentation and assumed he was feeling unwell due to the vaccine. Family wanted to take him to the hospital yesterday and earlier today but he refused. She left him in his home earlier this afternoon prior to presentation and returned to check on him finding him unresponsive and apneic at which time EMS was activated. #cardiac arrest -- suspect primary cardiac given collateral from family at home, consider hypoxemia which was corrected with advanced airway and 100% FiO2, patient clinically euvolemic and with soft brown stool in diaper not suggestive of GI hemorrhage, attempt to address acidosis with CPR and bicarbonate, not hypoglycemia, on bedside ultrasound FAST neg and no pericardial effusion suggestive of tamponade and +lung sliding bil not spontaneous pneumothorax Assessment/Diagnosis: -cardiac arrest, cause unspecified	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt with acute resp failure, COVID PNA, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior toa admit, then shortly after progressed with other covid symptoms and was admitted. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. Pt passed soon after(2/2).	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.		No prior vaccinations for this event.
	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
COVID 19 symptoms and a positive test was confirmed on 1/6, employee noted previous exposure to positive family members Narrative: Employee noted exposure to COVID prior to presenting for 1st dose of vaccine on 1/5/21. On 1/6/21 employee reported the onset of symptoms and was tested and was confirmed COVID positive that day. Positive result was reported to employee health on 1/8/21. Employee Health continued to track employees progress and was informed of the need for hospitalization on 1/14/21. Course of hospitalization noted the need for intubation and significant issue with comorbid condition (rheumatoid arthritis). Employee died on 2/9/2021. Unable to confirm a direct connection to Vaccine vs. COVID infection, but felt it should be reported.		No prior vaccinations for this event.
	ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He	No prior vaccinations for this event.

is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.	No prior vaccinations for this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Presented to ED via EMS c/o increasing shortness of breath, O2 sat mid to high 80s on 4L. When EMS arrived , pt was in distress, intubated by EMS and transported to ED. Pt had a PEA arrest	No prior vaccinations for

en route but resuscitated w/ return of spontaneous circulation after receiving a dose of epinephrine and chest compressions. Pt was hypotensive on arrival to ED. He was started on sepsis protocol , volume resuscitation and empiric antibiotics. Once stabilized, he was admitted to icu at hospital. Removed from respirator 2/22/21	this event.
ENDOTRACHEAL INTUBATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further	No prior vaccinations for this event.

improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was

pronounced at 2123 on 2/20/2021. Children were at bedside.

ENDOTRACHEAL INTUBATION	COVID19 (COVID19 (UNKNOWN)) (1202)
Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2 diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated) then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and was intubated. Transported to hospital. SARS CoV-2 and influenza negative.	No prior vaccinations for this event.

ENTERITIS	COVID19 (COVID19 (MODERNA)) (1201)
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.

ENTEROVIRUS TEST NEGATIVE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t	No prior vaccinations for this event.

patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.

EOSINOPHIL COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.

EOSINOPHIL COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-	No prior vaccinations for this event.

ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2

through

	EOSINOPHIL COUNT INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021		No prior vaccinations for this event.
	EOSINOPHIL COUNT INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
right arm swelling immediately after injection. followed by bilateral lower leg edema, chills and body aches that continued daily at 2 weeks post immunization admin 2/4/21 treated with dexamethasone 6mg PO x 7 days- this resolved his s/s 2/13/21 patient passed away at facility		No prior vaccinations for this event.
	EOSINOPHIL COUNT NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.

EOSINOPHIL COUNT NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.		No prior vaccinations for this event.
EOSINOPHIL PERCENTAGE		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.
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EOSINOPHIL PERCENTAGE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.

EOSINOPHIL PERCENTAGE INCREASED	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious,	No prior vaccinations for this event.

but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

EPIDERMAL NECROSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Presented from clinic with 3-4 days of extensive rash. There were multiple areas of skin sloughing on bilateral upper extremities and abdominal wall.	No prior vaccinations for this event.

EPINEPHRINE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all	No prior vaccinations for this event.

morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

EPISTAXIS

COVID19 (COVID19 (MODERNA)) (1201)

Resident became lethargic and reports of blood coming from resident's nose and mouth on the morning of 1/13/21. Resident went out to ER for eval, and came back to facility with dx of pneumonia and recommendations for resident to be placed on hospice. Resident deceased on 1/14/21. Unknown if vaccine related, but with timeline of events I was advised to report this per medical director of facility, as well as Pharmacy who administered the vaccine.

No prior vaccinations for this event.

EPISTAXIS

COVID19 (COVID19 (MODERNA)) (1201)

Patient received Moderna COVID vaccine on 12/30/2020 at a Pharmacy clinic where he was a resident. Nurses at the facility reported that he was responsive and showed no signs of any adverse effects until 1/2/2021 when he was observed slightly unresponsive and staring at the ceiling and trembling. He had a fever of 101F at this time. The facility ordered labs and a rapid COVID test (all of which came back normal) and

No prior vaccinations for this event.

started IV antibiotics. A few hours later, patient began bleeding from his eyes, nose, and mouth and was sent to the local ER. The patient refused being admitted to the ICU for possible sepsis/hemorrhage and died the following day on 1/3/2021. All healthcare professionals involved agreed that this was not likely due to the vaccine, but needed to be reported nonetheless.

EPISTAXIS **COVID19 (COVID19 (MODERNA)) (1201)**

epistaxis. No prior vaccinations for this event.

ERUCTATION COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 2/4/21, at around 3:00pm he began feeling very tired and he began burping in the evening. The following morning, he woke up early and was still burping and not feeling well. At around 5:00am, he collapsed. My mother called 9-1-1 and began giving CPR. The parademics arrived and tried to revive him, and transported him to the hospital but at 6:11am, he was pronounced dead of a heart attack. He was healthy. No prior vaccinations for this event.

ERYTHEMA **COVID19 (COVID19 (MODERNA)) (1201)**

Redness and warmth with edema to right side of neck and under chin. Resident was on Hospice services and expired on 1.1.21 No prior vaccinations for this event.

ERYTHEMA **COVID19 (COVID19 (MODERNA)) (1201)**

12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made No prior vaccinations for this event.

comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics

ERYTHEMA

COVID19 (COVID19 (MODERNA)) (1201)

death of unknown cause; Swelling on Right side of the neck and under chin; Warmth on right side of neck and under chin; Redness on right side of neck and under chin; A spontaneous report was received from a healthcare professional concerning an 89-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events of redness, warmth and swelling on right side of neck and under chin, and death of unknown cause. The patient's medical history included Alzheimer's and chronic obstructive pulmonary disease (COPD). No concomitant medications were reported. On 29 Dec 2020, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: Unknown) intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient experienced the events of redness, warmth and swelling on right side of neck and under chin. There was no indication that the patient was transferred out to hospital, which was unlikely because she was under hospice care. On 01 Jan 2021, the patient died due to an unknown cause of death. Action taken with mRNA-1273 in response to

No prior vaccinations for this event.

the events was not applicable. The patient died on 01 Jan 2020. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns a 89-year-old, female subject with a medical history of Alzheimer's and chronic obstructive pulmonary disease (COPD) who experienced redness, warmth and swelling on R side of neck and under chin and expired from an unknown cause. The events of redness, warmth and swelling on R side of neck and under chin occurred 2 days after administration of the first and only dose of the mRNA-1273 vaccine and patient expired 4 days after mRNA-1273 vaccine administration. Lot # of the vaccine was not provided. De-challenge and re-challenge are not applicable. The events of redness, warmth and swelling on R side of neck and under chin are temporarily associated with the administration of the mRNA-1273 and thus, a causal relationship cannot be excluded. Due to limited information, the fatal outcome was considered unrelated to mRNA-1273 administration pending additional information. Fatal outcome is confounded by the patient's underlying condition and advanced age.; Reported Cause(s) of Death: Unknown cause of death

ERYTHEMA

COVID19 (COVID19 (MODERNA)) (1201)

Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face, increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray

No prior vaccinations for this event.

showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

ERYTHEMA

COVID19 (COVID19 (MODERNA)) (1201)

"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal

No prior vaccinations for this event.

abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

ERYTHEMA

COVID19 (COVID19 (MODERNA)) (1201)

Death Narrative: Patient received the first COVID-19 dose on 12/23. Afterwards, patient complained of localized pain on L deltoid area where the vaccine was administered; his temperature was 98.1 F. On 12/26-27, staff reported that patient appeared more fatigued than usual and was shivering on 12/27, which seized after blanket was given. On 12/28, patient presented with fever (Tmax 100.2 F) and acetaminophen was administered for alleviation of fever. ADR was reported for the fever on 12/29. Patient continued to decline and was placed back on hospice care on 12/29; on 12/30. the symptoms reported on nursing note include erythema and pain on whole L arm. Lidocaine was applied. Patient's family and provider mutually agreed not to administer the second dose of vaccine. He continued to decline and was started on end-of-life care around 1/4 and passed on 1/20 1417.

No prior vaccinations for this event.

ERYTHEMA

COVID19 (COVID19 (MODERNA)) (1201)

Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until

No prior vaccinations for this event.

family could be reached and decision was made to stop resuscitation.

ERYTHEMA

COVID19 (COVID19 (MODERNA)) (1201)

Several days after vaccination his left arm turned red. He was taken to the hospital where he was evaluated and admitted with a diagnosis of left axillary vein thrombosis. A chest X-ray was taken and he presented bibasilar atelectasis and pneumonia with pleural effusions.

No prior vaccinations for this event.

ERYTHEMA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

right arm redness No prior vaccinations for this event.

ERYTHEMA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the

No prior vaccinations for this event.

emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

ESCHERICHIA BACTERAEMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Day after receiving the vaccine, the patient complained of abdominal pain which worsened over the day. She went to the ED and was hospitalized. Abdominal pain complaints increased and continued, she decompensated rapidly, was intubated and subsequently died 3 days later. Imaging results showed, progressive ovarian cancer in the bowels. Blood culture revealed that she had E.Coli in her blood. It is thought that this is NOT related to the vaccine.	No prior vaccinations for this event.
ESCHERICHIA INFECTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1 fall after first dose on 1/8/2021 at 1930; no injuries; 4 falls after second dose on 1/14/21 at 1545, 1/15/21 at 1700, 1/21/21/at 1220 and 1/21/21 at 1330 all falls with no injuries. Started Ceftriaxone 1 GM IM daily for 5 dyas on 1/21/21 for UTI: E. Coli	No prior vaccinations for this event.
ESCHERICHIA TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
ESSENTIAL HYPERTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	No prior vaccinations for this event.
EXPOSURE TO SARS-COV-2	**COVID19 (COVID19 (MODERNA)) (1201)**
At the time of vaccination, there was an outbreak of residents who had already tested positive for COVID 19 at the nursing home where patient was a resident. About a week later, patient tested positive for COVID 19. She had a number of chronic, underlying health conditions. The vaccine did not have enough time to prevent COVID 19. There is no evidence that the vaccination caused patient's death. It simply didn't have time to save her life.	No prior vaccinations for this event.
EXPOSURE TO SARS-COV-2	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient diagnosed with COVID on January 9, 2021 after being exposed to family member that was under quarantine in the same household. Admitted to the hospital and was discharged on January 14, 2021 with home hospice. Patient passed away on January 18, 2021	No prior vaccinations for this event.
EXPOSURE TO SARS-COV-2	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient rcvd 1st covid 19 vaccine on 1/26/2021. Patient had house guests on 1/30/21. Those house guests tested positive for covid on 2/1/2021. Patient started getting symptoms on 02/2/2021. Patient tested postivie on 2/4/2021. Patient was hospitalized 2/7/2021. Patient passed away on 2/21/21.	No prior vaccinations for this event.

EXPOSURE TO SARS-COV-2		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
71yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, VS taken at 10am, B/P 99/60, O2 sats, 95% (trach w/O2). At 11:30am, Patient showed no s/sx of distress, A&Ox3. At 11:50am, a nurse went to perform a COVID test and assessment (the facility is experiencing an outbreak), and found the patient unresponsive on the bathroom floor. CPR was immediately started; no shock advised per AED; 12:15pm EMS arrived and took over. At 12:38pm, EMT called time of death.		No prior vaccinations for this event.
EXPOSURE TO SARS-COV-2		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
All residents had been in isolation due to multiple cases of COVID in the facility. Resident voiced no health related complaints. He continued to visit with staff and required moderate assist with toileting. Resident had fall 0130 on 1-15-2021, which resulted in laceration with surgical repair. Resident was noted to change in mental status and respirations on morning of 1-16-2021 during morning blood sugar check. Resident had O2 @1.5l/m via n/c and respirations of 10 with periods of apnea and unresponsive to verbal stimuli. Blood sugar was 583. Resident deceased upon re-check after calling PCP to report status change.		No prior vaccinations for this event.
EXPOSURE TO SARS-COV-2		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was vaccinated on 12/31/20. Then on 1/14/21 he tested positive for SARS-CoV-2 on routine surveillance PCR testing. Another resident on the same hall was COVID positive on 1/11/21. Results of the PCR test were obtained on 1/16/21. He appeared asymptomatic at that time. Given his COVID positive status, all aerosol generating procedures had to be stopped. Overnight on 1/16/21 into 1/17/21, he had the		No prior vaccinations for this event.

onset of acute respiratory failure and was transported to the hospital. Per notes, he was put on BiPAP for several hours, but his CO2 level did not improve. Per prior advance directives completed with the resident and his two brothers, he had DNR/DNI orders. The hospital physician spoke with his brother and the decision was made to move to comfort care. He was discharged to inpatient hospice and died around 4pm on 1/18/21. This outcome does not appear to be vaccine-related, but death from COVID-19 infection is listed as a reportable event following COVID-19 vaccination.

EXPOSURE TO SARS-COV-2

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Client was administered the vaccine while symptomatic (01/25/21) although client did not know he was symptomatic for COVID-19. He had been exposed to a family member who had tested positive and should have been in quarantine but wasn't either because it was not felt he was considered a close contact by his family opinion or his family member never notified public health of this close contact...?. Clinet had presented to the ED following day after vaccination for shortness of breath and fatigue and an antigen test showed he was positive for COVID-19. He was sent home that same day 01/26/21. He was back in ED on 01/28/21 for worsening symptoms and admitted to hospital and later placed on ventilator. He passed away on 02/09/2021 (date of death was per his wife).

No prior vaccinations for this event.

EYE HAEMORRHAGE

COVID19 (COVID19 (MODERNA)) (1201)

Patient received Moderna COVID vaccine on 12/30/2020 at a Pharmacy clinic where he was a resident. Nurses at the facility reported that he was responsive and showed no signs of any adverse effects until 1/2/2021 when he was observed slightly unresponsive and staring at the ceiling and trembling. He had a fever of 101F at this time. The facility ordered labs and a rapid COVID test (all of which came back normal) and started IV antibiotics. A few hours later, patient began bleeding from his eyes, nose, and mouth and

No prior vaccinations for this event.

was sent to the local ER. The patient refused being admitted to the ICU for possible sepsis/hemorrhage and died the following day on 1/3/2021. All healthcare professionals involved agreed that this was not likely due to the vaccine, but needed to be reported nonetheless.		
	EYE MOVEMENT DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.		No prior vaccinations for this event.
	EYE MOVEMENT DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Few minutes post vaccination, after moving to observation area via wheelchair, the patient complained of dizziness. She took glucose tabs she had brought with her. Staff wheeled her to Triage # 1. Her eyes rolled back in her head and she lost consciousness. Staff (paramedics on site) transferred her to gurney and started compressions. AED placed, V- Fib was rhythm, Shock # 1 given, CPR resumed. Shocked again. Fire truck and additional EMT arrived on site and took over care. Epinephrine was given 3 times via intra-osseous route, Amiodarone given intra-osseous route. Additional defibrillation with on site AED for a total of 6-7 times. Patient had good chest rise with ambu-bag, no airway obstruction or peri-oral edema noted. Code called at 12:40 PM.		No prior vaccinations for this event.

EYE MOVEMENT DISORDER	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
My dad received the Pfizer vaccination on 2/5/21. He was admitted into the hospital the next day for C-Diff bacterial infection. He had been on dialysis treatments for kidney failure treatment since 2017 and had recently been diagnosed with stage 3 colon cancer in June 2020. He had completed his final treatment of chemotherapy on 2/4/21 and several weeks prior had been determined cancer free. On Tuesday 2/9/21 he was released from the hospital and went home. Early Thursday morning 2/11/21 @ approximately 1:30 am CST his eyes rolled back in head and he stopped breathing and was non responsive. My mother called 911 and attempted CPR. Paramedics arrived and were able to successfully get a pulse then transferred him to the hospital. He was put on a ventilator @ the hospital and then transferred to a different hospital a few hours later. He lost pulse/heartbeat several times @ the 2nd hospital he was transferred to. We were not allowed to travel with him or see him b/c of all of the COVID restrictions. We were communicating with the ICU doctor by phone who ultimately communicated to us that there was nothing further that could be done to save his life. He subsequently passed away @ approximately 8:55 am CST on 2/11/21.	No prior vaccinations for this event.

EYE SWELLING	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
On December 17, 2020, my husband, received his first BioNTech BNT162b2 COVID-19 vaccination. On Thursday January 7, 2021, he received this second COVID-19 vaccination. The following three days after his second vaccination, he felt fine. The fourth day, on Sunday January 10, my husband felt extremely fatigued. On Monday the 11th and Tuesday the 12th, he worked a full shift but complained of extreme fatigue and extreme chills to the point that his teeth were chattering while on the phone with me. He decided to work through it. When he got home on Monday night, he started vomiting. On Wednesday January 13, he woke up and had swollen eyes. Once again, he felt extremely fatigued, even after a full	No prior vaccinations for this event.

nights rest. He had the day off but had an early meeting. After his meeting, he was still tired so he went back to sleep. I left to get lunch, and drop off our kids, and upon my return, I found him on the walk in closet floor, face up, having passed away. He felt as cold as ice. The rapid test done after they called the paramedics resulted in a negative COVID-19 test for him.

FACIAL PARALYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Developed acute facial droop and slurred speech 2h after 1st dose of the vaccine on 2/17, found with R MCA stroke. Then became unresponsive on 2/27 and was found with an acute L MCA stroke. Was transferred from another hospital, was not a candidate for intervention, and was made comfort and died on 2/28	No prior vaccinations for this event.
FAECES DISCOLOURED	**COVID19 (COVID19 (MODERNA)) (1201)**
Hypoxia, Decreased responsiveness, Narrative: 86yo male with PMHx HTN, Afib not on AC after head trauma, CVA, and colon cancer who was brought to the ED by his family on 2/17. Per documentation the pt was in his usual state of health until 2/16. Received Moderna covid vaccine #2 on 2/16/21 at 0900, and was monitored for 15 minutes following immunization no noted issues. Later that night, had myalgias and took Tylenol. Per the family he slipped on the ice and fell on his butt. Overnight, had several dark stools and vomitus. was brought to the ED by his family because he was being less responsive. Pt arrived to the emergency department in extremis. No pulse identified. CPR immediately initiated for several rounds lasting about 25-30 minutes. ROSC unable to be achieved. Patient expired on 2/17 at 1941. Of note, per previous documentation had waxing and waning mental status at baseline. No symptoms noted with 1st dose of Moderna vaccine, which was administered on 1/16/21.	No prior vaccinations for this event.
FAILURE TO THRIVE	**COVID19 (COVID19 (PFIZER-BIONTECH))**

view 2/5/2021 09:23 e Progress Note Note Text: Patient passed away in the facility this morning. view 2/5/2021 08:39 Orders - Administration Note Note Text: Resident passed. view 2/5/2021 08:33 Nurses Note Note Text: Body released to funeral home at this time. Personal effects sent with resident include: 1 pair of glasses, 1 yellow wedding band, 1silver spoon ring, 1 ring with black and clear stones. Resident has own teeth view 2/5/2021 08:32 Nurses Note Note Text: cause of death per CRNP failure to thrive. view 2/5/2021 07:44 Orders - Administration Note Note Text: Take and document temp & PO2 every 4 hours for MONITORING Resident passed. view 2/5/2021 06:49 Nurses Note Note Text: Son returned call and was updated of resident's passing this am view 2/5/2021 06:33 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Unknown Resident expired @ 0604 [linked] view 2/5/2021 06:06 Nurses Note Note Text: Res found without pulse or respirations. Pronounced at 0604. Updated. N/o's for RN to pronounce, release body to funeral home, dispose of medications per facility policy. Daughter updated. Funeral Home called to release body. view 2/5/2021 05:26 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Pulse ox 60% on O2 @ 5L/min via mask. Resps 44 per minute. view 2/5/2021 01:57 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/5/2021 00:52 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Residents resps are 40 per minute, pulse ox 76% on O2 @ 5L/min via mask. Resps are labored, shallow and rapid. view 2/5/2021 00:48 Nurses Note Note Text: Nonresponsive to verbal and tactile stimulation. Appears comfortable. view 2/4/2021 22:01 Nurses Note Note Text: Resident resting comfortably, breathing becoming increasingly shallow, wearing O2 via mask at 5L via mask, no dyspnea noted, feet are mottled, oral and peri care provided Q2H. No s/s of pain or discomfort. view 2/4/2021 21:40 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective [linked] view 2/4/2021 19:32 Orders -

No prior vaccinations for this event.

Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger medicated for air hunger, RR 28 to 32/ min view 2/4/2021 19:22 Nurses Note Note Text: Daughter updated on N/O to increase Morphine Sulfate 20mg/mL 0.25mL to Q2H prn from Q6H prn. view 2/4/2021 18:06 Nurses Note Note Text: POA Daughter and daughter aware of residents current condition. view 2/4/2021 11:58 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/4/2021 11:13 Nurses Note Note Text: Pt. noted to be lethargic at this time. Does respond to verbal and tactile stimuli by opening her eyes but non verbal currently. Skin warm and dry. No mottling or apnea observed at this time. O2 sat 88% with O2 at 2 LPM via n/c. On increased to 3 LPM via mask as pt. noted to be mouth breathing. Respirations 28. F/U O2 sat 93%. HOB elevated. Pt. medicated with morphine by LPN. Daughter updated on pt.'s condition. Does not want pt. sent out to hospital and would like comfort measures to continue. Daughter also in agreement with delay in d/c d/t pt.'s condition.CRNP updated on pt.'s condition, delay in d/c and daughter's wishes. No n/o's at this time. view 2/4/2021 10:56 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB Resident showing s/s of discomfort. SOB at this time and high respirations. Repositioned, changed for incontinence care and mouth care provided. view 2/4/2021 10:34 Progress Note Note Text: Spoke with RN regarding change in condition. Updated Sr Living regarding change. Recommendation to cancel d/c/transfer for today, see how resident does through the weekend and re-evaluate on Monday. Daughter updated on cancellation of d/c today. view 2/4/2021 10:04 Nurses Note Note Text: Daughter aware that resident's O2 sat was 88% on room air on 3-11 shift and that oxygen was applied via nasal cannula. view 2/4/2021 10:03 Nurses Note Note Text: N/O: Discharge 2/4/21 with scripts to Sr. Living. Daughter aware. view 2/4/2021 09:53 Nurses Note Note Text: Pt. to be d/c'd to another facility this am as per MD order. Pt. alert and responsive. Skin assessment done as per facility policy. No pressure areas noted at this time. No s/sx of pain or discomfort observed at this time. V.S. 97.0 67 20 O2 sat 95% with O2 at 2 LPM via n/c. view 2/4/2021 07:45 Nurses Note Note Text: Resident seen by Dr. for discharge. Orders pending at this time. view 2/4/2021 07:36 Nurses Note Note Text: CRNP and Dr. updated on O2 sat 88% on RA with f/u of 93% with O2 on at 2 LPM as well as rest of VS, 3-11 shift 2/3/21. No n/o's at this time. view 2/3/2021 21:17 Nurses Note Note Text:

Resident Sp02 88% on RA. Pulse 124. Respirations 40. PRN morphine given and O2 applied via NC at 2L/min. After recheck pulse ox up to 93%, pulse 100, and respirations 22. Resident appears comfortable at this time. view 2/3/2021 20:05 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective [linked] view 2/3/2021 19:48 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN given for SOB after elevation of HOB not effective. view 2/3/2021 11:51 Nurses Note Note Text: CRNP updated rapid COVID test done for d/c tomorrow was negative. No n/o's at this time. view 2/3/2021 11:44 Nurses Note Note Text: Daughter notified of rapid covid swab being negative. view 2/3/2021 09:50 Orders - Administration Note Note Text: Obtain Rapid Covid test on 2/3/2021 for discharge. Please give copy of results to Social Worker every day shift for covid testing for 1 Day Completed and negative. view 2/3/2021 08:45 Skilled Nursing Note Reason for skilled service: Therapy describe skilled service: Nursing, therapy assessment: V.S. 97.8 79 18 138/84 Orientation: Oriented to self only. Oxygen: O2 sat 94% on RA Edema: Trace edema noted BLE. Pedal pulses present. Pain: Denies pain or discomfort at this time. Nursing note: Pt. alert and responsive. Skin warm and dry. Lung sounds diminished. No respiratory distress observed at this time. Abdomen soft. BS+ in all 4 quads. Continent/Incontinent of B&B. 1 assist with ambulation, transfers. 1 assist with ADL's. Working with therapy on gait training, therapeutic exercise, therapeutic activities & neuromuscular reeducation. view 2/2/2021 14:37 Progress Note Note Text: Per health professional at Sr Living, prepared to accept patient to their Memory Care Unit 2/4. Transportation arranged for 11 AM per family request. Daughter (POA) updated on d/c time on 2/4/21. Facility requesting rapid COVID test completed prior to d/c and results sent to them. All other information sent for continuity of care.

FAILURE TO THRIVE

Patient with failure to thrive symptoms prior to 2nd dose, not eating, not taking

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

No prior vaccinations for this event.

medications.

	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident had body aches, a low O2 sat and had chills starting on 12/30/20. He had stated that they had slightly improved. On 1/1/21 he sustained a fall with a diagnosis of a displaced hip fracture. On 1/2/21 during the NOC shift his O2 sat dropped again. He later went unresponsive and passed away.		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
Staff reported that patient was found Friday morning (Jan 8) sitting at a table with his head tilted forward and unresponsive to verbal or physical stimuli. Staff lowered patient to floor and started CPR. EMS was called and continued CPR at scene, however they were not able to revive patient. Patient was pronounced dead at the scene. Staff written statements following the death of patient show that he had a fall about 1 hr. prior. It is unknown if this fall contributed to patient's death. An autopsy has been requested.		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was noted to have increase weakness on 1/15/2021. Resident was warm to touch with low grade fever of 99.3 F. Resident was up propelling self in w/c on 1/16/2021 he was pleasant, accepted medications and ate lunch. He was found slumped over in his w/c not responding and vital signs absent.		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt developed COVID-19 infection, symptoms starting 7 days after first dose was given. Patient was admitted		No prior vaccinations for

to hospital on 1/21 after falling (secondary to weakness) and striking head on toilet. Patient expired due to respiratory complications of COVID on 1/25.		this event.
FALL		**COVID19 (COVID19 (MODERNA)) (1201)**
VACCINATION WAS RECEVIED THE MORNING OF 1/5/2021- IN THE EVENING OF THAT DAY RESIDENT SUSTAINED A FALL AND WAS TRASNPORTED TO FACILITY FOR TREATMENT. IT IS NOT UNUSUAL THAT RESIDENT WAS SELF TRANSFERRING AND HAS A HISTORY OF FALLS.		No prior vaccinations for this event.
FALL		**COVID19 (COVID19 (MODERNA)) (1201)**
on 1/13/2021 at 3:40am Cliff called for assistance. He lost his balance and had fallen. Cliff refused vitals, refused emergency department, denied hitting his head. As the day progressed patient developed a headache, diarrhea, and vomiting. He again declined the offer for the emergency room. At supper time wife and staff found Cliff unresponsive, 911 was called and he was taken to the emergency department. The ER did a CT scan and found an acute subdural hematoma. Patient was placed on comfort cares and expired at 3pm on 01/14/2021. Cliff did not have a history of falls.		Influenza vaccine 10/06/2020, age 88, fever, chills, vomiting, malaise
FALL		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient recieved vaccine 1 of covid 19 i 1/19/2021. She felt poorly on 1/20/2021. She felt dizzy and fell at 3 AM on 1/23/2021. She felt poorly and did not know her son's name which was not normal. She went to ER on 1/24. She was assessed as not having fractures. She was going to be transferred to a skilled nursing facility. She was not having respiratory complaints. She was awaiting transfer when her O2 levels started dropping substantially. She declined aggressive intervention and she died within a few hours.		No prior vaccinations for this event.

	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
weakness and fallsNarrative: 95 yo male w/ a PMH significant for Afib, legal blindness, Hx of CVA, cognitive impairment, GERD, HTN, pseudogout, BPH, chronic knee infection, and DJD who received his first dose of the Moderna COVID-19 vaccine on 01/08/21. The pt's COVID-19 screening questionnaire prior to receiving the vaccine was negative. The pt presented to the ED on 01/13/21 for weakness and m PCR test on ultiple recent falls (since receiving his first dose of the COVID-19 vaccine). The pt's COVID-19 01/13/20 was positive and he was admitted. He was started on treatment with remdesivir + dexamethasone on 1/14. The pt initially required supplemental oxygen via low-flow NC, however his oxygen requirements increased to 100% NRB. On 01/16/21 his MPOA elected for hospice care. The pt passed on 01/17/21. Unclear if the COVID-19 vaccine attributed to the patient's hospitalization and eventual death, or whether these events occurred from COVID-19 itself, however this case is being reported the FDA since this vaccine is under an emergency use authorization (EUA).		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of the MCA territory (TPA not recommended). CTA did show distal L M1/M2 occulsion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**

itchy skin, swelling, disorientation that led to a fall No prior vaccinations for this event.

FALL **COVID19 (COVID19 (MODERNA)) (1201)**

Patient found down at home with agonal respirations and per EMS asystole, received 2 rounds of epi at her house with return of spontaneous pulses, lost pulse again in route to ER and another round of epi was given, CPR in progress when arrived at hospital. Prior to this patient's husband states he heard her fall in the bathroom but did not immediately check on her as he states that this has happened before. He checked on her 10 min later and that's when he found her unconscious. Daughter called 911 and she began CPR. No previous complaints of headache, chest pain, back pain, fever or chills. Husband states patient was drinking that evening which is not unusual for her. Patient died at hospital.

No prior vaccinations for this event.

FALL

COVID19 (COVID19 (MODERNA)) (1201)

"Patient had COVID vaccination on 2/3 with no adverse s/s before leaving unit. Upon coming to treatment Friday 2/5 he reported to the RN that he had fallen on thursday 2/4 due to ""getting up fast"" did not hit head or hurt anything per RN discussion. Began treatment without difficulty. About 3/4 way through treatment was talking with staff and became unresponsive - code was called and pt expired after 30 minute resuscitation efforts."

No prior vaccinations for this event.

FALL

COVID19 (COVID19 (MODERNA)) (1201)

Vaccine given in clinic per protocol - patient monitored for 15 minutes, no adverse reactions noted at the time. Patient stated he felt fine following 15 minute monitoring time. Patient left facility- it was later reported that pt had a fall at home. Upon review of pt's medical record - Pt's wife had to initiate CPR and call EMS for transportation and life saving measures enroute to the Emergency Room. Pt was intubated as pt was in asystole upon arrival to the ER, ACLS was continued, pt was noted to have a traumatic brain injury from his

No prior vaccinations for this event.

fall at home, and pt was pronounced dead at 1620.

	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient fell the day after receiving the Moderna COVID-19 vaccine. She broke her hip in this fall. During surgery to correct the broken hip, she went in to sudden and unexpected cardiac arrest. The anesthetist did not notice any ST changes or A fib; dysrhythmia was very unexpected. The patient had a DNR. She died at 13:00 on 02/07/2021. Causes of death are listed as 1. Cardiac Arrest 2. Recent hip fracture with hip placement 3. History of Breast Cancer 4. Hypothyroid and 5. Dementia		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient previously had dizzy spills, but about a week after receiving the vaccine her dizzy spills began to get worse. The whole prior she kept saying I am just not right. On the 2/7/21 she a COVID test done, a nurse came to her house and preformed. On the morning of the 8th patient was on the phone with someone else and patient asked this person to call me and go check on her. Within 5 minutes I was over at her house, and I found her on the floor, she on her belly facedown. It looked like she was on the toilet, and it looked like she fall getting her off, she was still wet, she still felt warm. I called the ambulance and immediately began CPR. When EMS arrived they took over the CPR and transported her to the Hospital. The EMS was there for about 40 minutes and used an machine to preform the compressions. She was pronounced deceased at the hospital. No autopsy was done.		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient described feeling nervous, anxious the next morning (Wednesday) after the vaccine. He later fell in the bathroom after using the restroom, his legs gave out (his words) and consequently was on the ground for		No prior vaccinations

23 hours before being transported to the hospital. That was Thursday afternoon. He was diagnosed with COVID-19 on Saturday night and died the following Friday morning.	for this event.
FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt was hospitalized Jan 18, 2021 after he had fallen outside overnight and lay there approximately 12 hours until he was found. Hypothermic & rhabdomyolis diagnosis. Gradually improved w/ strength & mental status - was in swing bed @ hospital. He got his first Covid 19 shot on 2-8-21. Was fine @ 0300 on 2-9-21 and @ 0430 he was found unresponsive. Dx: probable arrythmia & pronounced dead @ 0454. Noted on pain scale @ 2/8/21 @ 21:11, clients pain was a 7/10 They offered pain med & he refused They repositioned & distracted him @ 2047 on 2/8/21 Pain had decreased to 3/10 and nothing given. Then @ 0300 check he was sleeping and @ 0430 unresponsive.	No prior vaccinations for this event.
FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
"Was given vaccine around 1:30Pm on 2-11-2021. He and his wife waited in the building for 15 minutes and then left. he denied complaint. (He was waiting to have both Covid shots before he went to cardiologist Re: CAD.) He had an alarm going off in his house, was going to basement to check it out. Police officer heard alarm, came into house, & heard a thud when Doc fell. He was in PEA (Pulseless Electrical Activity) when brought into ER. Given 5 ""rounds of Epinephrine with no response."	No prior vaccinations for this event.
FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident yelling for assistance in apartment. Nursing personnel found resident on floor at 6:10 AM on 2/18/2021. Resident was transported to Hospital on 2/18/2021. Status update on 2/18/2021 from son, resident CT & X-rays were done all normal. Labs done and WBC count was elevated and awaiting results.	No prior vaccinations for this event.

Resident stable and admitted to hospital for observation. Resident passed away on 2.21.2021.

FALL		**COVID19 (COVID19 (MODERNA)) (1201)**
Since I was not with my husband I can only tell you what was told to me. He walked out of the store toward our car. Someone watched him, concerned, because he was walking very slowly (normally has a slow gait because of leg braces and toe amputations so I don't know if it was unusually slow). The woman saw him fall and she ran to help-administered CPR immediately-and told me he died instantly. Medics tried to resuscitate and failed to bring a pulse. (My husband left our home around 11:15 to drop a package off at store. The store is one mile from our home. At around 12:30 a deputy came to my door and when I saw him my knees buckled. I knew something horrible happened.		No prior vaccinations for this event.
FALL		**COVID19 (COVID19 (MODERNA)) (1201)**
loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and		No prior vaccinations for this event.

vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

FALL

COVID19 (COVID19 (MODERNA)) (1201)

Hypoxia, Decreased responsiveness, Narrative: 86yo male with PMHx HTN, Afib not on AC after head trauma, CVA, and colon cancer who was brought to the ED by his family on 2/17. Per documentation the pt was in his usual state of health until 2/16. Received Moderna covid vaccine #2 on 2/16/21 at 0900, and was monitored for 15 minutes following immunization no noted issues. Later that night, had myalgias and took Tylenol. Per the family he slipped on the ice and fell on his butt. Overnight, had several dark stools and vomitus. was brought to the ED by his family because he was being less responsive. Pt arrived to the emergency department in extremis. No pulse identified. CPR immediately initiated for several rounds lasting about 25-30 minutes. ROSC unable to be achieved. Patient expired on 2/17 at 1941. Of note, per previous documentation had waxing and waning mental status at baseline. No symptoms noted with 1st dose of

No prior vaccinations for this event.

Moderna vaccine, which was administered on 1/16/21.

	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
2-24-21 patient with development of cough, fatigue, increasing on chronic disability worsening debility and falls. scheduled for office visit 2-25.21 0900 call from spouse 0210 am patient was not breathing and lvad alarming low flow alarm on arrival of ems confirm asystolic not breathing and dead		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccination at 14:20 2/26/21. Was observed until discharged at 15:15. Discharged per wheel chair to lobby in alert/stable condition, to wait on bus to take him home. At 18:00 his neighbor heard him fall, could not get patient to answer phone, found him unresponsive. Neighbor called 9-1-1, ambulance personnel could not revive patient. Coroner's office ruled his death as Natural Causes due to Hypertension, Cardiac disease, Diabetes, ESRD. There were no indication of anaphylactic reaction noted when I questioned the coroner's office. The Coroner's office/EMS were aware the patient had received the Moderna COVID 19 vaccination that day.		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (MODERNA)) (1201)**
Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.		No prior vaccinations for this event.

	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.		Influenza Virus Vaccines - Unknown date/type or brand

	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away		No prior vaccinations for this event.

	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1 fall after first dose on 1/8/2021 at 1930; no injuries; 4 falls after second dose on 1/14/21 at 1545, 1/15/21 at 1700, 1/21/21/at 1220 and 1/21/21 at 1330 all falls with no injuries. Started Ceftriaxone 1 GM IM daily for 5 dyas on 1/21/21 for UTI: E. Coli		No prior vaccinations for this event.

	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
All residents had been in isolation due to multiple cases of COVID in the facility. Resident voiced no health related complaints. He continued to visit with staff and required moderate assist with toileting. Resident had fall 0130 on 1-15-2021, which resulted in laceration with surgical repair. Resident was noted to change in mental status and respirations on morning of 1-16-2021 during morning blood sugar check. Resident had O2 @1.5l/m via n/c and respirations of 10 with periods of apnea and unresponsive to verbal stimuli. Blood sugar was 583. Resident deceased upon re-check after calling PCP to report status change.		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Heart stopped; Could not swallow; This is a spontaneous report from a contactable nurse (patient's wife). An 85-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 21Jan2021 at a single dose for COVID-19 immunization. Medical history included blood pressure abnormal (verbatim: blood pressure) from an unknown date and unknown if ongoing, neuropathy from an unknown date and unknown if ongoing, weight issue from an unknown date and unknown if ongoing, diabetes from an unknown date and unknown if ongoing, walker user from an unknown date and unknown if ongoing. Concomitant medications included insulin aspart (NOVOLOG) taken for diabetes from an unspecified date to an unspecified date; and he was taking a long acting one as well. The patient previously received the influenza vaccine (MANUFACTURER UNKNOWN) for immunization on unknown dates (""had flu shots before with no reactions and everything, nothing before""). On 24Jan2021, the patient's heart stopped (death, medically significant), and could not swallow (medically significant). The clinical course was reported as follows: The patient's wife stated the patient was taking insulin aspart (NOVOLOG) and he was taking a long acting one as well. The reporter, the		No prior vaccinations for this event.

patient's wife and a retired registered nurse (RN) stated, her husband (patient) just died and she thought he died from the COVID vaccine (later clarified the reason of death was-heart stopped). The patient had the vaccine on 21Jan2021, which was on a Thursday, and he was fine. On the following Sunday around 1:30 (on 24Jan2021), the patient was feeling a little weak, however, the patient's wife thought maybe his blood sugar was low. The patient's wife checked, and the patient's blood sugar was 91. The patient's wife went to get some yogurt to feed him in order to get his blood sugar up a little; ""which was a normal thing for him, it was not that low for him."" Then, suddenly, the patient fell, and the patient's wife could not get a pulse or anything. The patient's wife called an unspecified number and she started compressions; however, he was dead. The patient's wife stated the patient just had his heart test, a three hour long one, and it was ""perfect three weeks ago."" The patient had just gone to the doctor the other day and his blood pressure was ""fine and everything."" The patient's wife stated that other than his diabetes, ""which he had for (sentence incomplete)."" Regarding lab tests, the patient's wife stated, ""No, he had it before but not in the last two weeks. He was going for one because we just went to the doctor last week and he was going to call yesterday to make the appointment request to get his blood work done. Blood work has been good except his A1C was always high, but other than that everything was good"" (as reported). Regarding causality, the patient's wife stated, ""I do, because he was fine until about half an hour before he died. He said to me, I feel a little weak today and then I was talking to him that your upper body strength is really good and then I said, we just have to work on your weight a little more because he did have neuropathy. And then, I went out of the room and all of a sudden I just heard him fall and that is when I just went in to check his blood sugar and it was 91 and I got him yogurt and he started eating that and then that was it, he started spitting it out and he said, I could not swallow and that was it, he just died."" The patient's wife further added, ""I just wanted other people to know that things like this happen and I am sure it was from that because he was healthy as could be. He was walking with his walker, the day before outside and he felt fine."" The clinical outcome of the event, heart stopped, was fatal. The clinical outcome of the event, could not swallow, was unknown. The patient died on 24Jan2021 due to ""heart stopped."" An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: Heart stopped"

	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Myocardial infarction Narrative: PMH significant for aortic valve stenosis, mitral valve stenosis, CKD, CHF, DM, HTN, obesity, hypothyroidism and dyslipidemia. Per report from primary care - the patients wife reports that the patient went on Saturday (1/30/21 - about 1050) morning to receive his COVID vaccine. He returned home and told her about the experience and denied any side effects. He then proceeded to sit in his easy chair for a while and around 1:30, she asked him if he wanted any lunch. The patient's wife reports he ""grumbled"" at her, and then got up to go to the bathroom. She then heard a loud crash and found him lying on the floor of the bathroom, with his head knocking hole in the wall as he fell. She could not detect a pulse. She called 911 and began compressions. First responders to the scene likewise tried to revive him but were not successful in her efforts. Per primary care documentation - Uncertain if related to Pfizer vaccine; vaccine administered on 1/30/21 and approximately 3 hours later suffered fatal MI at home."		No prior vaccinations for this event.

	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient expired. Per Emergency MD note: ""This is a 72-year-old male with what sounds like diabetes, atrial fibrillation, and hypertension who presents via EMS in cardiac arrest. It sounds like he received his Covid vaccine last week. Initially he had some mild effects from it. However over the last day or so he has felt very unwell. He apparently called his wife today and told her that he was not feeling well and so she returned home. Shortly thereafter he attempted to get up from his chair. He then collapsed and fell forward onto his face. Sounds like his wife had some difficulty rolling him over to perform CPR. When EMS arrived they found him in PEA. He received a total of 5 rounds of epinephrine. At some point they did have return of spontaneous circulation. However just prior to arriving in the emergency department they lost pulses again. The patient was intubated with an 8 oh endotracheal tube prior to arrival.""""		No prior vaccinations for this event.

FALL	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information	No prior vaccinations for this event.

and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note).	No prior vaccinations for this event.

Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."

	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received the vaccine at an outside healthcare facility on 2/11/21. At approximately 1 pm she screamed out and fell out of her chair. EMS was called and patient was found to be in Vfib. ACLS was performed for approximately 42 minutes prior to arrival at ED. At that time the patient had been pulseless for 25 minutes. Patient received 450 mg of amiodarone, epinephrine x7, sodium bicarbonate x2, and 7 AED shocks. In the ED 3 more doses of epinephrine were given, one more dose of sodium bicarbonate, and 5 additional shocks. ROSC was not achieved and time of death was called at 1416.		No prior vaccinations for this event.

	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident had slight/slow decline in health prior to vaccine but continued to be able to walk around with		No prior vaccinations for

walker at community. The day of the vaccine she had a fever. 2 days after vaccine resident did not get out of bed all day and refused to eat. She had small amounts of orange juice as her blood sugar level was low due to not eating. Resident was diagnosed with a UTI and began an oral antibiotic. 3 days after and on day 5 after vaccine resident began feeling weak and had a fall on each day. The following day again resident spent the day in bed. The next day she was quite restless, was on the edge of her bed attempting to self transfer often throughout the day. Resident continued to be restless on the 10th of Feb, had further decline on the 11th of Feb. Resident passed away early the AM of Feb. 12th.		this event.
	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"The day after the 2nd shot, patient developed blisters on his lips and mouth. The care facility said that he had a nut allergy -- but he had never been allergic to nuts. He stopped eating and drinking and his BP had dropped to 60/40. By Jan 16th they called to say he was dying and he passed away on 1/18/21. Patient had COVID19 from Oct 29th - early November. By Nov 21st he had lost 40 lbs. He was 6'3"" and had gone from 189lbs to 149 lbs with COVID. By Nov 21st when we could visit, he had recovered from COVID, but was very thin and weak. He could not bathroom alone and kept falling. He didn't seem to have a bad reaction to the 1st COVID shot, But he immediately reacted to the 2nd shot and passed away within 6 days."		Shingles - Glaxo 8/22/2020, resulted in hospitalization and LTC.
	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall; fatigued; arm pain; AML; Sepsis secondary to AML; This is a spontaneous report from a contactable consumer. An 88-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EL3249), via an unspecified route of administration on 19Jan2021 17:30 in right arm at single dose for covid-19 immunization. Medical history included hypertension, hyperlipidemia, OA		No prior vaccinations for this event.

(osteoarthritis), cognitive impairment. No other vaccine in four weeks was administrated. Concomitant medication in two weeks included atorvastatin, aspirin, calcium, gabapentin, losartan and memantine hydrochloride (NAMENDA). The patient previously took lisinopril and tetracycline and both experienced allergies. The patient had no covid prior vaccination. The patient initially had no symptoms but arm pain in Jan2021, no bleeding or bruising from injection. On 31Jan2021 19:00, patient felt fatigued. Patient suffered fall on 01Feb2021. She was admitted to hospital. All cell lines were down in Feb2021. She was diagnosed with AML (acute myeloid leukemia) in 2021. She expired 07Feb2021. Events resulted in emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event) and patient died. The patient received the treatment of blood and platelet transfusions, bone marrow biopsy, cytogenetic testing, antibiotics, intubation for events. The patient died on 07Feb2021 due to sepsis secondary to AML. An autopsy was not performed. Outcome of events were fatal.; Reported Cause(s) of Death: arm pain; fatigued; fall; Sepsis secondary to AML; Sepsis secondary to AML

	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Diarrhea , fatigue on 2/10 Fall 2/12 out to hospital Resident Expired 2/14 No prior vaccinations for this event.		
	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death was from natural causes; collapsed; This is a spontaneous report from a contactable consumer. A 73-year-old female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA		No prior vaccinations for

VACCINE), via an unspecified route of administration on 05Feb2021 at 73-years-old at a single dose for COVID-19 immunization. The patient's medical history included chronic obstructive pulmonary disease (COPD) from an unknown date and unknown if ongoing (on oxygen as needed, but not every day), oxygen therapy from an unknown date and unknown if ongoing. Concomitant medications were not reported. The patient previously received the influenza vaccine (MANUFACTURER UNKNOWN) for immunization on unknown dates (Gets flu shot every year around October). On 06Feb2021, the patient collapsed (medically significant) and experienced death was from natural causes (death, medically significant). The clinical course was reported as follows: The reporter stated that his grandmother received the first dose of the Pfizer COVID-19 vaccine on 05Feb2021 and passed away on the morning of 06Feb2021. The patient went to bed and woke up in the middle of the night around 03:00 to use the bathroom and collapsed and died within 10-15 minutes of collapsing. The patient was pronounced dead at the scene. The reporter asked: ""What do you know about the news in the media about reports of death in nursing home elderly patients?"" The reporter wanted to know the ingredients of the Pfizer COVID-19 vaccine. The reporter wanted to know about the use of the Pfizer COVID-19 vaccine in patients with underlying conditions. The patient had COPD and was on oxygen as needed, but not every day. The Medical examiner said the death was from natural causes and the family was not doing an autopsy. The patient had been tested for COVID and was negative. The patient underwent lab tests and procedures which COVID test: negative on an unspecified date. The clinical outcome of the event, death was from natural causes, was fatal. The clinical outcome of the event, collapsed, was unknown. The patient died on 06Feb2021 due to death was from natural causes. An autopsy was not performed. The batch/lot numbers for the vaccine, bnt162b2, were not provided and will be requested during follow up.; Reported Cause(s) of Death: death was from natural causes"	this event.
FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Decedent had unwitnessed fall out of wheelchair 1/25/21 around 9:43am, denied head strike, pain, discomfort. Around 10:02pm, 1/25/21, decedent noted to have slurred speech and fluctuating HR,	No prior vaccinations for this

transported to Hospital and made cmo.		event.
	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt fell within 24 hours after vaccine. was sent to hospital. pt was found to be hypoxic with multifocal opacities on CT scan		No prior vaccinations for this event.
	FALL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received the vaccine around 11 am. He hadn't been feeling well (headache, dizziness) per report and initially called in to work. He then decided to come to work and was found down in a patient bathroom during his shift on our Facility while taking care of a patient (he was a nurse aid). Patient was coded and the team and was transferred to our Facility ED. He expired 3/3 2112		No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident in our long term care facility who received first dose of Moderna COVID-19 Vaccine on 12/22/2020,		No prior vaccinations

only documented side effect was mild fatigue after receiving. She passed away on 12/27/2020 of natural causes per report. Has previously been in & out of hospice care, resided in nursing home for 9+ years, elderly with dementia. Due to proximity of vaccination we felt we should report the death, even though it is not believed to be related.	for this event.
FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Extreme Fatigue No prior vaccinations for this event.	
FATIGUE COVID19 (COVID19 (MODERNA)) (1201)	
1/13/21 pt came into clinic for vaccine. Had difficulty remembering age. Called me Mon. 1/18/21 stating she was sick. When asked what her sx were, she stated fatigue. She was well the night of the shot, Thur. and Fri. but became tired on Sat. and Sun. I went through other sx with her such as h/a, fever, n/v, muscle aches, weakness and she said she experienced none of those. I questioned her about eating and drinking and she said she ate and drank water. She seemed fine so I told her to call her doctor if she was worse or the fatigue persisted or call 911. She agreed. Two staff from clinic called her Mon. and Tues, (1/18 and 1/19). On Tues. she may have had sl slurred speech. She was found deceased on	No prior vaccinations for this event.
FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
My dad got the Moderna Vaccine on Tuesday, January 12, 2021 in his left arm at the Mall injection site for the Health Department. He was told that the side effects could mean his arm hurting, tiredness, headache, and even a low grade fever. Additionally, the site informed us both (as I was with him to get the injection) that this was all normal and not to seek medical attention unless these symptoms last longer than 72 hours. That evening, my dad was experiencing all of those symptoms, and went to bed at 7pm. A little after 10am on Wednesday, January 13, 2021, when he awoke, my dad went to the bathroom vomiting. This was where he	No prior vaccinations for this event.

collapsed and went into cardiac arrest. Fire/Rescue was dispatched about 10:30am after my mom started CPR. County Fire Rescue EMTs and Paramedics continued CPR and other attempts at reviving him all the way to Hospital Emergency Department. He was pronounced dead at 12:14pm on Wednesday, January 13, 2021. We have no doubt my dad, following the instructions of the injection facility, thought he was just experiencing the side effects of the vaccine. He had no chance. Had this injection been done in the RIGHT arm, perhaps he could have recognized the arm numbness being that of an impending heart attack. We really miss Dad. He served this country with distinction for over 50 years, and we believe his country failed him.

FATIGUE

COVID19 (COVID19 (MODERNA)) (1201)

Fever Feeling tired short of breath all night and morning after the vaccine My grandma had to be intubated and then passed away to a heart distress we think it was the vaccine because she was fine even with dialysis. When she got the vaccine it took hours and her health conditions changed.

No prior vaccinations for this event.

FATIGUE

COVID19 (COVID19 (MODERNA)) (1201)

"Pt. woke up the next morning after vaccination and ""didn't feel well"", described by wife as fatigue, no energy. At approximately 2 PM, he vomited. His wife checked on him at 4:20 PM and he wasn't breathing sitting in his chair. EMS squad was called but when they arrived he was asystole and mottling present. Did not start CPR since he was already gone too long. Pronounced by coroner on scene."

No prior vaccinations for this event.

FATIGUE

COVID19 (COVID19 (MODERNA)) (1201)

Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out

No prior vaccinations for this event.

bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.

FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.	No prior vaccinations for this event.
FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Got vaccine on 1/15/21. He was tired right away, bedridden the next 3 days. He couldn't breathe so he was taken by ambulance on 1/18/21. He was in hospital for several days. put on remdesivir cocktail for 10 days. Slowly getting worse and died in hospital on 1/30/21.	No prior vaccinations for this event.
FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021and felt poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as	No prior vaccinations for this event.

indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM CHLORIDE 1000 MG ONCE

FATIGUE		**COVID19 (COVID19 (MODERNA)) (1201)**
Death Narrative: Patient received the first COVID-19 dose on 12/23. Afterwards, patient complained of localized pain on L deltoid area where the vaccine was administered; his temperature was 98.1 F. On 12/26-27, staff reported that patient appeared more fatigued than usual and was shivering on 12/27, which seized after blanket was given. On 12/28, patient presented with fever (Tmax 100.2 F) and acetaminophen was administered for alleviation of fever. ADR was reported for the fever on 12/29. Patient continued to decline and was placed back on hospice care on 12/29; on 12/30. the symptoms reported on nursing note include erythema and pain on whole L arm. Lidocaine was applied. Patient's family and provider mutually agreed not to administer the second dose of vaccine. He continued to decline and was started on end-of-life care around 1/4 and passed on 1/20 1417.		No prior vaccinations for this event.

FATIGUE		**COVID19 (COVID19 (MODERNA)) (1201)**
The patient, who was a pharmacist, developed fatigue and shortness of breath hours after receiving vaccine. Two days later, on 01/28/2021, the patient went to local urgent care for worsening shortness of breath and was referred to Hospital for worsening dyspnea and hypoxia. The patient was admitted to the hospital We was found to have bilateral pulmonary infiltrates and treated for pneumonia with Rocephin and azithromycin. He was tested for COVID-19 multiple times, but each of the results were negative. Despite the negative results, there was high clinical suspicion for COVID-19 and the patient was started on Remdesivir and		No prior vaccinations for this event.

Decadron. The patient's oxygen requirements continued to worsen and the patient was transferred to another facility for higher level of care. There his hypoxia worsened and he required mechanical ventilation. Patient then developed hypotension and required vasopressors for blood pressure support. Furthermore, patient developed acute renal failure requiring hemodialysis. Despite mechanical ventilation with FiO2 100%, and for vasopressors, patient clinically deteriorated and family decided to palliatively extubate on 02/05/2021.

FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to emergency room on 2/1/2021 with a chief complaint of having a chronic headache and fatigue following receipt of the Moderna vaccine 10 days prior. Following examination by the physician, the patient was diagnosed with an acute subdural hematoma. The patient subsequently underwent decompressive surgery, however demonstrated worsening neurologic status over the next several days and ultimately expired on 2/4/2021.	No prior vaccinations for this event.
FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Within a few days, my mother started reporting profound fatigue and shortness of breath while conducting routine household activities. She no longer had to energy for her daily exercise walks and became increasingly lethargic. She died in her sleep while taking an afternoon nap on Thursday, February 4th. I am highly concerned this could be a vaccine related.	No prior vaccinations for this event.
FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received his second dose of Moderna COVID vaccine on 2/6 at 12:40PM. Patient was observed for 15 minutes post-vaccination with no adverse events. On the evening of 2/6 (time unknown) the patient began to develop dry cough and fatigue. He was checked by a physician at that time (who was a family member).	No prior vaccinations for this event.

Patient continued to feel unwell into Sunday. His lungs were clear when checked Sunday afternoon (time unknown). At approximately 5:30pm on 2/7 the patient began experiencing sudden onset shortness of breath. A pulse ox was conducted at that time and it was 92%, and again shortly thereafter and it was 90% (as reported by family member). 9-1-1 was contacted at this time. CPR was initiated when he arrived at the emergency department, pulse ox was 60% (as reported by family member). The patient passed away shortly thereafter on 2/8/2021.

FATIGUE

COVID19 (COVID19 (MODERNA)) (1201)

1-2 days after vaccine, pt developed weakness, fatigue, body aches, nausea, headache and poor appetite. Pt was admitted to the hospital on 2/5/21 and death occured on 2/6/21

No prior vaccinations for this event.

FATIGUE

COVID19 (COVID19 (MODERNA)) (1201)

Patient texted a friend on 2/7/2021 c/o arm pain and feeling tired. I don't know if he was taken to a hospital. Autopsy today.

No prior vaccinations for this event.

FATIGUE

COVID19 (COVID19 (MODERNA)) (1201)

"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."

No prior vaccinations for this event.

	FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Feb 8 states she had a cold. Feb 9 added stomach ache and nausea. Feb 9 visited urgent care facility for exam and Covid-19 test. Rapid test results were negative. Appeared tired but fine. Told to go home and rest. Feb 10 at 9:00 am found dead on the floor in pool of blood and aspirated. Excessive blood in toilet, pooled on floor and hallway rug.		No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received COVID19 vaccine at clinic at 11:52 am, discharge post treatment stable. Got home around 2:30 pm went to bed. He usually got tired post dialysis. He did not wake up at 6 pm. His wife went check on him. found patient cold and unresponsive. 911 pulseless PEA. ER Medical hospital. Pronounced death at 7:40 pm		No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
extreme fatigue. could not awaken for more than few seconds. When briefly awake she was coherent and not confused. slept deeply from 4pm and could not wake to eat or drink. No fever, bp normal, blood oxygen ok. Blood sugar at 11pm was 230. Gave her 15u lantus at 11pm (normally 25u). Was sleeping at 2:30am but had died at next check at 3:30am.		No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
I video chatted with her Thursday after receiving the vaccine. My mom was in poor health but she was talking in complete sentences and responded appropriately. She was upright in bed and made eye contact. She		No prior vaccinations

smiled and denied pain. By Sunday, she was extremely weak and unable to sip water with a straw. Her health had changed dramatically and rapidly. She moaned in pain and was very fatigued. Her condition continued to deteriorate over the week and she stopped talking and was constantly sleeping. They started antibiotics for the oozing cancer lesion and then morphine for pain and end of life care. She passed away on January 22nd which was 15 days post vaccination.	for this event.	
FATIGUE		**COVID19 (COVID19 (MODERNA)) (1201)**
2/10: Fever, fatigue, tylenol 2/11 @ 1300: pt made DNR, hospice consulted 2/11 @ 1800 decreased LOC, increased RR, fever, chills - 1/5L NS bolus IV, rectal tylenol. Refusing to eat/drink, PO morphine 2/12 @ 16:30, deceased at facility **resident was not doing well prior to vaccination	No prior vaccinations for this event.	
FATIGUE		**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away; tired; nonresponsive; cold; difficulty breathing; swelling; sore arm; feeling weird and funny; A spontaneous report (United States) was received from a consumer concerning a 63 year old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and the patient experienced limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal and the patient passed away . Medical history included treatment for tuberculosis and dialysis. Concomitant medication included calcium acetate, Renvela, glipizide, omeprazole, aspirin, vitamin D, losartan, furosemide, rifampin, and Sensipar. On 14 Jan 2021, the patient received the first of their first planned doses of mRNA-1273 (lot number 030L20A) for prophylaxis of COVID-19 infection. On 13 Jan2021, the patient tested negative for COVID-19). On 16 Jan 2021, the patient experienced a sore arm, and feeling weird/funny. On 17Jan2021, the patient experienced difficulty breathing and swelling. On 18 Jan 2021, the patient declined dialysis, was tired and wanted to lay down. At 8 am, the patient was found nonresponsive and cold and is believed to have passed away around 4 am. The coroner tested the deceased for COVID-19 and the test was positive. No	No prior vaccinations for this event.	

autopsy was reported. No death certificate was issued at the time of the report but the reporter believes it will list cause of death as COVID complications. Action taken with the mRNA-1273 was not applicable. The outcome of the events of limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal, was fatal. On 18 Jan 2021, the patient was died. Cause of death was COVID-19. Autopsy details were not provided.; Reporter's Comments: The events developed on four days after first dose of mRNA-1372. Dyspnea, unresponsive to stimuli, and death were consistent with infection in pandemic set up confounded by age of patient and refusal of dialysis Cause of death was reported as COVID-19. Autopsy details were not provided. Based on reporter's causality the events are assessed as unlikely related to mRNA-1273.; Reported Cause(s) of Death: COVID-19

FATIGUE

COVID19 (COVID19 (MODERNA)) (1201)

Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am

No prior vaccinations for this event.

unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

FATIGUE	COVID19 (COVID19 (MODERNA)) (1201)
Patient felt fine on Friday afternoon and evening after shot. Felt fine on Saturday until the afternoon when she started feeling fatigued and chilled. Decided to take a warm bath at about 6pm. Was found dead in bathtub at approximately 7pm with blisters on arms, legs, and face.	No prior vaccinations for this event.

FATIGUE	COVID19 (COVID19 (MODERNA)) (1201)
High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had	No prior vaccinations for this event.

profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

	FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was transferred from hospital for further evaluation and care by pulmonologist. He started having symptoms a week before with fatigue, emesis, decreased p.o. intake, shortness of breath, vomiting and diarrhea. The two previous takes before death required increasing oxygen and family wanted everything done including intubation. He was transferred to ICU.		No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Fever, chills, fatigue, muscle aches, nausea, death 48 hours after injection		No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
"Possible heart attack on 2/5/21. Complaint: "" On Feb 5th I believe I experienced a mild hear attack"" (Comment: He said he felt ""clammy, sweaty, excruciating pain on my left side - including his left arm, and left leg, dizzy, exhausted."" This happened after work, and after taking a shower. He said that was the first time he's experienced it, and that it has not happened since then. He said he has constant headaches, ""It just went away yesterday.""""		No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19**

	(MODERNA)) (1201)
2-24-21 patient with development of cough, fatigue, increasing on chronic disability worsening debility and falls. scheduled for office visit 2-25.21 0900 call from spouse 0210 am patient was not breathing and lvad alarming low flow alarm on arrival of ems confirm asystolic not breathing and dead	No prior vaccinations for this event.
FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation	No prior vaccinations for this event.
FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
approximately 24 hours post vaccine Patient developed a low grade fever of 99.5 and had increased fatigue. 48 hours later she had decreased neurological functioning. 02/23 she had difficulty swallowing. 02/23 She was admitted to hospice services. 02/26 she passed just before 10 am.	No prior vaccinations for this event.
FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Beginning in the evening 2/19/21, fever/chills/fatigue; worsening of symptoms 2/20/21 with lethargy/lack of appetite/weakness; unable to arouse on 2/21/21 then breathing stopped, patient's spouse called 911	No prior vaccinations

performed CPR, EMS continued for 15 min then while in ambulance to hospital where he was pronounced dead. Official time of death 2:20pm		for this event.
	FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Blood pressure went down until he died; Couldn't hear his heartbeat; neck was sweating; He was cold; Couldn't get up; Death; Sick; immediately very tired; he was tired; Hands were shaking; Slept for too long; A spontaneous report was received on 18 Feb 2021 from a consumer concerning a 81-years-old, male patient who received Moderna's COVID-19 vaccine and developed immediately very tired, hands were shaking, neck was sweating, was cold, sick, couldn't get up, couldn't hear his heartbeat and blood pressure went down until he died. Patients' medical history, as provided by patient's spouse, was emergency room(ER) admission in November 2020 because he had a congested chest (he had fluid around his heart). At that time, they gave him pills for kidney function. Other concomitant medication reported was Coumadin, blood thinner. Two weeks before receiving the vaccine, patient's EKG was normal. On 11 Feb 2021, in the morning, patient received their first of two planned doses of mRNA-1273(BATCH/LOT # 007M20A) probably in the right arm for the prophylaxis of COVID-19 infection. On 11 Feb 2021, approximately after 15 minutes of receiving vaccine, they left and patient was immediately very tired, his hands were shaking. So, patient's spouse made them down sleep for too long. On Friday, 12 Feb 2021 she tried to pick him up, but he was tired, exhausted, and sick. On Saturday, 13 Feb 2021, she brought him a coffee and he couldn't hold it because his hands were shaking, so she gave him the coffee and then made him pee on the bed because he couldn't get up. At lunch time she made him eat something and he fell sleep again. His wife was hanging around him all day and around 7:30pm she realized that he was cold, and his neck was sweating, she couldn't hear his heartbeat. So, she called emergency services and when they arrived, her husband's blood pressure went down until he died. Treatment for the events were not provided. Action taken with mRNA-1273 was not applicable. Patient was pronounced dead on 13 Feb 2021 20:00. The cause of death was not provided. The plans for an autopsy were not provided. The events of blood pressure went down until he died and couldn't hear his heartbeat were fatal. The outcome for the remaining events were unknown.; Reporter's Comments: This case concerns an 81 year		No prior vaccinations for this event.

old, male patient, who experienced a serious event of death among others, 2 days after receiving mRNA-1273 (Lot# 007M20A). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

FATIGUE	**COVID19 (COVID19 (MODERNA)) (1201)**
Chills; headache; extreme fatigue; gas or chest pain that was thought to be gas and went away Died 4 days later	No prior vaccinations for this event.

FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"The resident received is vaccine around 11:00 am and tolerated it without any difficulty or immediate adverse effects. He was at therapy from 12:36 pm until 1:22 pm when he stated he was too tired and could not do anymore. The therapist took him back to his room at that time and he got into bed himself but stated his legs felt heavy. At 1:50 pm the CNA answered his call light and found he had taken himself to the bathroom. She stated that when he went to get back into the bed it was ""abnormal"" how he was getting into it so she assisted him. At that time he quit breathing and she called a RN into the room immediately. He was found without a pulse, respirations, or blood pressure at 1:54 pm. He was a DNR."	No prior vaccinations for this event.

FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home	No prior vaccinations for this event.

she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.

	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021	No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Family was told that Patient expired in his sleep during the early morning hours of 1/15. I spoke with him the evening before (on 1/14), which was a day after he had received the Covid vaccine. He was not having any symptoms of allergy or reaction then. He did say that he felt tired, but he often complained of feeling tired over time.	No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	tired; legs felt heavy; stopped breathing; This is a spontaneous report from a Pfizer-sponsored program a non-contactable consumer. A 93-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 11:00 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Patient received vaccine around 11:00 a.m. About two hours later, he said he was tired and couldn't continue with the	No prior vaccinations for this event.

physical therapy he was doing. He was taken back to his room, where he said his legs felt heavy. Soon after, he stopped breathing. A nurse declared a do-not-resuscitate order. The patient died on 04Jan2021. It was not reported if an autopsy was performed. Outcome of stopped breathing was fatal. Outcome of tired and legs felt heavy was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: stopped breathing		
	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Admitted 1/14/21: Patient is an elderly 93-year-old female with multiple medical problems including chronic combined CHF, P 80, diabetes mellitus, HTN, hyperlipidemia, CKD stage 3, has been complaining of generalized weakness, fatigue, decreased appetite for the past few days. She had an outpatient COVID-19 vaccine earlier today. Within 2 hr of admitting the patient to the hospital, condition clinically deteriorated. Patient elected to be DNR/DNI while in the ED. Patient was pronounced dead at 10:30 p.m. earlier today. Preliminary cause of death: Hypoglycemia induced lactic acidosis.		No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21		No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

loss of consciousness; respiratory distress Narrative: Patient tolerated his 1st dose of the COVID-19 vaccine well, on 12/16/2020, and received his 2nd dose on 1/6/2021. Patient had some mild clinical decline the past few days prior to 2nd vaccination, with a decreased appetite and some increased fatigue per nursing report, but no significant changes. He experienced nausea on the evening of 1/6/21, which was effectively managed, but by early morning he spiked a fever of 102.9 with a sat of 86.1%. He continued to deteriorate from that point on and died 1/7/21 @13:20. Clinically, the presentation was most consistent with an aspiration pneumonia.

No prior vaccinations for this event.

FATIGUE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Fatigue, muscle aches, vomiting, hematoma No prior vaccinations for this event.

FATIGUE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

family states seemed short of breath since after the covid vaccine. Staff said beginning on 1/22/21 the patient seemed sluggish, more tired, and nausea noted. She stayed in her room more after the vaccine because worried about giving/getting COVID to others. was talking on the phone at 11:30 PM on 1/26/21 to staff person about temperature of room. at 12:15 AM on 1/27/21 staff noted not breathing, started CPR and called EMS. When EMS arrived they stopped the code because she was too long deceased.

No prior vaccinations for this event.

FATIGUE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

The next morning after vaccine, patient ran a fever, vomited, and was very tired. Mom laid her

No prior vaccinations for this

down to sleep and when she checked later, patient had passed away.		event.
FATIGUE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
fatigue x 5 days, including day of vaccination, death the night of day 5/early morning of day 6		No prior vaccinations for this event.
FATIGUE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My father was in weak condition to begin with. He didn't get out of bed for the next few days after receiving the vaccine. The little amount that he ate was consumed in bed. He began aspirating his food which lead to pneumonia. He wasn't strong enough to fight off the pneumonia even with antibiotics. He died on 1/23/21. While he might have passed soon in any case, I believe that the vaccine may possibly have increased his weakness/exhaustion thereby hastening his demise.		No prior vaccinations for this event.
FATIGUE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom received the Covid 19 vaccine on Jan 5, 2021 and became very about a week later. I was informed that she tested positive for Covid 19 on January 14th. One January 17th she became very tired and weak and would not eat. Hospice called me and told me that she was in a decline state. I saw her on January 25 and 26 and she was just sleeping and could not open her eyes. Her vitals were good and she seemed to understand when I talked to her - she would squeeze my hand and moan but she could not talk or open her eyes. My mom passed away on January 27, 2021 just 22 days after receiving the Covid 19 vaccine. She was very think to begin with and being to weak and tired to eat resulted in her losing even more weight. Some of the other residents were given fluids to help and they recovered. My mom was not		No prior vaccinations for this event.

given fluids. I believe there were 20 deaths in her care home for the month of January when they vaccinated. This was an alarming number of deaths for the home. The facility had very few Covid deaths in 2019 and 2020. I asked every week if they had any Covid and or Covid deaths and this amount was shocking to me and the workers there.

	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Early in the shift on January 31 resident was noticed to be more tired than usual and was not eating well. Lung sounds were crackly and resident was found to be hypotensive. He was evaluated in emergency department. He was diagnosed with pneumonia. Received a loading dose of antibiotic and returned to facility.		No prior vaccinations for this event.

	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated at 11:30am. By 7pm he started presenting symptoms of fatigue, chest pain. Patient urinated and defecated in himself. Was not feeling well. Patient died at 10:30pm.		No prior vaccinations for this event.

	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was weak, fatigued and had a fever of 101. F the following morning after receiving the 2nd dose of vaccine. Later in the day she was feeling better and vital signs were WNL. The next morning, she was found unresponsive and pronounced dead by paramedics.		No prior vaccinations for this event.

	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver failure, pneumonia, and DIC>"		No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client was administered the vaccine while symptomatic (01/25/21) although client did not know he was symptomatic for COVID-19. He had been exposed to a family member who had tested positive and should have been in quarantine but wasn't either because it was not felt he was considered a close contact by his family opinion or his family member never notified public health of this close contact...?. Clinet had presented to the ED following day after vaccination for shortness of breath and fatigue and an antigen test showed he was positive for COVID-19. He was sent home that same day 01/26/21. He was back in ED on 01/28/21 for worsening symptoms and admitted to hospital and later placed on ventilator. He passed away on 02/09/2021 (date of death was per his wife).		No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer Covid Vaccine in the AM on 2/9/21. Arrived to emergency department later the same		No prior vaccinations for this

day complaining of nausea, weakness, fatigue, Vomiting, Diarrhea. Post operative diagnosis, Ischemic colon/toxic megacolon. event.

	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	On December 17, 2020, my husband, received his first BioNTech BNT162b2 COVID-19 vaccination. On Thursday January 7, 2021, he received this second COVID-19 vaccination. The following three days after his second vaccination, he felt fine. The fourth day, on Sunday January 10, my husband felt extremely fatigued. On Monday the 11th and Tuesday the 12th, he worked a full shift but complained of extreme fatigue and extreme chills to the point that his teeth were chattering while on the phone with me. He decided to work through it. When he got home on Monday night, he started vomiting. On Wednesday January 13, he woke up and had swollen eyes. Once again, he felt extremely fatigued, even after a full nights rest. He had the day off but had an early meeting. After his meeting, he was still tired so he went back to sleep. I left to get lunch, and drop off our kids, and upon my return, I found him on the walk in closet floor, face up, having passed away. He felt as cold as ice. The rapid test done after they called the paramedics resulted in a negative COVID-19 test for him.	No prior vaccinations for this event.

	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Patient (now deceased) received 1st dose of Pfizer-BioNTech vaccine around December 21, 2020 and was noticed to be scratching, fatigued, and unresponsive by a family member on December 24, 2020. He received the second dose of the same vaccine around January 22, 2021. Pockmarks and bleeding scratch marks were noted by a family member on the patient's face prior to this second dose. On January 28, 2021 a family member was alerted that the patient was suffering from severe bullous pemphigoid- a skin	No prior vaccinations for this event.

condition that has never been experienced by the patient, has been reported to be related to COVID-19 viral infection, and to T-cell responses promoted by vaccines. A corticosteroid was given, but did not work. Blisters developed to the point hands had to be dressed.

	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/4/21, at around 3:00pm he began feeling very tired and he began burping in the evening. The following morning, he woke up early and was still burping and not feeling well. At around 5:00am, he collapsed. My mother called 9-1-1 and began giving CPR. The parademics arrived and tried to revive him, and transported him to the hospital but at 6:11am, he was pronounced dead of a heart attack. He was healthy.		No prior vaccinations for this event.
	FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall; fatigued; arm pain; AML; Sepsis secondary to AML; This is a spontaneous report from a contactable consumer. An 88-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EL3249), via an unspecified route of administration on 19Jan2021 17:30 in right arm at single dose for covid-19 immunization. Medical history included hypertension, hyperlipidemia, OA (osteoarthritis), cognitive impairment. No other vaccine in four weeks was administrated. Concomitant medication in two weeks included atorvastatin, aspirin, calcium, gabapentin, losartan and memantine hydrochloride (NAMENDA). The patient previously took lisinopril and tetracycline and both experienced allergies. The patient had no covid prior vaccination. The patient initially had no symptoms but arm pain in Jan2021, no bleeding or bruising from injection. On 31Jan2021 19:00, patient felt fatigued. Patient suffered fall on 01Feb2021. She was admitted to hospital. All cell lines were down in Feb2021. She was diagnosed		No prior vaccinations for this event.

with AML (acute myeloid leukemia) in 2021. She expired 07Feb2021. Events resulted in emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event) and patient died. The patient received the treatment of blood and platelet transfusions, bone marrow biopsy, cytogenetic testing, antibiotics, intubation for events. The patient died on 07Feb2021 due to sepsis secondary to AML. An autopsy was not performed. Outcome of events were fatal.; Reported Cause(s) of Death: arm pain; fatigued; fall; Sepsis secondary to AML; Sepsis secondary to AML

FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Diarrhea , fatigue on 2/10 Fall 2/12 out to hospital Resident Expired 2/14 No prior vaccinations for this event.

FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Light headedness, fatigue, nausea No prior vaccinations for this event.

FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease	No prior vaccinations for this event.

progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or

if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

FATIGUE

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Patient was found with no pulse no heart rate by a staff member around 11 pm. Earlier that day seen by myself for fatigue, sorethroat, nausea.

No prior vaccinations for this event.

FATIGUE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

02/07/21 through 2/13/21 slightly fatiqued, took all his prescribed medications, ate breakfast, lunch and dinner was drinking eight 10 oz bottles of water. On 02/14/21 was very tired had a difficult time breathing after taking the normal meds. He took a breathing treatment with his prescribed Ipratropium Bromide and Albuterol Sulfate via home nebulizer. This did not improve his breathing. He was very weak and breathing was labored. 911 was called by wife. 911EMTchecked pulse and breathing. Informed him they would give him a breathing treatment.He started to go limp. EMT's got him to Ambulance and to Medical Center to the ER. Heroics done. He died. Pulmonary and Cardiac Arrest

No prior vaccinations for this event.

FATIGUE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Patient felt achy, tired starting the day after the vaccine. Per his wife, he was very tired and ""losing stamina"". On 2/13/21, he woke up feeling dizzy and weak. His wife asked him if he wanted to go to the doctor and he declined. He ate breakfast and went to rest in his easy chair. He passed away an hour later."

No prior vaccinations for this event.

FATIGUE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Extreme Fatigue, slurring speech, unable to stand, eat. Death on 2/5/21 No prior vaccinations for this event.

FATIGUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Patient had declining health for the past 6 months, dementia and unable to walk. Patient had decreased appetite starting 1/1/21. After 1st vaccine shot patient appetite decreased further. After 2nd vaccine shot patient fatigue increased to the point where she could not get out of bed and had minimal appetite. Patient passed away 10 days after receiving 2nd shot on 2/22/21. Patient did not go to ED and was not hospitalized.		No prior vaccinations for this event.

FATIGUE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Possible Stroke per Medical examiner but Reported symptoms after covid vaccine 2/11 therefore being considered poss Covid vaccine related also. No hospitalization prior to death. (Symptoms reported to office 2/17) Fatigue, decreased appetite-		No prior vaccinations for this event.

FATIGUE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On date on second dose, 2/27/2021, the pt began have fatigue and diarrhea at around 10:30 am. This continued to the following day. On 2/28/2021, the patient was last seen around 4:20 pm by his wife in their residence. She found him unresponsive at 5:30 pm in their bedroom. EMS was called and the decedent was declared deceased. The pt had his first dose on 2/9/2021. Both doses were given at the hospital. Per family, the pt had no adverse affects following the first dose.		No prior vaccinations for this event.

FATIGUE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
1. Fatigue ? day 1 - Tuesday 2. Loss of appetite ? day 1 Tuesday 3. Fever 102.0 ? day 2 - Wednesday 4. Chills ? day 2 - - Wednesday 5. Weak ? day 2 - - Wednesday 6. Non-ambulatory (unusual) ? day 2 - - Wednesday 7. Two emergency service ambulance assessment ? day 2 - - Wednesday 8. Symptoms improved ? day 3 - Thursday 9. Ambulatory - day 3 - Thursday 10. Symptoms worsened ? day 4 - Friday 11. Chills ? day 4 - Friday 12. Non-ambulatory again ? day 4 - Friday 13. Fever 102.0 ? day 4 - Friday 14. Left side flank pain ? day 4 - Friday 15. CPR and declared decease at home by paramedics - day 5 - Saturday morning @ 1:32am	No prior vaccinations for this event.

FATIGUE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
blood clot; death cause: Heart Problems; tired; nauseous; This is a spontaneous report from a contactable consumer. An 81-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number EL3248), via an unspecified route of administration at single dose in the left arm on 19Jan2021 14:00 for covid-19 immunisation. Medical history included heart problems, pacemaker. Concomitant medication included heparin. The patient experienced death cause: heart problems on 20Jan2021, blood clot on an unspecified date with outcome of unknown that required hospitalization, tired on 19Jan2021 with outcome of unknown, nauseous on 19Jan2021 with outcome of unknown. The patient was hospitalized for blood clot from 16Jan2021 to 18Jan2021. The patient died on 20Jan2021. An autopsy was not performed. The events were described as follows: The patient was tired and nauseous about 3 hours after her vaccine. She had been in the hospital 16Jan2021 to 18Jan2021 for a blood clot. The patient died at her home on 20Jan2021 between 4 and 7 pm. No treatment required. The vaccine was administered at Hospital Facility. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the	No prior vaccinations for this event.

patient had not been tested for COVID-19.; Reported Cause(s) of Death: death cause: Heart Problems

	FEEDING DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received vaccine on 1/4/2021. He was in Hospice for CHF and renal failure, but was able to get up in his wheelchair and eat and take medications and talk. On 1/5/2021 am, he was noted to be very lethargic an could only mumble, could not swallow. No localizing neurologic findings. He was too lethargic to get up in chair.		No prior vaccinations for this event.
	FEEDING DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
On the evening of 10JAN2021, patient experienced a low grade fever, decreased oxygen saturation of 38%, heart rate of 124, confusion. Patient received oxygen via face mask, morphine and ativan. By 11JAN2021, patient was no longer verbal, able to eat or communicate and was kept on comfort measure only. On the morning of 17JAN2021, the patient passed away.		No prior vaccinations for this event.
	FEEDING DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
I video chatted with her Thursday after receiving the vaccine. My mom was in poor health but she was talking in complete sentences and responded appropriately. She was upright in bed and made eye contact. She smiled and denied pain. By Sunday, she was extremely weak and unable to sip water with a straw. Her health had changed dramatically and rapidly. She moaned in pain and was very fatigued. Her condition continued to deteriorate over the week and she stopped talking and was constantly sleeping. They started antibiotics for the oozing cancer lesion and then morphine for pain and end of life care. She passed away on January 22nd which was 15 days post vaccination.		No prior vaccinations for this event.

	FEEDING DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient tested positive for COVID-19 on 1/8/21. She demonstrated a decline in appetite and the ability to feed herself d/t this illness, but no respiratory or other symptoms. She received COVID-19 vaccine #2 on 1/26/21. She demonstrated an SDTI wound to the Lt. heel on 1/27/21. On 1/31/21 she was noted to have a significant weight loss. She was admitted to services on 2/1/21 with comfort care orders. On 2/2/21 she was observed to be without vital signs. Orders were for DNR, and CPR was not initiated in accordance with that order. She was pronounced dead at 0112 on 2/1/21.		No prior vaccinations for this event.

	FEEDING DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom received the Covid 19 vaccine on Jan 5, 2021 and became very about a week later. I was informed that she tested positive for Covid 19 on January 14th. One January 17th she became very tired and weak and would not eat. Hospice called me and told me that she was in a decline state. I saw her on January 25 and 26 and she was just sleeping and could not open her eyes. Her vitals were good and she seemed to understand when I talked to her - she would squeeze my hand and moan but she could not talk or open her eyes. My mom passed away on January 27, 2021 just 22 days after receiving the Covid 19 vaccine. She was very think to begin with and being to weak and tired to eat resulted in her losing even more weight. Some of the other residents were given fluids to help and they recovered. My mom was not given fluids. I believe there were 20 deaths in her care home for the month of January when they vaccinated. This was an alarming number of deaths for the home. The facility had very few Covid deaths in 2019 and 2020. I asked every week if they had any Covid and or Covid deaths and this amount was shocking to me and the workers there.		No prior vaccinations for this event.

FEEDING DISORDER **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Extreme Fatigue, slurring speech, unable to stand, eat. Death on 2/5/21 No prior vaccinations for this event.

FEELING ABNORMAL **COVID19 (COVID19 (MODERNA)) (1201)**

Started with cough, mild shortness of breath and feeling terrible in evening of 1/19. No prior vaccinations for this event.

FEELING ABNORMAL **COVID19 (COVID19 (MODERNA)) (1201)**

"Patient is reported to have died at home, the day after his COVID test. Family member states that he did good the afternoon and evening after his COVID-19 injection, but that he started not feeling good the next day. The patient ""was having palpitations"". The family tried to convince him to go to the Emergency Room, but he refused. Patient died at home." No prior vaccinations for this event.

FEELING ABNORMAL **COVID19 (COVID19 (MODERNA)) (1201)**

Patient recieved vaccine 1 of covid 19 i 1/19/2021. She felt poorly on 1/20/2021. She felt dizzy and fell at 3 AM on 1/23/2021. She felt poorly and did not know her son's name which was not normal. She went to ER on 1/24. She was assessed as not having fractures. She was going to be transferred to a skilled nursing facility. She was not having respiratory complaints. She was awaiting transfer when her O2 levels started dropping substantially. She declined aggressive intervention and she died within a few hours. No prior vaccinations for this event.

FEELING ABNORMAL **COVID19 (COVID19 (MODERNA)) (1201)**

Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021and felt poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM CHLORIDE 1000 MG ONCE

No prior vaccinations for this event.

FEELING ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."

No prior vaccinations for this event.

FEELING ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

covid shot 2/2; feel bad 2/5; covid positive diagnosis - 2/8 s/s cough, fever, shortness of breath , hypertension, afib (in er) - admitted went into DIC per intensivist 2/11 patient died

No prior vaccinations for this event.

FEELING ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Passed away; tired; nonresponsive; cold; difficulty breathing; swelling; sore arm; feeling weird and funny; A spontaneous report (United States) was received from a consumer concerning a 63 year old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and the patient experienced limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal and the patient passed away . Medical history included treatment for tuberculosis and dialysis. Concomitant medication included calcium acetate, Renvela, glipizide, omeprazole, aspirin, vitamin D, losartan, furosemide, rifampin, and Sensipar. On 14 Jan 2021, the patient received the first of their first planned doses of mRNA-1273 (lot number 030L20A) for prophylaxis of COVID-19 infection. On 13 Jan2021, the patient tested negative for COVID-19). On 16 Jan 2021, the patient experienced a sore arm, and feeling weird/funny. On 17Jan2021, the patient experienced difficulty breathing and swelling. On 18 Jan 2021, the patient declined dialysis, was tired and wanted to lay down. At 8 am, the patient was found nonresponsive and cold and is believed to have passed away around 4 am. The coroner tested the deceased for COVID-19 and the test was positive. No autopsy was reported. No death certificate was issued at the time of the report but the reporter believes it will list cause of death as COVID complications. Action taken with the mRNA-1273 was not applicable. The outcome of the events of limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal, was fatal. On 18 Jan 2021, the patient was died. Cause of death was COVID-19. Autopsy details were not provided.; Reporter's Comments: The events developed on four days after first dose of mRNA-1372. Dyspnea, unresponsive to stimuli, and death were consistent with infection in pandemic set up confounded by age of patient and refusal of dialysis Cause of death was reported as COVID-19. Autopsy details were not provided. Based on reporter's causality the events are assessed as unlikely related to mRNA-1273.; Reported Cause(s) of Death: COVID-19

No prior vaccinations for this event.

FEELING ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient previously had dizzy spills, but about a week after receiving the vaccine her dizzy spills began to get worse. The whole prior she kept saying I am just not right. On the 2/7/21 she a COVID test done, a nurse came to her house and preformed. On the morning of the 8th patient was on the phone with someone else

No prior vaccinations for this event.

and patient asked this person to call me and go check on her. Within 5 minutes I was over at her house, and I found her on the floor, she on her belly facedown. It looked like she was on the toilet, and it looked like she fall getting her off, she was still wet, she still felt warm. I called the ambulance and immediately began CPR. When EMS arrived they took over the CPR and transported her to the Hospital. The EMS was there for about 40 minutes and used an machine to preform the compressions. She was pronounced deceased at the hospital. No autopsy was done.

FEELING ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

"My grandpa had a stroke on the 15th of February. He claimed he had been feeling ""off"" for a few days, but didn't say anything. A blood clot had formed in his brain. He was doing better and about to go to rehab to strength his right side of his body. On the 22nd he took a turn for the worst. He was having trouble breathing and they sedated and partially paralyzed him to put a tube in his mouth. I believe another blood clot had formed and oxygen wasn't properly going through his body. They could not stabilize him, and he passed away the same day."

No prior vaccinations for this event.

FEELING ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

My grandpa got his second covid vaccine on Thursday. Saturday he complained of stiff neck. Sunday he had low grade fever, nausea and vomiting, chills, and mild headache. He was feeling bad enough to call squad at 3 pm. The paramedics did evaluation and thought he was just experiencing normal side effects from vaccine and felt no need to transport to hospital so my grandpa decided to stay home and just rest. At 2 am that same night he went into cardiac arrest and was not able to be brought back

No prior vaccinations for this event.

FEELING ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

"83yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, the patient reportedly got up in the middle of the night with c/o feeling ""blah"", restlessness, and nausea. VS normal, no other s/sx. At 4:15am, the patient was asked to go back to bed, assisted by a nurse and GNA. At 6am, GNA was going to do morning VS and found the patient unresponsive, no pulse, no respirations. GNA notified the nurse. At 6:03am, CPR started and EMS called. At 6:15am, EMS arrived and took over. At or around 6:30am, EMT called time of death"

No prior vaccinations for this event.

FEELING ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30

No prior vaccinations for this event.

minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."

	FEELING ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt son, reports patient passed away on 2/1/21 in the early hours. Pt wife, told Pt's son that patient started feeling ""bad"" with common cold like symptoms on 1/31/21, had a temp of 99.0. Pt's wife went to take a shower, when she got out patient was unresponsive. She called EMS, they pronounced patient deceased upon arrival. á Pt's son also reports patient and Pt's wife both had their 1st COVID-19 vaccine 13 days prior. He was told by EMT on sight to notify the facility where they received their vaccines. He did contact them and was told to notify PCP."		No prior vaccinations for this event.
	FEELING ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received the 2nd dose of the Covid vaccine approximately around 1105 by pharmacy through the pharmacy LTC partnership vaccination program. Resident had no adverse effects until around 8:00 pm she began complaining of body aches, and chills, Tylenol was given at this time. Around 9:30pm resident was sleeping in bed. Around 12:00 am the CNA called nurse into room to assess resident as the resident stated she did not feel good. Temperature at that time was 102.2, and vomiting. RN came to assess @ 1220 am She was noted to be vomiting, diaphoretic, pale and having trouble breathing. Temp was 97.3 after vomting, Pulse 53, Resp 20, o2 sats were 40-45%, unable to obtain Blood pressure, Applied 5 L of oxygen at this time and had LPN call 911 immediately. Resident was repsonsive and able to follow staff members instructions but was only answering yes or no simple questions at the time time of assessment. Paramedics arrived at 0040 and resident was sent to Hospital. @ 0130 ER nurse called to nursing facility to notify		No prior vaccinations for this event.

resident had coded in the ER and passed away @ 0110.

FEELING ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Heard through a family member had some feeling badly and some respiratory symptoms. We do not have any real information. This is a coroners case.	No prior vaccinations for this event.

FEELING ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pfizer-BioNTech COVID- 19 Vaccine EUA Patient received COVID-19 Vaccine dose #2 on February 24, 2021. On February 25th at 10:36 AM,Patient's son called physician to report some side effects to second dose of Covid vaccine. She had diarrhea when she came home yesterday. Son has been up all night with her as patient has had a ""hacking cough,feels terrible, and now has had diarrhea x2"". Patient has taken Advil and will be taking tylenol periodically through out the day for her side effects. Patients son notified physician at 09:55 AM on February 26 that the patient has expired."	No prior vaccinations for this event.

FEELING ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death Narrative: 86 year old MALE with PMH of Afib s/p AICD/PPM, HFrEF (EF< 20% 10/2019), DM2, HTN, HLD, BPH, Depression. Was stable and feeling well when he was administered Covid-19 vaccine on 02/17/2021- Pfizer COVID-19 Vaccine 0.3 ml IM. MVX (Manuf); PFR; Lot#; EL9267; Exp Date:05/31/2021 Administration Anatomic site: Right Deltoid; Pt was monitored for 30 minutes after administration and had no adverse effects. He was called later in the day and reports he feels well and has had no adverse reactions, he endorsed his arm is a little sore at injection site. ON 02/19/2021- his dghter found him on the floor, next to his	No prior vaccinations for this event.

bed, dead. She reported on 2/19/2021- that she was out with him to dinner on 2/18/2021, and he stated he did not feel well, that his insides did not feel right. He proceeded to have dinner and 2 drinks. HE was doing ok, when she took him home.

FEELING COLD

COVID19 (COVID19 (MODERNA)) (1201)

Blood pressure went down until he died; Couldn't hear his heartbeat; neck was sweating; He was cold; Couldn't get up; Death; Sick; immediately very tired; he was tired; Hands were shaking; Slept for too long; A spontaneous report was received on 18 Feb 2021 from a consumer concerning a 81-years-old, male patient who received Moderna's COVID-19 vaccine and developed immediately very tired, hands were shaking, neck was sweating, was cold, sick, couldn't get up, couldn't hear his heartbeat and blood pressure went down until he died. Patients' medical history, as provided by patient's spouse, was emergency room(ER) admission in November 2020 because he had a congested chest (he had fluid around his heart). At that time, they gave him pills for kidney function. Other concomitant medication reported was Coumadin, blood thinner. Two weeks before receiving the vaccine, patient's EKG was normal. On 11 Feb 2021, in the morning, patient received their first of two planned doses of mRNA-1273(BATCH/LOT # 007M20A) probably in the right arm for the prophylaxis of COVID-19 infection. On 11 Feb 2021, approximately after 15 minutes of receiving vaccine, they left and patient was immediately very tired, his hands were shaking. So, patient's spouse made them down sleep for too long. On Friday, 12 Feb 2021 she tried to pick him up, but he was tired, exhausted, and sick. On Saturday, 13 Feb 2021, she brought him a coffee and he couldn't hold it because his hands were shaking, so she gave him the coffee and then made him pee on the bed because he couldn't get up. At lunch time she made him eat something and he fell sleep again. His wife was hanging around him all day and around 7:30pm she realized that he was cold, and his neck was sweating, she couldn't hear his heartbeat. So, she called emergency services and when they arrived, her husband's blood pressure went down until he died. Treatment for the events were not provided. Action taken with mRNA-1273 was not applicable. Patient was pronounced dead on 13 Feb 2021 20:00. The cause of death was not provided. The plans for an autopsy were not provided. The events of blood pressure

No prior vaccinations for this event.

went down until he died and couldn't hear his heartbeat were fatal. The outcome for the remaining events were unknown.; Reporter's Comments: This case concerns an 81 year old, male patient, who experienced a serious event of death among others, 2 days after receiving mRNA- 1273 (Lot# 007M20A). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

	FEELING COLD	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.		No prior vaccinations for this event.
	FEELING COLD	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test		No prior vaccinations for this event.

negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

FEELING COLD

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically

No prior vaccinations for this event.

significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away

FEELING HOT

COVID19 (COVID19 (MODERNA)) (1201)

"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"

No prior vaccinations for this event.

FEELING HOT		**COVID19 (COVID19 (MODERNA)) (1201)**
"""Feeling Hot"" without fever and nausea 10 hours post vaccine and resolved within 1 hour. Seizure, Hypotension, Unresponsive followed shortly by cardiac arrest and pulseless electrical activity 21 hours post vaccine. Pronounced dead 22 hours post vaccine"		No prior vaccinations for this event.
FEELING HOT		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.		No prior vaccinations for this event.
FEMORAL NECK FRACTURE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho		No prior vaccinations for this event.

evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."

FIBRIN D DIMER

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

FIBRIN D DIMER

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After

No prior vaccinations for this event.

discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.

	FIBRIN D DIMER INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.		No prior vaccinations for this event.
	FIBRIN D DIMER INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.
	FIBRIN D DIMER INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration		No prior vaccinations for this event.

FIBRIN D DIMER INCREASED	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a	No prior vaccinations for this event.

possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced

pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

FIBRIN D DIMER INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

No prior vaccinations for this event.

FIBRIN D DIMER INCREASED

COVID19 (COVID19

	(PFIZER-BIONTECH)) (1200)
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	No prior vaccinations for this event.
FIBRIN D DIMER INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
FIBRIN D DIMER INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.	No prior vaccinations for this event.
FIBRIN D DIMER INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o	No prior vaccinations for

of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.	this event.
FIBRIN D DIMER INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.	No prior vaccinations for this event.
FIBRIN D DIMER INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197,	No prior vaccinations for this event.

creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

FIBRIN D DIMER INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival

No prior vaccinations for this event.

he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was

diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

FLANK PAIN

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1. Fatigue ? day 1 - Tuesday 2. Loss of appetite ? day 1 Tuesday 3. Fever 102.0 ? day 2 - Wednesday 4. Chills ? day 2 - - Wednesday 5. Weak ? day 2 - - Wednesday 6. Non-ambulatory (unusual) ? day 2 - - Wednesday 7. Two emergency service ambulance assessment ? day 2 - - Wednesday 8. Symptoms improved ? day 3 - Thursday 9. Ambulatory - day 3 - Thursday 10. Symptoms worsened ? day 4 - Friday 11. Chills ? day 4 - Friday 12. Non-ambulatory again ? day 4 - Friday 13. Fever 102.0 ? day 4 - Friday 14. Left side flank pain ? day 4 - Friday 15. CPR and declared decease at home by paramedics - day 5 - Saturday morning @ 1:32am

No prior vaccinations for this event.

FLATULENCE

COVID19 (COVID19

(MODERNA)) (1201)

Chills; headache; extreme fatigue; gas or chest pain that was thought to be gas and went away Died 4 days later

No prior vaccinations for this event.

FLUID INTAKE REDUCED

COVID19 (COVID19 (MODERNA)) (1201)

Patient became nauseated about 10 minutes after vaccine administered, this subsided but returned several hours after the vaccine was given. She continued with intractable nausea and vomiting for about 24 hours. This patient was enrolled in hospice and she continued to decline and refused to eat or drink. She was taking Ibuprofen due to intractable back pain. Her emesis was coffee ground color. After this her condition continued to decline until her death

No prior vaccinations for this event.

FLUID INTAKE REDUCED

COVID19 (COVID19 (MODERNA)) (1201)

EXTREME PAIN, STOPPED EATING/DRINKING -- STARTED MORPHINE No prior vaccinations for this event.

FLUID INTAKE REDUCED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no

No prior vaccinations for this event.

longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21

FLUID INTAKE REDUCED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic #1. Patient tested positive for COVID-19 by rapid testing on 1/6/21. She demonstrated poor appetite and fluid/food intake and an IV of Normal Saline was initiated on 1/7/21. Oxygen saturation was initiated on 1/12/21 at 4L per nasal cannula. for shortness of breath. On 1/22/21 at 0310 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.	No prior vaccinations for this event.
FLUID OVERLOAD	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and	No prior vaccinations for this event.

pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib

fractures on the right at ribs 2 through

FLUID RETENTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Legs started swelling and shortness of breath Thursday January 21 2021 Was rushed to hospital with kidney failure and fluid build up around lungs and entire body Blood pressure dropped and had multiple organ failure	No prior vaccinations for this event.
FLUID RETENTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
FLUSHING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Elevated heart rate, flushing of the face and ears, vomiting, trouble breathing, pulmonary edema	No prior vaccinations for this event.
FOAMING AT MOUTH	**COVID19 (COVID19 (MODERNA))**

	(1201)
on 12/24/2020 the resident was sleepy and stayed in bed most of the shift. He stated he was doing okay but requested pain medication for his legs at 250PM. At 255AM on 12/25/2020 the resident was observed in bed lying still, pale, eyes half open and foam coming from mouth and unresponsive. He was not breathing and with no pulse	No prior vaccinations for this event.
FOAMING AT MOUTH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had COVID in Sept. Minimal symptoms. Received 1st dose 1/18 without adverse reactions. Second dose on 2/8-had complaints of arm soreness several days after then appeared in usual state of health. On 2/14 @ 2 hours after having lunch, patient was found unresponsive with Respirations 60, pulse 130, PO 84%, blood pressure 105/68. Patient with lots of white foam coming out of mouth. Temperature to 101.3. Patient DNR B and family deferred transfer, wanted comfort measures only. Nursing received order for MSIR. Patient continued with temps in 99-100 range with tylenol suppositories. Patient passed on 2/16.	No prior vaccinations for this event.
FOETAL HEART RATE ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Maternal exposure during pregnancy; Fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected; This is a spontaneous report from a contactable consumer (parent). This consumer reported information for both mother and fetus. This is a fetus report. A patient of unspecified age and gender (fetus) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269), transplacental on 04Feb2021 at 14:00 at single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medication included ergocalciferol (VIT D), folic acid (FOLATE), ascorbic acid/betacarotene/calcium sulfate/colecalciferol/cyanocobalamin/ferrous fumarate/folic acid/ nicotinamide/pyridoxine hydrochloride/retinol	No prior vaccinations for this event.

acetate/riboflavin/thiamine mononitrate/tocopheryl acetate/zinc oxide (PRENATAL VITAMINS) and sertraline hydrochloride (ZOLOFT) at 25 mg, all transplacental. It was reported that OB exam on 03Feb21 showed healthy baby at 7weeks 5days heartbeat detected 152 bpm; no abnormalities identified via ultrasound; labs and hormone levels all within normal ranges. No issues detected. Mother received 1st dose of vaccine on 04Feb2021. Per ultrasound on 20Feb2021, fetus stopped growing on 09Feb2021 (8 weeks 4 days); no heartbeat detected. Miscarriage occurred on 22Feb2021. The fetus died on 22Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021204433 same drug and reporter, different patient and event; Reported Cause(s) of Death: Fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected; Mother received 1st dose of vaccine 04Feb21. Per ultrasound on 20Feb21, fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected. Miscarriage occurred 22Feb21.

FOOD ALLERGY	**COVID19 (COVID19 (MODERNA)) (1201)**
2/12/2021 woke up with sore arm and back. 2/13/2021 woke up with headache around 1am. Headache and nausea all morning. Mid-late afternoon started having seizures. Admitted to Hospital 2/15/2021 expired. Reported per wife on 2/25/2021.	No prior vaccinations for this event.
FOOD REFUSAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Per granddaughter's report, pt became very weak within hours of receiving the first dose of the Moderna COVID-19 vaccine and could not get out of bed the next morning without assistance, reported difficulty seeing, and did not recognize some family members. By Sunday, 1/31, pt was unable to be awakened, would not eat, and had low urinary output. Granddaughter reports that the morning of 2/1 he was awake and ate a small amount and seemed to be improving although still weak and unable to get out of bed. Granddaughter reported he died 2/1 around 10am in the morning.	No prior vaccinations for this event.

FOOD REFUSAL		**COVID19 (COVID19 (MODERNA)) (1201)**
2/10: Fever, fatigue, tylenol 2/11 @ 1300: pt made DNR, hospice consulted 2/11 @ 1800 decreased LOC, increased RR, fever, chills - 1/5L NS bolus IV, rectal tylenol. Refusing to eat/drink, PO morphine 2/12 @ 16:30, deceased at facility **resident was not doing well prior to vaccination		No prior vaccinations for this event.
FOOD REFUSAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.		
FOOD REFUSAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Resident had slight/slow decline in health prior to vaccine but continued to be able to walk around with walker at community. The day of the vaccine she had a fever. 2 days after vaccine resident did not get out of bed all day and refused to eat. She had small amounts of orange juice as her blood sugar level was low due to not eating. Resident was diagnosed with a UTI and began an oral antibiotic. 3 days after and on day 5 after vaccine resident began feeling weak and had a fall on each day. The following day again resident spent the day in bed. The next day she was quite restless, was on the edge of her bed attempting to self transfer often throughout the day. Resident continued to be restless on the 10th of Feb, had further decline on the 11th of Feb. Resident passed away early the AM of Feb. 12th.		No prior vaccinations for this event.
FOOD REFUSAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"The day after the 2nd shot, patient developed blisters on his lips and mouth. The care facility said that	Shingles - Glaxo 8/22/2020,	

he had a nut allergy -- but he had never been allergic to nuts. He stopped eating and drinking and his BP had dropped to 60/40. By Jan 16th they called to say he was dying and he passed away on 1/18/21. Patient had COVID19 from Oct 29th - early November. By Nov 21st he had lost 40 lbs. He was 6'3"" and had gone from 189lbs to 149 lbs with COVID. By Nov 21st when we could visit, he had recovered from COVID, but was very thin and weak. He could not bathroom alone and kept falling. He didn't seem to have a bad reaction to the 1st COVID shot, But he immediately reacted to the 2nd shot and passed away within 6 days."	resulted in hospitalization and LTC.
FRACTION OF INSPIRED OXYGEN	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
FREE THYROXINE INDEX	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
FREQUENT BOWEL MOVEMENTS	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310

No prior vaccinations for this event.

MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

FULL BLOOD COUNT

COVID19 (COVID19 (MODERNA)) (1201)

12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family

No prior vaccinations for this event.

on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics

FULL BLOOD COUNT	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21	No prior vaccinations for this event.
FULL BLOOD COUNT	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.	No prior vaccinations for this event.
FULL BLOOD COUNT	**COVID19 (COVID19 (MODERNA)) (1201)**
ON 1/14/2021 TYPICAL UTI SYMPTOMS FOR RESIDENT DEVELOPED INCLUDING FEVER AND RIGIDITY. RESIDENT IS NON-VERBAL. IV ANTIBIOTICS WERE STARTED. FREQUENT UTI'S ARE COMMON FOR THIS RESIDENT.	No prior vaccinations for this event.
FULL BLOOD COUNT	**COVID19 (COVID19 (MODERNA)) (1201)**

cough congestive heart failure death No prior vaccinations for this event.

FULL BLOOD COUNT **COVID19 (COVID19 (MODERNA)) (1201)**

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

FULL BLOOD COUNT

COVID19 (COVID19 (MODERNA)) (1201)

Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127

No prior vaccinations for this event.

FULL BLOOD COUNT

COVID19 (COVID19 (MODERNA)) (1201)

"Was given vaccine around 1:30Pm on 2-11-2021. He and his wife waited in the building for 15 minutes and then left. he denied complaint. (He was waiting to have both Covid shots before he went to cardiologist Re: CAD.) He had an alarm going off in his house, was going to basement to check it out. Police officer heard alarm, came into house, & heard a thud when Doc fell. He was in PEA (Pulseless Electrical Activity) when brought into ER. Given 5 ""rounds of Epinephrine with no response."

No prior vaccinations for this event.

FULL BLOOD COUNT

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.	No prior vaccinations for this event.

FULL BLOOD COUNT	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506	No prior vaccinations for this event.

FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fever, Malaise	No prior vaccinations for this event.

FULL BLOOD COUNT COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before	No prior vaccinations for

with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing. this event.

FULL BLOOD COUNT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Fatigue, muscle aches, vomiting, hematoma No prior vaccinations for this event.

FULL BLOOD COUNT **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

The patient was observed to be lethargic on 1/29/21 at 1515. BP-80/50, P-75, RR-27, T-100.1. No prior vaccinations for this event.

He was given a bolus of NS 150 mlx2. and Rocephin 1 gram IM.		
	FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began with vomiting and diarrhea. C/O chest pain. Bradycardia. Hypotension. 2 seizures in 45 minutes after not having one in years. We gave fluids. Gave Zofran. Comfort measures. Pt passed at midnight. Was completely fine one day before. Had minimal issues with COVID though did have a pneumonia that was treated w ATB early on and resolved.		No prior vaccinations for this event.
	FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began feeling nauseated on 1/18/21 around 6pm, and had uncontrolled diarrhea, reported that she did not feel right. Staff reported to this writer, that her skin tone was gray in tone and she just didn't look good. She was transferred to the HOSPITAL ER VIA AMBULANCE.		No prior vaccinations for this event.
	FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021		No prior vaccinations for this event.
	FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90%		No prior vaccinations for this

O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.	event.
FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/5/2021 resident noted to be azotemic. Creatinine up to 3.8 and BUN in 80's. He was started on NS hydration. On 2/7/2021 he was noted without VS, per MD notes, possible VF arrest, renal failure; death unclear exact cause.	No prior vaccinations for this event.
FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
right arm swelling immediately after injection. followed by bilateral lower leg edema, chills and body aches that continued daily at 2 weeks post immunization admin 2/4/21 treated with dexamethasone 6mg PO x 7 days- this resolved his s/s 2/13/21 patient passed away at facility	No prior vaccinations for this event.
FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall; fatigued; arm pain; AML; Sepsis secondary to AML; This is a spontaneous report from a contactable consumer. An 88-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-	No prior vaccinations for

19 VACCINE, lot# EL3249), via an unspecified route of administration on 19Jan2021 17:30 in right arm at single dose for covid-19 immunization. Medical history included hypertension, hyperlipidemia, OA (osteoarthritis), cognitive impairment. No other vaccine in four weeks was administrated. Concomitant medication in two weeks included atorvastatin, aspirin, calcium, gabapentin, losartan and memantine hydrochloride (NAMENDA). The patient previously took lisinopril and tetracycline and both experienced allergies. The patient had no covid prior vaccination. The patient initially had no symptoms but arm pain in Jan2021, no bleeding or bruising from injection. On 31Jan2021 19:00, patient felt fatigued. Patient suffered fall on 01Feb2021. She was admitted to hospital. All cell lines were down in Feb2021. She was diagnosed with AML (acute myeloid leukemia) in 2021. She expired 07Feb2021. Events resulted in emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event) and patient died. The patient received the treatment of blood and platelet transfusions, bone marrow biopsy, cytogenetic testing, antibiotics, intubation for events. The patient died on 07Feb2021 due to sepsis secondary to AML. An autopsy was not performed. Outcome of events were fatal.; Reported Cause(s) of Death: arm pain; fatigued; fall; Sepsis secondary to AML; Sepsis secondary to AML	this event.
FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.	No prior vaccinations for this event.
FULL BLOOD COUNT	**COVID19 (COVID19**

(PFIZER-BIONTECH))
(1200)

1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

No prior vaccinations for this event.

FULL BLOOD COUNT

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19)

No prior vaccinations for this event.

pneumonia á Disposition: Deceased

FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.	No prior vaccinations for this event.

FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt fell within 24 hours after vaccine. was sent to hospital. pt was found to be hypoxic with multifocal opacities on CT scan	No prior vaccinations for this event.

FULL BLOOD COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to	No prior vaccinations for this event.

death of patient prior to lab company arrival.

FULL BLOOD COUNT ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

No prior vaccinations for this event.

FULL BLOOD COUNT ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

See initial report

No prior vaccinations for this event.

FULL BLOOD COUNT ABNORMAL COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.

No prior vaccinations for this event.

FULL BLOOD COUNT NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Presented to Urgent Care for weakness and confusion, transferred to ED, patient had a cardiac

No prior vaccinations for this

arrest and was unable to be resuscitated event.

FULL BLOOD COUNT NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient received Moderna COVID vaccine on 12/30/2020 at a Pharmacy clinic where he was a resident. Nurses at the facility reported that he was responsive and showed no signs of any adverse effects until 1/2/2021 when he was observed slightly unresponsive and staring at the ceiling and trembling. He had a fever of 101F at this time. The facility ordered labs and a rapid COVID test (all of which came back normal) and started IV antibiotics. A few hours later, patient began bleeding from his eyes, nose, and mouth and was sent to the local ER. The patient refused being admitted to the ICU for possible sepsis/hemorrhage and died the following day on 1/3/2021. All healthcare professionals involved agreed that this was not likely due to the vaccine, but needed to be reported nonetheless.

No prior vaccinations for this event.

FULL BLOOD COUNT NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29

No prior vaccinations for this event.

FULL BLOOD COUNT NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1 fall after first dose on 1/8/2021 at 1930; no injuries; 4 falls after second dose on 1/14/21 at 1545, 1/15/21 at 1700, 1/21/21/at 1220 and 1/21/21 at 1330 all falls with no injuries. Started Ceftriaxone 1 GM IM daily for 5 dyas on 1/21/21 for UTI: E. Coli

No prior vaccinations for this event.

FULL BLOOD COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was noted on 1/25 with an increased functional decline as she would not feed herself with utensils, but would eat finger foods if placed in her hand. She was started on Rocephin IM for possible infections. Labs had been obtained on 1/21/21, unremarkable for CBC and CMP. 75,000 colony count on urine. On 1/26/21 she was noted with right sided weakness and further decline. She was sent to Hospital for further evaluation. We were notified that she expired on 1/28/2021. Resident had been noted with a decline in function about 2 weeks earlier when she would not stand or transfer any longer. She was still responsive, taking meds, and feeding herself until 1/26/21. Further information on admitting diagnoses and progress notes from hospital have not been available to date.	No prior vaccinations for this event.
FULL BLOOD COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids	No prior vaccinations for this event.

were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

FUNGAL TEST NEGATIVE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a	No prior vaccinations for this event.

possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced

pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

	GAIT DISTURBANCE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21		No prior vaccinations for this event.

	GAIT DISTURBANCE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
02/07/21 through 2/13/21 slightly fatiqued, took all his prescribed medications, ate breakfast, lunch and dinner was drinking eight 10 oz bottles of water. On 02/14/21 was very tired had a difficult time breathing after taking the normal meds. He took a breathing treatment with his prescribed Ipratropium Bromide and Albuterol Sulfate via home nebulizer. This did not improve his breathing. He was very weak and breathing was labored. 911 was called by wife. 911EMTchecked pulse and breathing. Informed him they would give him a breathing treatment.He started to go limp. EMT's got him to Ambulance and to Medical Center to the ER. Heroics done. He died. Pulmonary and Cardiac Arrest		No prior vaccinations for this event.

GAIT INABILITY		**COVID19 (COVID19 (MODERNA)) (1201)**
"86yo female alert, stable with ankle abrasion eating 100% prior to vaccine in assisted living facility. On 2/1/2021, received Moderna vaccine. Starting thereafter, eating 50% on 2/2/21. Temperature was 98 tympanic. On 2/3, the leg abrasion started having moderate bleeding. On 2/4, the caregiver noted patient ""not looking good, unable to talk, arms moving aimlessly, grasping"". BP 95/41, temperature 98, oxygen on room air 92-93%. POA did not want hospital transfer. 2/5 Hospice started, oxygen given, morphine given. 2/5-2/8 comfort care given, patient responsive to tactile stimuli, resting, not taking oral medications or food. 2/8/2021 patient expired."		No prior vaccinations for this event.
GAIT INABILITY		**COVID19 (COVID19 (MODERNA)) (1201)**
On January 1, 2021, patient was admitted to Medical Center with COVID. Tested positive on January 2, 2021. Spent 10 days in hospital. Once recovered from pneumonia and fever gone, on January 10, 2021, she was transferred to Rehabilitation Center for continued treatment. She spent 16 days there. She developed UTI and CDIF infections and was on/off oxygen. She started physical therapy. She was scheduled to be released to go home on January 27, 2021. On January 26, 2021, the day before going home, Rehabilitation Center gave her the Moderna vaccine. On January 27, the day she went home, she started feeling very weak and couldn't walk. My dad tried lifting her and they both fell to the ground. My dad called 911 and she was taken to Medical Center, with high fever and possible stroke symptoms (which later was negative). Two days later, she had difficulty breathing and was put on a ventilator. She was on a ventilator for about three days. They took it off and she slowly started recovering. The doctors did all kinds of tests (blood clot in lung, heart, etc.) and all was negative. The only thing they could trace it to was an adverse reaction to the vaccine. After spending 11 days at hospital and treating her for various infections, her heart stopped and she passed away suddenly.		No prior vaccinations for this event.

	GAIT INABILITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."		No prior vaccinations for this event.

	GAIT INABILITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient reported to emergency room on 2/20 with increasing of shortness of breath, quantitated unable to walk from room to room in his house. Patient was admitted.		No prior vaccinations for this event.

GAIT INABILITY		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1. Fatigue ? day 1 - Tuesday 2. Loss of appetite ? day 1 Tuesday 3. Fever 102.0 ? day 2 - Wednesday 4. Chills ? day 2 - - Wednesday 5. Weak ? day 2 - - Wednesday 6. Non-ambulatory (unusual) ? day 2 - - Wednesday 7. Two emergency service ambulance assessment ? day 2 - - Wednesday 8. Symptoms improved ? day 3 - Thursday 9. Ambulatory - day 3 - Thursday 10. Symptoms worsened ? day 4 - Friday 11. Chills ? day 4 - Friday 12. Non-ambulatory again ? day 4 - Friday 13. Fever 102.0 ? day 4 - Friday 14. Left side flank pain ? day 4 - Friday 15. CPR and declared decease at home by paramedics - day 5 - Saturday morning @ 1:32am		No prior vaccinations for this event.
GASTRITIS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.		No prior vaccinations for this event.
GASTROINTESTINAL HAEMORRHAGE		**COVID19 (COVID19 (MODERNA)) (1201)**
Client unexpectedly collapsed and passed away on 1/13/21 from suspected sudden cardiac death. Prior to her death, she was in skilled care for rehabilitation following hospitalization from 12/21-12/31/20 for an acute lower GI bleed. Her hospitalization and skilled care stay were complicated by delirium and she was being		No prior vaccinations for this event.

treated for delirium with olanzapine (Zyprexa) at time of death.

GASTROINTESTINAL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.

GASTROINTESTINAL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death ""cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its components or a severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed. MDs recommending hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative status. 1/29 Pt passed away."	No prior vaccinations for this event.
GASTROINTESTINAL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code	No prior vaccinations for this event.

was stopped.

GASTROINTESTINAL TUBE INSERTION		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident getting rehab therapy in the facility and has a long history of Parkinson's Disease. On 01/29/21, he received the COVID vaccine on left deltoid, resident was recently hospitalized due to Pneumonia and was on antibiotic IV and was recently placed on GT feeding due to severe dysphagia from his Parkinson's disease. On 01/31/21, started having increased congestion. On 02/02/21, started having increased temperature and WBC went up >20,000 on 02/03/21, started on Vancomycin IV on 02/04/21 but was transferred to the hospital. Facility was notified today (02/18/21) that resident expired in the hospital.		No prior vaccinations for this event.
GASTROINTESTINAL TUBE INSERTION		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient experienced an episode of emesis and loss of consciousness several hours after vaccine on 2/16/21. He was taken by EMS to the hospital and was noted to be hypoxic and hypotensive. He was admitted to the hospital and subsequently intubated. He was also found to have a small bowel obstruction and a nasogastric tube was placed to decompress the bowel. He required pressor support as well. He expired on 2/17/21.		No prior vaccinations for this event.
GASTROINTESTINAL TUBE INSERTION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death ""cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its		No prior vaccinations for this event.

components or a severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed. MDs recommending hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative status. 1/29 Pt passed away."

GAZE PALSY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29	No prior vaccinations for this event.

more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

GENERAL PHYSICAL CONDITION ABNORMAL

COVID19 (COVID19

	(MODERNA)) (1201)
Around 00:50am on 01/15/21, C.N.A. reported that the resident looked different and not responding. Initiated Code Blue and started CPR. 911 arrived and pronounced resident dead at 1:01 am.	No prior vaccinations for this event.
GENERAL PHYSICAL CONDITION ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Fever Feeling tired short of breath all night and morning after the vaccine My grandma had to be intubated and then passed away to a heart distress we think it was the vaccine because she was fine even with dialysis. When she got the vaccine it took hours and her health conditions changed.	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Accelerated decline in condition with decreased input, decreased responsiveness, somnolence, and death	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
patient started to decline 1/10/2021, patient seen at facility by medical professional - patient deceased 1/13/2021	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
36 hours after vaccination, the patient had increased respiratory distress. He was placed on high flow nasal cannula oxygen with mild improvement. He then continued to be hypotensive requiring IV fluids and	No prior vaccinations

subsequently IV vasopressors. Patient's BP was stabilized with vasopresor, however he continued to deteriorate clinically with altered mental status and lethargy, concerned for bowel peroration based on physical exam by MD. He was then emergency intubated and placed on mechanical ventilation. He was then transferred to acute care hospital near by.	for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the vaccine on 12/29/20 and presented at the ER at the Hospital on 12/30/20 stating that he wasn't feeling well. It is stated that his health had declined over the past few weeks and currently on hospice. Visit was unremarkable. Patient stated that wanted to stop dialysis. Patient passed away on 01/02/2021.	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Death Narrative: Patient received the first COVID-19 dose on 12/23. Afterwards, patient complained of localized pain on L deltoid area where the vaccine was administered; his temperature was 98.1 F. On 12/26-27, staff reported that patient appeared more fatigued than usual and was shivering on 12/27, which seized after blanket was given. On 12/28, patient presented with fever (Tmax 100.2 F) and acetaminophen was administered for alleviation of fever. ADR was reported for the fever on 12/29. Patient continued to decline and was placed back on hospice care on 12/29; on 12/30. the symptoms reported on nursing note include erythema and pain on whole L arm. Lidocaine was applied. Patient's family and provider mutually agreed not to administer the second dose of vaccine. He continued to decline and was started on end-of-life care around 1/4 and passed on 1/20 1417.	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Rapid decline in health status, Elevated BP&P, posturing, loss of consciousness, Glasgow coma	No prior vaccinations for this

Scale 4 starting 2/1/2021, Deceased 2/3/21		event.
	GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Nursing home called 911 for decline in condition. Patient transported to ER where she was admitted to inpatient care and expired 1/30 at 16:13		No prior vaccinations for this event.
	GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient, who was a pharmacist, developed fatigue and shortness of breath hours after receiving vaccine. Two days later, on 01/28/2021, the patient went to local urgent care for worsening shortness of breath and was referred to Hospital for worsening dyspnea and hypoxia. The patient was admitted to the hospital We was found to have bilateral pulmonary infiltrates and treated for pneumonia with Rocephin and azithromycin. He was tested for COVID-19 multiple times, but each of the results were negative. Despite the negative results, there was high clinical suspicion for COVID-19 and the patient was started on Remdesivir and Decadron. The patient's oxygen requirements continued to worsen and the patient was transferred to another facility for higher level of care. There his hypoxia worsened and he required mechanical ventilation. Patient then developed hypotension and required vasopressors for blood pressure support. Furthermore, patient developed acute renal failure requiring hemodialysis. Despite mechanical ventilation with FiO2 100%, and for vasopressors, patient clinically deteriorated and family decided to palliatively extubate on 02/05/2021.		No prior vaccinations for this event.
	GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the Moderna COVID vaccine 1/28/21. He was tested for COVID 19 on 1/29/31. Results were received 1/30/21, at which time he was evaluated and found to be hypoxic with tachycardia. He was sent to the local ER and returned this same day. On 2/2/21, he was evaluated by the provider, who sent him to the		No prior vaccinations for this event.

emergency room with acute respiratory distress and poor O2 sats

GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Received Moderna covid vaccination 1/14/2021. 1/16/2021 received report of cough and difficulty breathing. Proceeded to hospital and was diagnosed Covid+ on testing. Continued to decline, died 1/31/2021.	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
I video chatted with her Thursday after receiving the vaccine. My mom was in poor health but she was talking in complete sentences and responded appropriately. She was upright in bed and made eye contact. She smiled and denied pain. By Sunday, she was extremely weak and unable to sip water with a straw. Her health had changed dramatically and rapidly. She moaned in pain and was very fatigued. Her condition continued to deteriorate over the week and she stopped talking and was constantly sleeping. They started antibiotics for the oozing cancer lesion and then morphine for pain and end of life care. She passed away on January 22nd which was 15 days post vaccination.	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient became nauseated about 10 minutes after vaccine administered, this subsided but returned several hours after the vaccine was given. She continued with intractable nausea and vomiting for about 24 hours. This patient was enrolled in hospice and she continued to decline and refused to eat or drink. She was taking Ibuprofen due to intractable back pain. Her emesis was coffee ground color. After this her condition continued to decline until her death	No prior vaccinations for this event.

GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident tested NEGATIVE for COVID-19 on 1/25/2021. She was on monitoring for declining in condition on 1/29/2021.	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
On monitoring for declining in condition, loss of appetite and generalized body weakness on2/1/2021. Was confirmed COVID-19 positive 4/23/2020.	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart	No prior vaccinations for this event.

block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."

GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Admitted 1/14/21: Patient is an elderly 93-year-old female with multiple medical problems including chronic combined CHF, P 80, diabetes mellitus, HTN, hyperlipidemia, CKD stage 3, has been complaining of generalized weakness, fatigue, decreased appetite for the past few days. She had an outpatient COVID-19 vaccine earlier today. Within 2 hr of admitting the patient to the hospital, condition clinically deteriorated. Patient elected to be DNR/DNI while in the ED. Patient was pronounced dead at 10:30 p.m. earlier today. Preliminary cause of death: Hypoglycemia induced lactic acidosis.	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness; respiratory distress Narrative: Patient tolerated his 1st dose of the COVID-19 vaccine well, on 12/16/2020, and received his 2nd dose on 1/6/2021. Patient had some mild clinical decline the past few days prior to 2nd vaccination, with a decreased appetite and some increased fatigue per nursing report, but no significant changes. He experienced nausea on the evening of 1/6/21, which was effectively managed, but by early morning he spiked a fever of 102.9 with a sat of 86.1%. He continued to deteriorate from that point on and died 1/7/21 @13:20. Clinically, the presentation was most consistent with an aspiration pneumonia.	No prior vaccinations for this event.
GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT	No prior vaccinations for this event.

cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21

GENERAL PHYSICAL HEALTH DETERIORATION **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient sent to hospital 1/2 and 1/5. Returned both times to nursing home covid unit without a hospital admission. Resident had been diagnosed with COVID later in the day on 12/30, when routine testing PCR results returned to facility, after resident had already had her first covid vaccination on 12/30/20 in the morning. Resident continued decline, was again sent to hospital on 1/24/21, and expired in hospital 1/25/21.

No prior vaccinations for this event.

GENERAL PHYSICAL HEALTH DETERIORATION **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

See initial report

No prior vaccinations for this event.

GENERAL PHYSICAL HEALTH DETERIORATION COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident was noted on 1/25 with an increased functional decline as she would not feed herself with utensils, but would eat finger foods if placed in her hand. She was started on Rocephin IM for possible infections. Labs had been obtained on 1/21/21, unremarkable for CBC and CMP. 75,000 colony count on urine. On 1/26/21 she was noted with right sided weakness and further decline. She was sent to Hospital for further evaluation. We were notified that she expired on 1/28/2021. Resident had been noted with a decline

No prior vaccinations for this event.

in function about 2 weeks earlier when she would not stand or transfer any longer. She was still responsive, taking meds, and feeding herself until 1/26/21. Further information on admitting diagnoses and progress notes from hospital have not been available to date.

GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 10 minutes after receiving the COVID- 19 vaccine resident displayed seizure activity, staring straight ahead and strong allover muscle jerking of both the up and lower extremities, color became gray, activity lasted approximately 3 minutes, resident then became relaxed, color returned to normal, BP-140/80, 97.8, 60, 16, sleeping the remainder of the shift,. Resident continued to decline until resident CTB on 1/19/21	No prior vaccinations for this event.

GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom received the Covid 19 vaccine on Jan 5, 2021 and became very about a week later. I was informed that she tested positive for Covid 19 on January 14th. One January 17th she became very tired and weak and would not eat. Hospice called me and told me that she was in a decline state. I saw her on January 25 and 26 and she was just sleeping and could not open her eyes. Her vitals were good and she seemed to understand when I talked to her - she would squeeze my hand and moan but she could not talk or open her eyes. My mom passed away on January 27, 2021 just 22 days after receiving the Covid 19 vaccine. She was very think to begin with and being to weak and tired to eat resulted in her losing even more weight. Some of the other residents were given fluids to help and they recovered. My mom was not given fluids. I believe there were 20 deaths in her care home for the month of January when they vaccinated. This was an alarming number of deaths for the home. The facility had very few Covid deaths in	No prior vaccinations for this event.

2019 and 2020. I asked every week if they had any Covid and or Covid deaths and this amount was shocking to me and the workers there.

GENERAL PHYSICAL HEALTH DETERIORATION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Ongoing decline overall. Remained on Hospice with increased lethargy documented on 1/20/21 and progressively worsening thereafter.

No prior vaccinations for this event.

GENERAL PHYSICAL HEALTH DETERIORATION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for

No prior vaccinations for this event.

Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Individual collapsed 9 days post-vaccination with no known reason. Despite being healthy prior to vaccination, individual's condition deteriorated rapidly. Individual passed away on 1-17-2021.	No prior vaccinations for this event.

GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
This 96 year old resident was diagnosed with COVID on 10/28/2020. She has a significant, complicated medical history and did not return to her pre-infection level of health. She began declining in early January and was made care and comfort measures only on 1/2/2021. Most of her medications were d/c'd except for those that provided comfort. No obvious reaction to the vaccine was seen and we do not suspect that her death was vaccine related, however we were directed by Dept of Epidemiology to report her death as it was within one week of receiving the vaccine.	No prior vaccinations for this event.

GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident had slight/slow decline in health prior to vaccine but continued to be able to walk around with walker at community. The day of the vaccine she had a fever. 2 days after vaccine resident did not get out of bed all day and refused to eat. She had small amounts of orange juice as her blood sugar level was low	No prior vaccinations for this event.

due to not eating. Resident was diagnosed with a UTI and began an oral antibiotic. 3 days after and on day 5 after vaccine resident began feeling weak and had a fall on each day. The following day again resident spent the day in bed. The next day she was quite restless, was on the edge of her bed attempting to self transfer often throughout the day. Resident continued to be restless on the 10th of Feb, had further decline on the 11th of Feb. Resident passed away early the AM of Feb. 12th.

	GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.		No prior vaccinations for this event.
	GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had sore arm on the day of vaccination. Per patient's nephew , the next morning patient experienced body pains, aches, headache . Onn Tuesday patient had fever. Patient's condition progressively got worse. He had difficulty breathing by Wednesday night. He had low oxygen levels at 80 per pulse ox reading. Patient was coughing up blood. Family took him to hospital on Thursday morning due to breathing difficulty and patient died 2.18.21 at 10 am		No prior vaccinations for this event.
	GENERAL PHYSICAL HEALTH DETERIORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt received vaccine on 1/29/2021 and died on 2/13/2021. Wife called agency and noted the pt received his 1st dose of vaccine and was having ""side effects and began declining"". It is unknown what side		No prior vaccinations for this event.

effects he was having."

GENERAL PHYSICAL HEALTH DETERIORATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Three days after second COVID-19 vaccine, patient became lethargic. Due to advance directive that instructed that no life saving interventions to take place, patient continued to decline and expired on 29 January 2021.	No prior vaccinations for this event.	
GENERAL PHYSICAL HEALTH DETERIORATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.	
GENERAL PHYSICAL HEALTH DETERIORATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Caller is nephew of patient. Patient was admitted to Hospital on 2/15/21 with Covid like symptoms and decreased O2 sat. He tested positive for Covid 2/15/21. Treated with Remdesivir. Patient status continued to decline and he passed away in hospital 2/22/21 0612.	No prior vaccinations for this event.	
GENERAL PHYSICAL HEALTH DETERIORATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient, age 101, was having a period of declining health prior to vaccine administration. This continued after	No prior vaccinations	

the vaccine to include increased pain, inability to swallow and ultimately Patient passed away on 1/9/2021. The physician does not believe this is due to vaccine administration, however family asked that this information be reported for record keeping.		for this event.
GENERALISED OEDEMA		**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.		No prior vaccinations for this event.
GLOBULIN		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.		No prior vaccinations for this event.
GLOBULINS DECREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o		No prior vaccinations

some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or for this event.

multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

GLOBULINS INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

No prior vaccinations for this event.

GLOBULINS INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death on 1/31/2021 multiple comorbidities No prior vaccinations for this event.	
GLOBULINS INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.	No prior vaccinations for this event.
GLOMERULAR FILTRATION RATE	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.	No prior vaccinations for this event.
GLOMERULAR FILTRATION RATE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to emergency room on 2/1/2021 with a chief complaint of having a chronic headache and fatigue following receipt of the Moderna vaccine 10 days prior. Following examination by the physician, the patient was diagnosed with an acute subdural hematoma. The patient subsequently underwent decompressive surgery, however demonstrated worsening neurologic status over the next several days and	No prior vaccinations for this event.

ultimately expired on 2/4/2021.

GLOMERULAR FILTRATION RATE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.

GLOMERULAR FILTRATION RATE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death on same day as vaccination	No prior vaccinations for this event.

GLOMERULAR FILTRATION RATE DECREASED COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.

GLOMERULAR FILTRATION RATE DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER	No prior vaccinations

diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.	for this event.
GLOMERULAR FILTRATION RATE DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration	No prior vaccinations for this event.
GLOMERULAR FILTRATION RATE DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg	No prior vaccinations for this event.

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GLOMERULAR FILTRATION RATE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.

GLOMERULAR FILTRATION RATE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.

GLOMERULAR FILTRATION RATE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the	No prior vaccinations for this event.

emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

GLOMERULAR FILTRATION RATE DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.

No prior vaccinations for this event.

GLOMERULAR FILTRATION RATE DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death within thirty days of vaccine. Multiple co-morbidities and placed on hospice 12/28/20.

No prior vaccinations for this event.

GLUCOSE URINE ABSENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT

No prior vaccinations for this event.

revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

GLUCOSE URINE ABSENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency

No prior vaccinations for this event.

department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

GLYCOSYLATED HAEMOGLOBIN

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-

No prior vaccinations for this event.

2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

	GLYCOSYLATED HAEMOGLOBIN INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Heart stopped; Could not swallow; This is a spontaneous report from a contactable nurse (patient's wife). An		No prior vaccinations

85-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 21Jan2021 at a single dose for COVID-19 immunization. Medical history included blood pressure abnormal (verbatim: blood pressure) from an unknown date and unknown if ongoing, neuropathy from an unknown date and unknown if ongoing, weight issue from an unknown date and unknown if ongoing, diabetes from an unknown date and unknown if ongoing, walker user from an unknown date and unknown if ongoing. Concomitant medications included insulin aspart (NOVOLOG) taken for diabetes from an unspecified date to an unspecified date; and he was taking a long acting one as well. The patient previously received the influenza vaccine (MANUFACTURER UNKNOWN) for immunization on unknown dates (""had flu shots before with no reactions and everything, nothing before""). On 24Jan2021, the patient's heart stopped (death, medically significant), and could not swallow (medically significant). The clinical course was reported as follows: The patient's wife stated the patient was taking insulin aspart (NOVOLOG) and he was taking a long acting one as well. The reporter, the patient's wife and a retired registered nurse (RN) stated, her husband (patient) just died and she thought he died from the COVID vaccine (later clarified the reason of death was-heart stopped). The patient had the vaccine on 21Jan2021, which was on a Thursday, and he was fine. On the following Sunday around 1:30 (on 24Jan2021), the patient was feeling a little weak, however, the patient's wife thought maybe his blood sugar was low. The patient's wife checked, and the patient's blood sugar was 91. The patient's wife went to get some yogurt to feed him in order to get his blood sugar up a little; ""which was a normal thing for him, it was not that low for him."" Then, suddenly, the patient fell, and the patient's wife could not get a pulse or anything. The patient's wife called an unspecified number and she started compressions; however, he was dead. The patient's wife stated the patient just had his heart test, a three hour long one, and it was ""perfect three weeks ago."" The patient had just gone to the doctor the other day and his blood pressure was ""fine and everything."" The patient's wife stated that other than his diabetes, ""which he had for (sentence incomplete)."" Regarding lab tests, the patient's wife stated, ""No, he had it before but not in the last two weeks. He was going for one because we just went to the doctor last week and he was going to call yesterday to make the appointment request to get his blood work done. Blood work has been good except his A1C was always high, but other than that everything was good"" (as reported). Regarding causality, the patient's wife stated, ""I do, because he was fine until about half an hour before he died. He said to me, I feel a little weak today and then I was talking to

for this event.

him that your upper body strength is really good and then I said, we just have to work on your weight a little more because he did have neuropathy. And then, I went out of the room and all of a sudden I just heard him fall and that is when I just went in to check his blood sugar and it was 91 and I got him yogurt and he started eating that and then that was it, he started spitting it out and he said, I could not swallow and that was it, he just died."" The patient's wife further added, ""I just wanted other people to know that things like this happen and I am sure it was from that because he was healthy as could be. He was walking with his walker, the day before outside and he felt fine."" The clinical outcome of the event, heart stopped, was fatal. The clinical outcome of the event, could not swallow, was unknown. The patient died on 24Jan2021 due to ""heart stopped."" An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: Heart stopped"		
GRAM STAIN POSITIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.		No prior vaccinations for this event.
GRANULOCYTE COUNT		**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with		No prior vaccinations

Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	for this event.

GRANULOCYTE PERCENTAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	No prior vaccinations for this event.

GRIP STRENGTH DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Staff walked into resident's room around 10:00am and noted resident's left side of his face was flaccid. Nurse was called and upon assessment resident noted to have an unequal hand grasp with left worse. He was able to talk but was mumbled and hard to understand. Physician, hospice, and family were notified. Resident had a stroke at 10:06 am on 1/8/2020. He lost all ability to use his left side. Resident passed away on 1/11/2020.	No prior vaccinations for this event.

	GRUNTING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."		No prior vaccinations for this event.
	GUILLAIN-BARRE SYNDROME	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.		No prior vaccinations for this event.
	GUILLAIN-BARRE SYNDROME	**COVID19 (COVID19**

(PFIZER-BIONTECH))
(1200)

92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.

Influenza Vaccine

GUN SHOT WOUND

COVID19 (COVID19 (PFIZER-BIONTECH))
(1200)

death by suicide Narrative: death by suicide; 12/26/20, self inflicted gun shot wound; found deceased by family member

No prior vaccinations for this event.

HAEMATEMESIS

COVID19 (COVID19 (MODERNA))
(1201)

Patient became nauseated about 10 minutes after vaccine administered, this subsided but returned several hours after the vaccine was given. She continued with intractable nausea and vomiting for about 24 hours. This patient was enrolled in hospice and she continued to decline and refused to eat or drink. She was taking Ibuprofen due to intractable back pain. Her emesis was coffee ground color. After this her condition continued to decline until her death

No prior vaccinations for this event.

	HAEMATEMESIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospice Resident received first Covid 19 vaccine dose on 1/6/21. 1/7/21 resident had decreased appetite noted in am but ate 100% of meal at dinner. 1/9/21 resident had decreased appetite with emesis x 2, loose BM x 2. Call placed to hospice. 1/10/21 5:44 am resident able to take HS meds, ingest 2 cups of shake. No emesis or loose stool noted. 12PM nurse noted resident not eating meals but ingesting milkshake and medications without any problems. Hospice contacted for change in condition. 1:00 pm hospice ordered Phenergan 12.5 mg Q 6 hrs PRN. Labs to be drawn 1/11/21. Hospice notified POA. 1/11/21 12:24am Resident had blood in stool. Resident denies any pain, on 2L of O2 for comfort.		No prior vaccinations for this event.
	HAEMATEMESIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death ""cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its components or a severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed. MDs recommending hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative		No prior vaccinations for this event.

status. 1/29 Pt passed away."

	HAEMATEMESIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
New onset dizziness with hypotension, tachycardia, and vomiting blood. Sent to ER - told he went into cardiac arrest and died.		No prior vaccinations for this event.

	HAEMATEMESIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
He started vomiting 2 days later. we suspect he was having stool issues as well. he vomited blood at some point over the weekend. there was black vomit right before he passed. from 2am-6am he was wheezing and rattling and then he passed at approximately 6am 3/1/2021 at home. EMS did come and try to revive him and were unsuccessful.		No prior vaccinations for this event.

	HAEMATOCHEZIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospice Resident received first Covid 19 vaccine dose on 1/6/21. 1/7/21 resident had decreased appetite noted in am but ate 100% of meal at dinner. 1/9/21 resident had decreased appetite with emesis x 2, loose BM x 2. Call placed to hospice. 1/10/21 5:44 am resident able to take HS meds, ingest 2 cups of shake. No emesis or loose stool noted. 12PM nurse noted resident not eating meals but ingesting milkshake and medications without any problems. Hospice contacted for change in condition. 1:00 pm hospice ordered Phenergan 12.5 mg Q 6 hrs PRN. Labs to be drawn 1/11/21. Hospice notified POA. 1/11/21 12:24am Resident had blood in stool. Resident denies any pain, on 2L of O2 for comfort.		No prior vaccinations for this event.

	HAEMATOCRIT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
	HAEMATOCRIT DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.		No prior vaccinations for this event.
	HAEMATOCRIT DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.

HAEMATOCRIT DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

HAEMATOCRIT DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on

No prior vaccinations for this event.

hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

HAEMATOCRIT DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021

No prior vaccinations for this event.

HAEMATOCRIT DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on

No prior vaccinations for this event.

vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

HAEMATOCRIT DECREASED	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few	No prior vaccinations for this event.

weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP.

Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

HAEMATOCRIT DECREASED	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37,	No prior vaccinations for this event.

she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

HAEMATOCRIT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.

HAEMATOCRIT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.

HAEMATOCRIT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP	No prior vaccinations for this event.

improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th

time at 08:18. Family at beside, Mother asks for code to be stopped."

HAEMATOCRIT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
HAEMATOCRIT INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).	No prior vaccinations for this event.
HAEMATOCRIT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside	No prior vaccinations for this event.

ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

HAEMATOCRIT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	No prior vaccinations for this event.
HAEMATOCRIT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.	No prior vaccinations for this event.
HAEMATOCRIT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained.	No prior vaccinations for this event.

He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

HAEMATOLOGY TEST	COVID19 (COVID19 (MODERNA)) (1201)
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.	No prior vaccinations for this event.

HAEMATOLOGY TEST	COVID19 (COVID19 (MODERNA)) (1201)
2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.	No prior vaccinations for this event.

HAEMATOMA	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Resident returned to the memory support unit at 1500. Resident was than toileted and transferred in to bed per his request. At 1515 resident was observed face down beside bed, resident sustained a 1inX1in eccyhmotic/hematoma to the forehead. Neuro Checks with in normal limes Vital signs: 100/52, 100, 97.2,	No prior vaccinations for this event.

28. Resident sent to ED for further medical evaluation via EMS.

HAEMATOMA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21

No prior vaccinations for this event.

HAEMATOMA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Fatigue, muscle aches, vomiting, hematoma No prior vaccinations for this event.

HAEMATOMA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood

No prior vaccinations for this event.

clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.

HAEMODIALYSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient, who was a pharmacist, developed fatigue and shortness of breath hours after receiving vaccine. Two days later, on 01/28/2021, the patient went to local urgent care for worsening shortness of breath and was referred to Hospital for worsening dyspnea and hypoxia. The patient was admitted to the hospital We was found to have bilateral pulmonary infiltrates and treated for pneumonia with Rocephin and azithromycin. He was tested for COVID-19 multiple times, but each of the results were negative. Despite the negative results, there was high clinical suspicion for COVID-19 and the patient was started on Remdesivir and Decadron. The patient's oxygen requirements continued to worsen and the patient was transferred to another facility for higher level of care. There his hypoxia worsened and he required mechanical ventilation. Patient then developed hypotension and required vasopressors for blood pressure support. Furthermore, patient developed acute renal failure requiring hemodialysis. Despite mechanical ventilation with FiO2 100%, and for vasopressors, patient clinically deteriorated and family decided to palliatively extubate on 02/05/2021.	No prior vaccinations for this event.
HAEMODYNAMIC INSTABILITY	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on	No prior vaccinations for this event.

forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse		
	HAEMODYNAMIC INSTABILITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt with acute resp failure, COVID PNA, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior toa admit, then shortly after progressed with other covid symptoms and was admitted. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. Pt passed soon after(2/2).		No prior vaccinations for this event.
	HAEMOGLOBIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient		No prior vaccinations for this event.

prior to lab company arrival.

	HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.		No prior vaccinations for this event.
	HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.		No prior vaccinations for this event.
	HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of		No prior vaccinations for this event.

severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.

HAEMOGLOBIN DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.
HAEMOGLOBIN DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient had COVID vaccination on 2/3 with no adverse s/s before leaving unit. Upon coming to treatment Friday 2/5 he reported to the RN that he had fallen on thursday 2/4 due to ""getting up fast"" did not hit head or hurt anything per RN discussion. Began treatment without difficulty. About 3/4 way through treatment was talking with staff and became unresponsive - code was called and pt expired after 30 minute resuscitation efforts."		No prior vaccinations for this event.
HAEMOGLOBIN DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.
HAEMOGLOBIN DECREASED		**COVID19 (COVID19**

	(MODERNA)) (1201)
jaundice->hemolytic anemia-> hemorrhagic shock->multi organ failure->death pt admitted to ICU 2/16 with Hgb=3.4, treated with steroids, supportive care , pressors, pt died 2/20/21	No prior vaccinations for this event.
HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with	No prior vaccinations for this event.

hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	No prior vaccinations for this event.

HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospice Resident received first Covid 19 vaccine dose on 1/6/21. 1/7/21 resident had decreased appetite noted in am but ate 100% of meal at dinner. 1/9/21 resident had decreased appetite with emesis x 2, loose BM x 2. Call placed to hospice. 1/10/21 5:44 am resident able to take HS meds, ingest 2 cups of shake. No emesis or loose stool noted. 12PM nurse noted resident not eating meals but ingesting milkshake and medications without any problems. Hospice contacted for change in condition. 1:00 pm hospice ordered	No prior vaccinations for this event.

Phenergan 12.5 mg Q 6 hrs PRN. Labs to be drawn 1/11/21. Hospice notified POA. 1/11/21 12:24am Resident had blood in stool. Resident denies any pain, on 2L of O2 for comfort.

HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	No prior vaccinations for this event.
HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an	No prior vaccinations for this event.

actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21

HAEMOGLOBIN DECREASED	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy,	No prior vaccinations for this event.

and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted

the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care	No prior vaccinations for this event.

center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.	No prior vaccinations for this event.
HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer,	No prior vaccinations for this event.

however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

HAEMOGLOBIN DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost

No prior vaccinations for

consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 this event. on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures

consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

HAEMOGLOBIN DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with

No prior vaccinations for this event.

IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."

HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received dose #1 of COVID-19 vaccine (Pfizer-BioNTech) on 12/18/20 and dose #2 (Pfizer-BioNTech) on 1/8/21. On 1/30, patient was evaluated at urgent care due to back pain. No bloodwork done; metronidazole prescribed for 7 days. On 2/8, patient was admitted to outside hospital due to ongoing symptom progression. At time of admission, hgb 5 g/dL and plt 9k. Per Dr. (hematology/oncology), pt with schistocytes, LDH 1500, and elevated reticulocyte count consistent with thrombotic thrombocytopenic purpura (TTP). SCr >2 mg/dL. Patient immediately treated with plasma exchange and steroids, however continued to decline. Patient expired on 2/14/21.	No prior vaccinations for this event.
HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema	No prior vaccinations for this event.

and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.

HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
HAEMOGLOBIN INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).	No prior vaccinations for this event.
HAEMOGLOBIN INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.	

HAEMOGLOBIN NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
HAEMOGLOBIN NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	No prior vaccinations for this event.
HAEMOGLOBIN NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
HAEMOLYTIC ANAEMIA	**COVID19 (COVID19 (MODERNA)) (1201)**
jaundice->hemolytic anemia-> hemorrhagic shock->multi organ failure->death pt admitted to ICU 2/16 with Hgb=3.4, treated with steroids, supportive care , pressors, pt died 2/20/21	No prior vaccinations for this event.
HAEMOPTYSIS	**COVID19 (COVID19 (PFIZER-**

	BIONTECH)) (1200)
coughing up blood, significant hemoptysis -- > cardiac arrest. started day after vaccine but likely related to ongoing progression of lung cancer	No prior vaccinations for this event.
HAEMOPTYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt had 2nd vaccine, went home and started having ""cramping"" in all of her muscles. It became bad enough that she was taken to local ED where she then started coughing up blood, required intubation and about 6 hrs later, died."	No prior vaccinations for this event.
HAEMOPTYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had sore arm on the day of vaccination. Per patient's nephew , the next morning patient experienced body pains, aches, headache . Onn Tuesday patient had fever. Patient's condition progressively got worse. He had difficulty breathing by Wednesday night. He had low oxygen levels at 80 per pulse ox reading. Patient was coughing up blood. Family took him to hospital on Thursday morning due to breathing difficulty and patient died 2.18.21 at 10 am	No prior vaccinations for this event.
HAEMORRHAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
Feb 8 states she had a cold. Feb 9 added stomach ache and nausea. Feb 9 visited urgent care facility for exam and Covid-19 test. Rapid test results were negative. Appeared tired but fine. Told to go home and rest. Feb 10 at 9:00 am found dead on the floor in pool of blood and aspirated. Excessive blood in toilet, pooled on	No prior vaccinations for this event.

floor and hallway rug.

	HAEMORRHAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the vaccine on 1/31/2021. Patient complained of bleeding 2/7/2021. Went to clinic where labs were conducted. Patient had an INR of 12. Previous INR results were normal prior to vaccination. Patient was also diagnosed with UTI and given antibiotics. Patient was encouraged to go to ER. Patient died on 2/12/2021.		No prior vaccinations for this event.
	HAEMORRHAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
Case passed away on 2/28/21. During post vaccination monitoring, case did not have any adverse reactions. When writer spoke to him on 2/26/21 to schedule his second dose, he sounded well.		No prior vaccinations for this event.
	HAEMORRHAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away; UTI; Abnormal bleeding; A spontaneous report was received from a healthcare professional concerning a patient who received the Moderna COVID-19 Vaccine (mRNA-1273) and experienced abnormal bleeding, UTI, and passed away. The patient's medical history included a long term history of anticoagulation therapy. Concomitant product use included anticoagulation therapy. On 31Jan2021 prior to the onset of the events the patient recieved their first dose of mRNA-1273 (Lot number:not reported) intramuscularly for prophylaxis of COVID-19 infection. On 07Feb2021, the patient complained of abnormal bleeding. Patient was seen at clinic on 10Feb2021 and was diagnosed with a UTI and given antibiotics. An INR was also completed that day due to patient having a long term history of anticoagulation therapy. Results of that showed the INR to be 12. Prior to vaccination, patient's INR was normal and no changes to medications and diet were made after vaccination and prior to complaint starting. On 12Feb2021 the patient passed away. Action taken with		No prior vaccinations for this event.

mRNA-1273 in response to the events was not applicable. The patient died on 12Feb2021. The cause of death was unknown. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns an 82 year old male patient, with history of long term anticoagulation therapy (unknown indication), who experienced a fatal event of death and abnormal hemorrhage, 13 days after receiving second dose of mRNA-1273 (Lot# Unknown). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

	HAEMORRHAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.		No prior vaccinations for this event.
	HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient (now deceased) received 1st dose of Pfizer-BioNTech vaccine around December 21, 2020 and was noticed to be scratching, fatigued, and unresponsive by a family member on December 24, 2020. He received the second dose of the same vaccine around January 22, 2021. Pockmarks and bleeding scratch marks were noted by a family member on the patient's face prior to this second dose. On January 28, 2021 a family member was alerted that the patient was suffering from severe bullous pemphigoid- a skin condition that has never been experienced by the patient, has been reported to be related to COVID-19 viral infection, and to T-cell responses promoted by vaccines. A corticosteroid was given, but did not work. Blisters developed to the point hands had to be dressed.		No prior vaccinations for this event.

	HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.		No prior vaccinations for this event.
	HAEMORRHAGIC STROKE	**COVID19 (COVID19 (MODERNA)) (1201)**
Hemorrhagic Stroke, Right Basal Ganglion No prior vaccinations for this event.		
HAEMORRHAGIC STROKE	**COVID19 (COVID19 (MODERNA)) (1201)**	
pt was given vaccine on the afternoon of 01-29-2021. Pt was administered the moderna covid-19 shot into the deltoid muscle of this pt. Pt was observed and left pharmacy. on 2-6, pts daughter calls pharmacy, and says the night of 1-29, after recieveing the vaccine, her mother had a hemmorhagic stroke and passed away		No prior vaccinations for this event.
	HAEMORRHAGIC STROKE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received vaccination on 1/15/2021. Hemorrhagic Stroke on 1/20 , then diagnosed with complicated idiopathic coagulopathy		No prior vaccinations for this event.
	HAEMORRHAGIC STROKE	**COVID19 (COVID19**

(MODERNA)) (1201)

Death due to hemorrhagic stroke. No prior vaccinations for this event.

HAEMORRHAGIC STROKE COVID19 (COVID19 (MODERNA)) (1201)

jaundice->hemolytic anemia-> hemorrhagic shock->multi organ failure->death pt admitted to ICU 2/16 with Hgb=3.4, treated with steroids, supportive care , pressors, pt died 2/20/21

No prior vaccinations for this event.

HEAD DISCOMFORT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing

No prior vaccinations for this event.

CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

HEAD INJURY

COVID19 (COVID19 (MODERNA)) (1201)

Pt developed COVID-19 infection, symptoms starting 7 days after first dose was given. Patient was admitted to hospital on 1/21 after falling (secondary to weakness) and striking head on toilet. Patient expired due to respiratory complications of COVID on 1/25.

No prior vaccinations for this event.

HEAD INJURY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021,

No prior vaccinations for this event.

pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."

HEADACHE

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21

No prior vaccinations for this event.

HEADACHE

COVID19 (COVID19 (MODERNA)) (1201)

"On 1/15/2021 at 1800, resident noted to be lethargic and shaking, stating ""I don't care."" repeatedly. C/O head and neck pain. T100.6. Given Tylenol with no relief of pain. Order received for Aleve and administered.. Assisted to bed as usual in evening. Monitored during night shift and noted to be resting comfortably/sleeping.. Noted agonal breathing at 4:10 AM 1/16/2021 , T 99.4, Absence of vital signs at 4:15AM 1/16/21 and death pronounced at 4:40AM 1/16/21."

No prior vaccinations for this event.

HEADACHE

COVID19 (COVID19 (MODERNA)) (1201)

Headache after dose was given at 10:00 a.m Died at after 7:30 pm the same night the dose was given.

No prior vaccinations for this event.

HEADACHE

COVID19 (COVID19 (MODERNA)) (1201)

Headache, pain in the injection site, threw up. A few hours later she died. No prior vaccinations for this event.

HEADACHE **COVID19 (COVID19 (MODERNA)) (1201)**

My dad got the Moderna Vaccine on Tuesday, January 12, 2021 in his left arm at the Mall injection site for the Health Department. He was told that the side effects could mean his arm hurting, tiredness, headache, and even a low grade fever. Additionally, the site informed us both (as I was with him to get the injection) that this was all normal and not to seek medical attention unless these symptoms last longer than 72 hours. That evening, my dad was experiencing all of those symptoms, and went to bed at 7pm. A little after 10am on Wednesday, January 13, 2021, when he awoke, my dad went to the bathroom vomiting. This was where he collapsed and went into cardiac arrest. Fire/Rescue was dispatched about 10:30am after my mom started CPR. County Fire Rescue EMTs and Paramedics continued CPR and other attempts at reviving him all the way to Hospital Emergency Department. He was pronounced dead at 12:14pm on Wednesday, January 13, 2021. We have no doubt my dad, following the instructions of the injection facility, thought he was just experiencing the side effects of the vaccine. He had no chance. Had this injection been done in the RIGHT arm, perhaps he could have recognized the arm numbness being that of an impending heart attack. We really miss Dad. He served this country with distinction for over 50 years, and we believe his country failed him.

No prior vaccinations for this event.

HEADACHE **COVID19 (COVID19 (MODERNA)) (1201)**

on 1/13/2021 at 3:40am Cliff called for assistance. He lost his balance and had fallen. Cliff refused vitals, refused emergency department, denied hitting his head. As the day progressed patient developed a headache, diarrhea, and vomiting. He again declined the offer for the emergency room. At supper time wife and staff found Cliff unresponsive, 911 was called and he was taken to the emergency department. The ER did a CT scan and found an acute subdural hematoma. Patient was placed on comfort cares and expired at 3pm on 01/14/2021. Cliff did not have a history of falls.

Influenza vaccine 10/06/2020, age 88, fever, chills, vomiting, malaise

HEADACHE **COVID19 (COVID19 (MODERNA)) (1201)**

On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene when EMS arrived. Autopsy showed a left temporal subdural hematoma.

No prior vaccinations for this event.

HEADACHE

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to emergency room on 2/1/2021 with a chief complaint of having a chronic headache and fatigue following receipt of the Moderna vaccine 10 days prior. Following examination by the physician, the patient was diagnosed with an acute subdural hematoma. The patient subsequently underwent decompressive surgery, however demonstrated worsening neurologic status over the next several days and ultimately expired on 2/4/2021.

No prior vaccinations for this event.

HEADACHE

COVID19 (COVID19 (MODERNA)) (1201)

1-2 days after vaccine, pt developed weakness, fatigue, body aches, nausea, headache and poor appetite. Pt was admitted to the hospital on 2/5/21 and death occured on 2/6/21

No prior vaccinations for this event.

HEADACHE

COVID19 (COVID19 (MODERNA)) (1201)

Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR

No prior vaccinations for this event.

initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.

	HEADACHE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had the first Moderna Covid vaccine on Thursday 1/21/2021. She had a bit of sore arm on that day and the day after. On Saturday 1/23/2021, she had a fever of 100.5 F (11AM), nausea, light headache and chills. The temperature went down after she took ibuprofen. Patient's husband enrolled her to V-Safe to report all the adverse effects she experienced. On Sunday 1/24/2021, her temperature was 98.3F. She still had nausea and no appetite. She and her husband watched a football game in their bedroom upstairs. Husband noticed that his wife was pacing around the room many times. At 7Pm, Husband went downstairs for dinner but she refused to come down to eat. He went upstairs around 8pm, TV was still on. He turned off TV and went down stairs again thinking his wife felt as sleep while watching TV. He went back upstairs for bed around 10:30 PM. Husband said his wife had a deviated septum so she would snore very loudly when asleep. He didn?t hear her snoring so he went to check on her and found her not responsive. Husband called emergency services. Paramedic came at 10:45 and said patient was passed. Husband sent many texts to V-safe after that to report the incident. No response was received from V-safe. Patient?s doctor told her husband that she died due to cardiac arrest.		No prior vaccinations for this event.

	HEADACHE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported at review of questionnaire had headache that day. Temp was taken, 97.8, okay. proceeded. Conversing customer friend in store afterward. When timer went off, said he was fine, he and his wife left. Daughter called to store Wednesday morning, said Pt had passed away Tuesday, that it was unknown the cause, and just wanted to let us know. We did not take down her phone number and last name. The patient was a long time customer.		No prior vaccinations for this event.

HEADACHE		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).		No prior vaccinations for this event.
HEADACHE		**COVID19 (COVID19 (MODERNA)) (1201)**
2/12/2021 woke up with sore arm and back. 2/13/2021 woke up with headache around 1am. Headache and nausea all morning. Mid-late afternoon started having seizures. Admitted to Hospital 2/15/2021 expired. Reported per wife on 2/25/2021.		No prior vaccinations for this event.
HEADACHE		**COVID19 (COVID19 (MODERNA)) (1201)**
Started feeling unwell; Headaches; Body aches; Chest pain; Didn't had wishes to eat; Diarrhea; COVID-19 pneumonia; A spontaneous report was received from a consumer concerning a 69-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced COVID-19 pneumonia, feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea The patient's medical history high blood pressure which was controlled with medication. Concomitant product use included nifedipine and fenofibrate. On 20-JAN-2021, approximately a week and a half or two prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number 030L20A) intramuscularly in the right		No prior vaccinations for this event.

arm for prophylaxis of COVID-19 infection. A week and a half or two later the patient stated feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea for which patient was hospitalized on 06-FEB-2021. Since everything seemed to be fine the patient was discharged on an unknown date in FEB-2021 however, patient's family was not notified that it was a late reaction to the vaccine's first dose. Later, due to shortness of breath he was hospitalized again on 08-FEB-2021 and was diagnosed for pneumonia and was intubated on the same day. Due to COVID-19 situation patient's family could not be in the facilities and that there wasn't any follow up of the patient given to the family, so family did not have much information. During the first hospitalization(06-FEB-2021) the patient had a blood test which showed a normal result and was tested for COVID-19 and Influenza, both were negative. During second hospitalization (08-FEB-2021) the hospital said that the patient was stable. The patient's family did not know the results of the tests conducted at the time. The action taken with the vaccine in response to the events is not applicable. The outcome of COVID-19 pneumonia was fatal. The patient died on 14 Feb 2021 The cause of death was reported as COVID-19 related pneumonia. The autopsy was not done.; Reporter's Comments: Very limited information regarding this event has been provided at this time. The cause of death was reported as COVID-19 related pneumonia. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the events are assessed as unlikely related. Further information has been requested.; Reported Cause(s) of Death: COVID-19 pneumonia		
	HEADACHE	**COVID19 (COVID19 (MODERNA)) (1201)**
"Possible heart attack on 2/5/21. Complaint: "" On Feb 5th I believe I experienced a mild hear attack"" (Comment: He said he felt ""clammy, sweaty, excruciating pain on my left side - including his left arm, and left leg, dizzy, exhausted."" This happened after work, and after taking a shower. He said that was the first time he's experienced it, and that it has not happened since then. He said he has constant headaches, ""It just went away yesterday.""""		No prior vaccinations for this event.
	HEADACHE	**COVID19 (COVID19**

(MODERNA)) (1201)

My grandpa got his second covid vaccine on Thursday. Saturday he complained of stiff neck. Sunday he had low grade fever, nausea and vomiting, chills, and mild headache. He was feeling bad enough to call squad at 3 pm. The paramedics did evaluation and thought he was just experiencing normal side effects from vaccine and felt no need to transport to hospital so my grandpa decided to stay home and just rest. At 2 am that same night he went into cardiac arrest and was not able to be brought back

No prior vaccinations for this event.

HEADACHE

COVID19 (COVID19 (MODERNA)) (1201)

Chills; headache; extreme fatigue; gas or chest pain that was thought to be gas and went away Died 4 days later

No prior vaccinations for this event.

HEADACHE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/7-21 - Received second dose of pfizer covid-19 vaccine 1/8/21 - Fever, dizziness, headache 1/10/21 0250 was found not breathing. EMS performed CPR and patient deceased

No prior vaccinations for this event.

HEADACHE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - anuerism lead to death approximately 14 hours after initial symptoms.

No prior vaccinations for this event.

HEADACHE

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

On 1/11/21 noted with headache, nausea/vomiting, severe melaise. On 1/12/21 resident expired.

No prior vaccinations for this event.

HEADACHE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

She had the first dose of Pfizer vaccine at the Campus on Friday 1/15 at 4:30 pm. After the vaccine, she had no new symptoms or signs of vaccine reaction and MD friend reports that he checked her pulse which was not elevated from baseline. On 1/16, she awakened and continued to feel at her recent baseline. However, in the early afternoon, she complained of headache, nausea/epigastric pain, and chest heaviness. These apparently were not unusual symptoms for her to feel intermittently. Per her niece, who has a home O2 sat device, her 02 sat that morning was 97 with a HR of 87 irregularly irregular. She was afebrile. (continue on page 2)

No prior vaccinations for this event.

HEADACHE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Patient's wife called this morning stating that her husband has passed away last night. After receiving first dose of Pfizer COVID-19 vaccine at around 0830, patient remained in the Immunizations Department for the 15-minute monitoring period. Per wife, patient's only complaint was pain at the injection site. At 1300, wife states that patient complaint of dizziness which ""dissipated after a few minutes"" followed by a headache which ""dissipated after a few minutes"" as well. Then patient complained of nausea, no vomiting and ""couldn't relax."" Per wife, from around 1400/1500, patient stayed on his recliner while still having a conversation with her--""he didn't get up to eat."" Last conversation they had was around 2000/2100. Per wife, at around 2100/2200, patient was quiet and when she checked on him, ""he wasn't responding

No prior vaccinations for this event.

anymore."" Wife then called 911, ""but they couldn't revive him."""

	HEADACHE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Jan 3 vaccine administered, jan 4 started headaches, vomiting, pain in the back of the neck, Headaches, chills, loss of speech,		No prior vaccinations for this event.
	HEADACHE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Same day as vaccination given, developed pain went from arm up to shoulder, to back, to neck to head - right side of body; chills/body aches		No prior vaccinations for this event.
	HEADACHE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death. I actually not sure which Covid Vaccine she took. I just know the date and time she took it at her local school where she worked. Died in her sleep after complaining of a headache. I talked to her around 5pm on sunday through a videochat and she seemed happy and well. But a local friend commented that she had complained of a headache late in the afternoon.		No prior vaccinations for this event.
	HEADACHE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had sore arm on the day of vaccination. Per patient's nephew , the next morning patient experienced body pains, aches, headache . Onn Tuesday patient had fever. Patient's condition		No prior vaccinations for

progressively got worse. He had difficulty breathing by Wednesday night. He had low oxygen levels at 80 per pulse ox reading. Patient was coughing up blood. Family took him to hospital on Thursday morning due to breathing difficulty and patient died 2.18.21 at 10 am	this event.	
HEADACHE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.	No prior vaccinations for this event.	
HEADACHE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per Patients Wife - Same day - Flu like symptoms, Nausea, Headache. Restless that night. Next day - Weak, shortness of breath. Wife called squad to get him out of his wheelchair but patient refused hospital as it gets him agitated. Patient passed away around 11 AM the day after vaccination.	No prior vaccinations for this event.	
HEADACHE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Severe headache, nausea and vomiting No prior vaccinations for this event.

HEADACHE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
death; severe headache; This is a spontaneous report from a non-contactable consumer from a Pfizer-sponsored program. A male patient of an unspecified age (Age: 83, unit: Unknown; as reported) received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number:EH9899), intramuscularly in the left arm on 20Jan2021 at a single dose for COVID-19 immunisation. The patient's medical history included sulfonamide allergy from an unknown date and unknown if ongoing. Concomitant medications were not reported. The patient previously took azithromycin [MANUFACTURER UNKNOWN] and experienced allergy on an unspecified date. On 22Jan2021, the patient experienced severe headache (non-serious). On 28Jan2021, the patient experienced death (death, medically significant); 8 days after receiving the vaccine. The patient died on 28Jan2021 due to unknown cause of death. It was unknown if an autopsy was performed. The clinical outcome of the event, death, was fatal. The clinical outcome of the event, severe headache, was not recovered. No follow-up attempts are possible. No further information is expected. ; Reported Cause(s) of Death: Unknown cause of death		No prior vaccinations for this event.

HEADACHE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion; On 21Feb he went to the ER after vomiting and passing out; On 21Feb he went to the ER after vomiting and passing out; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; fever; headache; stomach upset; This is a spontaneous report from a contactable consumer reporting for the father: A 75-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EL3428) at single dose at left arm on 03Feb2021 for Covid-19 immunisation. Medical history included type 2 diabetes mellitus. No known allergies. The patient had not experienced Covid-19		No prior vaccinations for this event.

prior vaccination. Concomitant medication in 2 weeks included amitriptyline hydrochloride (manufacturer unknown) 10 mg, atorvastatin (manufacturer unknown) 20 mg, dutasteride (manufacturer unknown) 0.5 mg, linaclotide (LINZESS) 290 mcg, gabapentin (manufacturer unknown) 300 mg, montelukast (manufacturer unknown) 10 mg, ramipril (manufacturer unknown) 5 mg, insulin degludec (TRESIBA) 100 unit/ml, liraglutide (VICTOZA) 18 mg/3ml solution. No other vaccine in 4 weeks. The patient experienced cardiac arrest due to pericardial effusion on 21Feb2021 14:15, fever on 13Feb2021, headache on 13Feb2021, stomach upset on 13Feb2021, on 19feb, he began to feel ill again with a fever, he felt worse on 20feb on 19Feb2021, on 21feb he went to the ER after vomiting and passing out on 21Feb2021. Events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of cardiac arrest due to pericardial effusion. Course of events: In Feb2021, 10 days after his 1st injection, the patient developed fever, headache, and stomach upset. He went for a rapid Covid-19 test (nasal swab) and it was negative on 11Feb2021. The doctor told him he might be having a delayed reaction to the vaccination. After a couple of days, he improved. On 19Feb2021, he began to feel ill again with a fever. He felt worse on 20Feb2021. On 21Feb2021 he went to the ER after vomiting and passing out and received treatment: IV fluids, diagnostic testing at ER. Rapid Covid test (nasal swab) at ER came back negative again on 21Feb2021. His heart arrested suddenly and he could not be resuscitated. CT scan results, that came back after death, showed Covid like pneumonia and pericardial effusion. The patient died on 21Feb2021 14:15. Cause of death was cardiac arrest due to pericardial effusion. An autopsy was not performed. The outcome of cardiac arrest due to pericardial effusion was fatal, of fever, headache, stomach upset was recovering, of he began to feel ill again with a fever, he felt worse was not recovered, of he went to the ER after vomiting and passing out was unknown.; Reported Cause(s) of Death: cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion

	HEADACHE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Patient received the vaccine around 11 am. He hadn't been feeling well (headache, dizziness) per report	No prior vaccinations for

and initially called in to work. He then decided to come to work and was found down in a patient bathroom during his shift on our Facility while taking care of a patient (he was a nurse aid). Patient was coded and the team and was transferred to our Facility ED. He expired 3/3 2112		this event.
	HEADACHE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Day After - severe headache, 2 days after headache continues, itchy scalp, day 3 rash visible at hair line headache continues, more confusion than normal, day 4 on site nurses check rash and think it is dermatitis, day 5 continues to get work nurse practitioner was to visit next day, day 6 NP thinks that she has UTI and sends her to hospital (2/11/21). Hospital determines - Rash is Shingles, UTI present, - MRSA is now present in shingles which is on right back of head and right neck and face. Next Sepsis is diagnosed. Since 2/11/21 patient was not conscious. 2/20/21 famiy is notified that she should be moved to Hospice. Moved to hospice on 2/20/21. The patient, my mother, died on 2/23/21 official cause of death is UTI.		No prior vaccinations for this event.
	HEART RATE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Is patient deceased: Yes; Low pulse; This is a spontaneous report from two contactable nurses reporting for a patient. A 70-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL0140 expiration date Mar2021) intramuscular on 22Dec2020 at 10:30 at single dose in right arm for COVID-19 immunisation. The patient was vaccinated at Nursing Home. Patient age at time of vaccination was 70 years. Patient's Medical History included ongoing Type 2 Diabetes Mellitus Without Complication onset date: admission 22Oct2020, ongoing morbid obesity due to excess calories onset date: admission 22Oct2020, cardiac disorder, essential hypertension, hypertension, schizophrenia,		No prior vaccinations for this event.

hyperlipidemia, benign prostatic hyperplasia (BPH), Gastrooesophageal reflux disease (GERD), depression, hypothyroid, epilepsy, pain, dry eyes, anxiety, restlessness, 17Jan2020 Slid out of chair to floor, no injury, on 27Jan2020, 28Jan2020, 29Jan2020 diarrhea noted. Concomitant medications included acetylsalicylic acid (ASPIRIN EC) for Cardiac Health, atenolol (ATENOLOL) for Essential Hypertension, atorvastatin calcium (ATORVASTATIN CALCIUM) for hyperlipidemia, finasteride (FINASTERIDE) for benign prostatic hyperplasia, tamsulosin hydrochloride (FLOMAX) benign prostatic hyperplasia, insulin glargine (LANTUS) for diabetes mellitus, lithium carbonate (LITHIUM CARBONATE) for Schizophrenia, losartan potassium (LOSARTAN POTASSIUM) for hypertension, lurasidone hydrochloride (LURASIDONE HYDROCHLORIDE) for Schizophrenia, omeprazole (OMEPRAZOLE) for gastrooesophageal reflux disease, sertraline hcl (SERTRALINE HCL) for depression, levothyroxine sodium (SYNTHROID) for hypothyroid, ergocalciferol (VIT D) for supplement, haloperidol (HALOPERIDOL) for Schizophrenia, levetiracetam (KEPPRA) for epilepsy, paracetamol (TYLENOL EXTRA-STRENGTH) for pain, propylene glycol (ARTIFICIAL TEARS) for dry eyes, lorazepam (ATIVAN) for a anxiety or restlessness. As antipyretic use was reported Tylenol ES (500 mg) Tab, 2 Tabs by Mouth Routine use three times a day given at time of vaccination and after. It was reported the patient was Covid+. He was tested on 21Dec2020 and was not admitted to hospital. Event Onset Date was reported as 24Dec2020 (clarification pending). On 30Dec2020 the patient was started on O2 at 2L for low pulse. O2 was increased over time to eventually O2 at 8L on 03Jan2021. Morphine Sulfate was started on 03Jan2021 at 5 mg sl/by mouth every 2 hours as needed for pain or airhunger. The patient deceased on 03Jan2021. The cause of death was unknown. It was not reported if an autopsy was performed. The AEs did not require a visit to Emergency Room or Physician Office. Outcome of Low pulse was unknown.; Sender's Comments: Based on the information available the events Death (unknown cause) and Heart rate decreased are attributed to patient's multiple underlying medical conditions including Type 2 Diabetes Mellitus, morbid obesity, cardiac disorder, hypertension, epilepsy etc. However, based solely on a vaccine-event chronological association, contributory role of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the above mentioned events cannot be completely excluded. The case will be reevaluated should additional information, including the cause of death, become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as

part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Is patient deceased: Yes

HEART RATE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They	No prior vaccinations for this event.

decided to put him in a medically induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away

HEART RATE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Maternal exposure during pregnancy; Fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected; This is a spontaneous report from a contactable consumer (parent). This consumer reported information for both mother and fetus. This is a fetus report. A patient of unspecified age and gender (fetus) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269), transplacental on 04Feb2021 at 14:00 at single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medication included ergocalciferol (VIT D), folic acid (FOLATE), ascorbic acid/betacarotene/calcium sulfate/colecalciferol/cyanocobalamin/ferrous fumarate/folic acid/ nicotinamide/pyridoxine hydrochloride/retinol acetate/riboflavin/thiamine mononitrate/tocopheryl acetate/zinc oxide (PRENATAL VITAMINS) and sertraline hydrochloride (ZOLOFT) at 25 mg, all transplacental. It was reported that OB exam on 03Feb21 showed healthy baby at 7weeks 5days heartbeat detected 152 bpm; no abnormalities identified via ultrasound; labs and hormone levels all within normal ranges. No issues detected. Mother received 1st dose of vaccine on 04Feb2021. Per ultrasound on 20Feb2021, fetus stopped growing on 09Feb2021 (8 weeks 4 days); no heartbeat detected. Miscarriage occurred on 22Feb2021. The fetus died on 22Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021204433 same drug and reporter, different patient and event; Reported Cause(s) of Death: Fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected; Mother received 1st dose of vaccine 04Feb21. Per ultrasound on 20Feb21, fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected. Miscarriage occurred 22Feb21.	No prior vaccinations for this event.

	HEART RATE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
pulmonary edema; Low heart rate; chest pain; This is a spontaneous report from a contactable pharmacist. An 80-years-old male patient received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in left arm on 28Jan2021 at single dose for COVID-19 Immunisation. Medical history included dementia, high blood pressure, COVID prior vaccination. He had no known allergies. Concomitant medication included diltiazem hydrochloride (CARDIZEM), anastrozole (ARIMIDEX), simvastatin and lorazepam. Historical Vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 07Jan2021 (at the age of 80-years-old) at single dose for COVID-19 Immunization. There was no other vaccine received in four weeks. The patient experienced pulmonary edema, low heart rate and chest pain on 26Feb2021. The events resulted in hospitalization and patient died. The patient was hospitalized from 26Feb2021 for 1 day. Treatment received for the events included Epinephrine, morphine, nitroglycerine. The patient underwent lab tests and procedures which included Covid test Nasal Swab post vaccination on 26Feb2021 indicated Negative. The patient died on 26Feb2021. An autopsy was not performed. information on the lot/batch number has been requested.; Sender's Comments: Pulmonary edema, low heart rate, and chest pain, all reported as fatal, are deemed unrelated to BNT162B2 vaccine, being rather accidental occurrences, likely favored by the patient's age and by the mentioned high blood pressure, known risk factor for cardiovascular diseases. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Low heart rate; pulmonary edema; chest pain		No prior vaccinations for this event.
	HEART RATE ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**

DISCOVERED UNRESPONSIVE WITHOUT PULSE, RESPIRATIONS, HEART BEAT ON 2/7/21 AT 0435 A.M. RESIDENT WAS DNR STATUS.	No prior vaccinations for this event.
HEART RATE ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received vaccine at Public Health Clinic. Patient ended up having a seizure 3 days later and ended up in the hospital. Found to have right lobe pneumonia and low depakote level. Patient noted to have multiple seizures at hospital, issues with stabilizing HR and BP, and passed away on 1/20/21.	No prior vaccinations for this event.
HEART RATE ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Decedent had unwitnessed fall out of wheelchair 1/25/21 around 9:43am, denied head strike, pain, discomfort. Around 10:02pm, 1/25/21, decedent noted to have slurred speech and fluctuating HR, transported to Hospital and made cmo.	No prior vaccinations for this event.
HEART RATE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Is patient deceased: Yes; Low pulse; This is a spontaneous report from two contactable nurses reporting for a patient. A 70-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL0140 expiration date Mar2021) intramuscular on 22Dec2020 at 10:30 at single dose in right arm for COVID-19 immunisation. The patient was vaccinated at Nursing Home. Patient age at time of vaccination was 70 years. Patient's Medical History included ongoing Type 2 Diabetes Mellitus Without Complication onset date: admission 22Oct2020, ongoing morbid obesity due to excess calories onset date: admission 22Oct2020, cardiac disorder, essential hypertension, hypertension, schizophrenia,	No prior vaccinations for this event.

hyperlipidemia, benign prostatic hyperplasia (BPH), Gastrooesophageal reflux disease (GERD), depression, hypothyroid, epilepsy, pain, dry eyes, anxiety, restlessness, 17Jan2020 Slid out of chair to floor, no injury, on 27Jan2020, 28Jan2020, 29Jan2020 diarrhea noted. Concomitant medications included acetylsalicylic acid (ASPIRIN EC) for Cardiac Health, atenolol (ATENOLOL) for Essential Hypertension, atorvastatin calcium (ATORVASTATIN CALCIUM) for hyperlipidemia, finasteride (FINASTERIDE) for benign prostatic hyperplasia, tamsulosin hydrochloride (FLOMAX) benign prostatic hyperplasia, insulin glargine (LANTUS) for diabetes mellitus, lithium carbonate (LITHIUM CARBONATE) for Schizophrenia, losartan potassium (LOSARTAN POTASSIUM) for hypertension, lurasidone hydrochloride (LURASIDONE HYDROCHLORIDE) for Schizophrenia, omeprazole (OMEPRAZOLE) for gastrooesophageal reflux disease, sertraline hcl (SERTRALINE HCL) for depression, levothyroxine sodium (SYNTHROID) for hypothyroid, ergocalciferol (VIT D) for supplement, haloperidol (HALOPERIDOL) for Schizophrenia, levetiracetam (KEPPRA) for epilepsy, paracetamol (TYLENOL EXTRA-STRENGTH) for pain, propylene glycol (ARTIFICIAL TEARS) for dry eyes, lorazepam (ATIVAN) for a anxiety or restlessness. As antipyretic use was reported Tylenol ES (500 mg) Tab, 2 Tabs by Mouth Routine use three times a day given at time of vaccination and after. It was reported the patient was Covid+. He was tested on 21Dec2020 and was not admitted to hospital. Event Onset Date was reported as 24Dec2020 (clarification pending). On 30Dec2020 the patient was started on O2 at 2L for low pulse. O2 was increased over time to eventually O2 at 8L on 03Jan2021. Morphine Sulfate was started on 03Jan2021 at 5 mg sl/by mouth every 2 hours as needed for pain or airhunger. The patient deceased on 03Jan2021. The cause of death was unknown. It was not reported if an autopsy was performed. The AEs did not require a visit to Emergency Room or Physician Office. Outcome of Low pulse was unknown.; Sender's Comments: Based on the information available the events Death (unknown cause) and Heart rate decreased are attributed to patient's multiple underlying medical conditions including Type 2 Diabetes Mellitus, morbid obesity, cardiac disorder, hypertension, epilepsy etc. However, based solely on a vaccine-event chronological association, contributory role of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the above mentioned events cannot be completely excluded. The case will be reevaluated should additional information, including the cause of death, become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as

part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Is patient deceased: Yes

	HEART RATE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	pulmonary edema; Low heart rate; chest pain; This is a spontaneous report from a contactable pharmacist. An 80-years-old male patient received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in left arm on 28Jan2021 at single dose for COVID-19 Immunisation. Medical history included dementia, high blood pressure, COVID prior vaccination. He had no known allergies. Concomitant medication included diltiazem hydrochloride (CARDIZEM), anastrozole (ARIMIDEX), simvastatin and lorazepam. Historical Vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 07Jan2021 (at the age of 80-years-old) at single dose for COVID-19 Immunization. There was no other vaccine received in four weeks. The patient experienced pulmonary edema, low heart rate and chest pain on 26Feb2021. The events resulted in hospitalization and patient died. The patient was hospitalized from 26Feb2021 for 1 day. Treatment received for the events included Epinephrine, morphine, nitroglycerine. The patient underwent lab tests and procedures which included Covid test Nasal Swab post vaccination on 26Feb2021 indicated Negative. The patient died on 26Feb2021. An autopsy was not performed. information on the lot/batch number has been requested.; Sender's Comments: Pulmonary edema, low heart rate, and chest pain, all reported as fatal, are deemed unrelated to BNT162B2 vaccine, being rather accidental occurrences, likely favored by the patient's age and by the mentioned high blood pressure, known risk factor for cardiovascular diseases. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as	No prior vaccinations for this event.

appropriate.; Reported Cause(s) of Death: Low heart rate; pulmonary edema; chest pain

	HEART RATE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Rapid decline in health status, Elevated BP&P, posturing, loss of consciousness, Glasgow coma Scale 4 starting 2/1/2021, Deceased 2/3/21		No prior vaccinations for this event.

	HEART RATE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was seen at 0710 he was sleeping but at normal cognitive behavior Patient was again assessed at 0720 where he was noted to be unresponsive, BP 180/100s, HR 230s, he was a DNR therefore not CPR was administered. EMS arrived at facility patient was noted to be in full cardiac and respiratory arrest. Time of death 0735		No prior vaccinations for this event.

	HEART RATE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/9/2021 observed with elevated respirations of 38-42 per minute, BP manually 72/50. pulse is jumping rapidly between 110-16 bpm. oxygen sat 76% RA, resident refusing oxygen at first attempt, allowed oxygen to be placed, is now 84% on 4L. resident shaking head yes that he is hurting, and yes that he would take medication for pain. Dr. notified, branch block. Received order for morphine 2mg per hr as needed for elevated respirations and pain. Dr. also gave orders to D/C Tamsulosin and finasteride. Resident continue with decreased O2 sats and elevated respirations. Absence of vital signs on 1/10/21 at 826PM.		No prior vaccinations for this event.

	HEART RATE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Unresponsive, Increase BP and H. Hospital Dx Renal Failure No prior vaccinations for this event.

HEART RATE INCREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21- N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

No prior vaccinations for this event.

HEART RATE INCREASED **COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Elevated heart rate, flushing of the face and ears, vomiting, trouble breathing, pulmonary edema

No prior vaccinations for this event.

HEART RATE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically

No prior vaccinations for this event.

induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away

HEART RATE IRREGULAR		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient found down at home with agonal respirations and per EMS asystole, received 2 rounds of epi at her house with return of spontaneous pulses, lost pulse again in route to ER and another round of epi was given, CPR in progress when arrived at hospital. Prior to this patient's husband states he heard her fall in the bathroom but did not immediately check on her as he states that this has happened before. He checked on her 10 min later and that's when he found her unconscious. Daughter called 911 and she began CPR. No previous complaints of headache, chest pain, back pain, fever or chills. Husband states patient was drinking that evening which is not unusual for her. Patient died at hospital.	No prior vaccinations for this event.	
HEART RATE IRREGULAR		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
She had the first dose of Pfizer vaccine at the Campus on Friday 1/15 at 4:30 pm. After the vaccine, she had no new symptoms or signs of vaccine reaction and MD friend reports that he checked her pulse which was not elevated from baseline. On 1/16, she awakened and continued to feel at her recent baseline. However, in the early afternoon, she complained of headache, nausea/epigastric pain, and chest heaviness. These apparently were not unusual symptoms for her to feel intermittently. Per her niece, who has a home O2 sat device, her 02 sat that morning was 97 with a HR of 87 irregularly irregular. She was afebrile. (continue on page 2)	No prior vaccinations for this event.	

	HEART RATE IRREGULAR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
	HEART SOUNDS ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.		No prior vaccinations for this event.
	HEMIPARESIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient vaccinated on 12/28. Approximately one day later, develops cough and on azithromycin x 1 week. On 1/3, patient develops left-sided weakness and aphasia. Taken to the hospital, tested COVID+, required intubation -- acute hypoxic respiratory failure secondary to COVID - on H&P. Patient died on 1/4/21 at 7:20am.		No prior vaccinations for this event.

	HEMIPARESIS	**COVID19 (COVID19 (MODERNA)) (1201)**
death; hemiparesis; respiratory failure; Aphasia; SARS-COV-2 test positive; cough; A spontaneous report was received from other health care professional concerning a 32- year -female patient who received Modena's COVID-19 vaccine (mRNA-1273) and experienced aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive. The patient's medical history was not provided. No relevant concomitant medications were reported. On 28-Dec-2020, the patient received their first of two planned doses of mRNA-1273 (lot/batch 039k20A) intramuscularly on left arm for prophylaxis of COVID-19 infection. Approximately, one day later, patient developed cough and on treatment with azithromycin for one week. On 03-jan-2021, she experienced left sided weakness and aphasia and was shifted to hospital. Patient was confirmed COVID-19 positive which required intubation for acute hypoxic respiratory failure secondary to COVID-19. No laboratory data was provided. Action taken with mRNA-1273 in response to the events aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive not applicable. On an unknown date, the outcome of the events aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive was fatal. On 04 Jan 2021, the patient passed away due to the unknown cause. Autopsy results were unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the event of COVID-19 is assessed as unlikely related. The cause of death was not reported. Autopsy results were unknown.; Reported Cause(s) of Death: Unknown cause of death		No prior vaccinations for this event.
	HEMIPARESIS	**COVID19 (COVID19 (MODERNA)) (1201)**
"My grandpa had a stroke on the 15th of February. He claimed he had been feeling ""off"" for a few days, but didn't say anything. A blood clot had formed in his brain. He was doing better and about to go to rehab to strength his right side of his body. On the 22nd he took a turn for the worst. He was having trouble		No prior vaccinations for this event.

breathing and they sedated and partially paralyzed him to put a tube in his mouth. I believe another blood clot had formed and oxygen wasn't properly going through his body. They could not stabilize him, and he passed away the same day."

	HEMIPARESIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Has underlying dementia and often with difficulty eating. 1 week after immunization she developed a stroke with left sided weakness and difficulty swallowing. Comfort measures instituted. Not sure if this is related to the vaccine, but thought I should report		No prior vaccinations for this event.

	HEMIPARESIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was noted on 1/25 with an increased functional decline as she would not feed herself with utensils, but would eat finger foods if placed in her hand. She was started on Rocephin IM for possible infections. Labs had been obtained on 1/21/21, unremarkable for CBC and CMP. 75,000 colony count on urine. On 1/26/21 she was noted with right sided weakness and further decline. She was sent to Hospital for further evaluation. We were notified that she expired on 1/28/2021. Resident had been noted with a decline in function about 2 weeks earlier when she would not stand or transfer any longer. She was still responsive, taking meds, and feeding herself until 1/26/21. Further information on admitting diagnoses and progress notes from hospital have not been available to date.		No prior vaccinations for this event.

	HEMIPARESIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Adverse reaction to the vaccine started with variable weakness beginning 1/29/2021. On 1/30/21 around 8:30pm, he needed assistance in the bathroom related to weakness and had what was later identified as a stroke with left side weakness and slurred speech. In accordance with his wishes, he had care at home. Due to his advanced age and frailty, a CT scan was not pursued. The 325 mg of aspirin that he was previously taking daily was discontinued. After the stroke, he needed total care. Hospice was established at home. Nursing assistant care was delivered by daughter. Death followed 9 days later (2/9/2021).

No prior vaccinations for this event.

HEMIPLEGIA

COVID19 (COVID19 (MODERNA)) (1201)

Staff walked into resident's room around 10:00am and noted resident's left side of his face was flaccid. Nurse was called and upon assessment resident noted to have an unequal hand grasp with left worse. He was able to talk but was mumbled and hard to understand. Physician, hospice, and family were notified. Resident had a stroke at 10:06 am on 1/8/2020. He lost all ability to use his left side. Resident passed away on 1/11/2020.

No prior vaccinations for this event.

HEPATIC ENZYME INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21

No prior vaccinations for this event.

HEPATIC ENZYME INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia

No prior vaccinations for this event.

(80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

HEPATIC FUNCTION ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.	No prior vaccinations for this event.
HEPATORENAL SYNDROME	**COVID19 (COVID19 (MODERNA)) (1201)**

Hepatorenal syndrome- Death No prior vaccinations for this event.

HERNIA REPAIR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Vaccinated 2/20. At that time, had symptoms of incarcerated hernia, went to ED for evaluation. Not felt to warrant hospital admission. Returned two days later with agitation, altered mental status, and incarceration. Went to OR, uncomplicated hernia repair. Postoperatively, did not recover mental status. Went into arrythmias POD 4, hypotension ensued, had multiple interventions and evaluations without satisfying answers for clinical course.		No prior vaccinations for this event.
HERPES ZOSTER		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/29/21 patient began not feeling well and saw her provider. The doctor gave her fluids and tramadol for pain. They noticed increased confusion, but thought that could have been due to the tramadol. They also increased her gabapentin as she was experiencing nerve pain. Patient also developed a rash and was diagnosed with shingles on 2/1/21. Patient died on 2/3/21		No prior vaccinations for this event.
HERPES ZOSTER		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Day After - severe headache, 2 days after headache continues, itchy scalp, day 3 rash visible at hair line headache continues, more confusion than normal, day 4 on site nurses check rash and think it is dermatitis, day 5 continues to get work nurse practitioner was to visit next day, day 6 NP thinks that she has UTI and sends her to hospital (2/11/21). Hospital determines - Rash is Shingles, UTI present, - MRSA is now present in shingles which is on right back of head and right neck and face. Next Sepsis is diagnosed. Since 2/11/21 patient was not conscious. 2/20/21 famiy is notified that she should be moved to Hospice. Moved to hospice		No prior vaccinations for this event.

on 2/20/21. The patient, my mother, died on 2/23/21 official cause of death is UTI.

	HIATUS HERNIA	**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"		No prior vaccinations for this event.

	HIATUS HERNIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at		No prior vaccinations for this event.

01:53 on 1/19/21.

HIP ARTHROPLASTY	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient fell the day after receiving the Moderna COVID-19 vaccine. She broke her hip in this fall. During surgery to correct the broken hip, she went in to sudden and unexpected cardiac arrest. The anesthetist did not notice any ST changes or A fib; dysrhythmia was very unexpected. The patient had a DNR. She died at 13:00 on 02/07/2021. Causes of death are listed as 1. Cardiac Arrest 2. Recent hip fracture with hip placement 3. History of Breast Cancer 4. Hypothyroid and 5. Dementia	No prior vaccinations for this event.
HIP FRACTURE	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident had body aches, a low O2 sat and had chills starting on 12/30/20. He had stated that they had slightly improved. On 1/1/21 he sustained a fall with a diagnosis of a displaced hip fracture. On 1/2/21 during the NOC shift his O2 sat dropped again. He later went unresponsive and passed away.	No prior vaccinations for this event.
HIP FRACTURE	**COVID19 (COVID19 (MODERNA)) (1201)**
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HIP FRACTURE	**COVID19 (COVID19**

	(MODERNA)) (1201)
Approximately 2 weeks after the first COVID vaccine she developed shortness of breath that was much more significant than she had previously. This was the first time she had expressed this symptom to me as being something she was concerned about and difficult for her to manage (we have spoken almost daily for many years). Within 24 hours of the second dose of the mRNA vaccine, they called an ambulance to get her and she was taken to the hospital and diagnosed with bacterial pneumonia. The doctors said it was unrelated, but I found a study with a different vaccine (LAIV) that also seemed to increase the incidence of bacterial pneumonia. They hypothesized through diverting the immune system. So while I don't think the vaccine gave her the bacteria, I do think it may have caused her immune system to be temporarily compromised allowing the bacteria to grow out of control. I feel this is important to report to look for these types of patterns as perhaps it can help others avoid the death spiral that happened to my mother. There were also intervening events between her hospitalization and her death including two successful surgeries (one for a broken hip and another to put in stents in her leg). So to summarize, the first vaccine was within about 2 weeks of the onset of her breathing problems. Within 24 hours of the second vaccine she was hospitalized and diagnosed with bacterial pneumonia. As she was battling bacterial pneumonia in the hospital she broke her hip and was found to have reduced peripheral circulation and had 2 surgeries to correct those. They were successful according to the surgeons, however she died within a week or so of the surgeries. She had other comorbidities as well which I'm sure predisposed her such as diabetes, hypertension and cancer for many years.	Breathing issues ~2 weeks after first dose of mRNA vaccine in the series but were not nearly as acute or severe as they were fol
HIP FRACTURE	**COVID19 (COVID19 (MODERNA)) (1201)**
Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley	No prior vaccinations for this event.

insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.

HIP SURGERY

COVID19 (COVID19 (MODERNA)) (1201)

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HIP SURGERY	**COVID19 (COVID19 (MODERNA)) (1201)**
Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.	No prior vaccinations for this event.
HOSPICE CARE	**COVID19 (COVID19 (MODERNA)) (1201)**
Redness and warmth with edema to right side of neck and under chin. Resident was on Hospice services and expired on 1.1.21	No prior vaccinations for this event.
HOSPICE CARE	**COVID19 (COVID19 (MODERNA)) (1201)**
12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was	No prior vaccinations for this event.

abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics

HOSPICE CARE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident became SOB, congested and hypoxic requiring oxygen, respiratory treatments and suctioning. Stabilized after treatment and for the next 72 hours with oxygen saturations in the 90s. On 1/3/2021 was found without pulse and respirations. Resident was a DNR on Hospice.

No prior vaccinations for this event.

HOSPICE CARE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.

Influenza Virus Vaccines - Unknown date/type or brand

HOSPICE CARE

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Resident was vaccinated on 12/31/20. Then on 1/14/21 he tested positive for SARS-CoV-2 on routine surveillance PCR testing. Another resident on the same hall was COVID positive on 1/11/21. Results of the PCR test were obtained on 1/16/21. He appeared asymptomatic at that time. Given his COVID positive status, all aerosol generating procedures had to be stopped. Overnight on 1/16/21 into 1/17/21, he had the onset of acute respiratory failure and was transported to the hospital. Per notes, he was put on BiPAP for several hours, but his CO2 level did not improve. Per prior advance directives completed with the resident and his two brothers, he had DNR/DNI orders. The hospital physician spoke with his brother and the decision was made to move to comfort care. He was discharged to inpatient hospice and died around 4pm on 1/18/21. This outcome does not appear to be vaccine-related, but death from COVID-19 infection is listed as a reportable event following COVID-19 vaccination.

No prior vaccinations for this event.

HOT FLUSH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.

No prior vaccinations for this event.

HUMAN CHORIONIC GONADOTROPIN NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was

No prior vaccinations for

not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

this event.

HUMAN METAPNEUMOVIRUS TEST

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow

No prior vaccinations for this event.

agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.

HUMAN RHINOVIRUS TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.	No prior vaccinations for this event.

HUNT AND HESS SCALE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head	No prior vaccinations for this event.

notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

	HYPERAESTHESIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient obtained initial dose of Moderna vaccine on Thurday, Jan 14. No adverse effects reported during initial 15 minute post vaccine waiting period. Saturday morning (Jan 16), patient developed severe cough, labored breathing, and fever. Additionally patient mental status changed suddenly, became non-communicative (unable to speak, but would scream if she was touched). O2 status was irregular, dropping to 78. Sunday morning, EMT and then hospice was hospice called. Monday morning, after hospice emergency kit was initiated, patient passed away.		No prior vaccinations for this event.
	HYPERCAPNIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Lethargy/altered level of consciousness lead to hospital admission. Multiple interventions during hospitalization. Final hospital diagnoses: Acute respiratory failure with hypercapnia, acute pansinusitis.		No prior vaccinations for this event.

HYPERGLYCAEMIA		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).		No prior vaccinations for this event.
HYPERHIDROSIS		**COVID19 (COVID19 (MODERNA)) (1201)**
ON 1/21/2020 RESIDENT WAS EXPERINCING CHILLS AND LOOSE STOOLS. FOLLOWING THIS EPISODE BECAME UNRESPONSIVE, PALE, DIAPHORETIC AND BRADYCARDIC. PALLIATIVE CARE WAS PROVIDED. RESIDENT PASSED AWAY APPROX. 10 HOURS LATER.		No prior vaccinations for this event.
HYPERHIDROSIS		**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive MI, PE or ruptured AAA"". Death certificate notes indicate ""signficant conditions contributing to death after		No prior vaccinations for this event.

cardiac arrest; ASCVD""."

	HYPERHIDROSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
"Possible heart attack on 2/5/21. Complaint: "" On Feb 5th I believe I experienced a mild hear attack"" (Comment: He said he felt ""clammy, sweaty, excruciating pain on my left side - including his left arm, and left leg, dizzy, exhausted."" This happened after work, and after taking a shower. He said that was the first time he's experienced it, and that it has not happened since then. He said he has constant headaches, ""It just went away yesterday.""""		No prior vaccinations for this event.
	HYPERHIDROSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Blood pressure went down until he died; Couldn't hear his heartbeat; neck was sweating; He was cold; Couldn't get up; Death; Sick; immediately very tired; he was tired; Hands were shaking; Slept for too long; A spontaneous report was received on 18 Feb 2021 from a consumer concerning a 81-years-old, male patient who received Moderna's COVID-19 vaccine and developed immediately very tired, hands were shaking, neck was sweating, was cold, sick, couldn't get up, couldn't hear his heartbeat and blood pressure went down until he died. Patients' medical history, as provided by patient's spouse, was emergency room(ER) admission in November 2020 because he had a congested chest (he had fluid around his heart). At that time, they gave him pills for kidney function. Other concomitant medication reported was Coumadin, blood thinner. Two weeks before receiving the vaccine, patient's EKG was normal. On 11 Feb 2021, in the morning, patient received their first of two planned doses of mRNA-1273(BATCH/LOT # 007M20A) probably in the right arm for the prophylaxis of COVID-19 infection. On 11 Feb 2021, approximately after 15 minutes of receiving vaccine, they left and patient was immediately very tired, his hands were shaking. So, patient's spouse made them down sleep for too long. On Friday, 12 Feb 2021 she tried to pick him up, but he was tired, exhausted, and sick. On Saturday, 13 Feb 2021, she brought him a coffee and he couldn't		No prior vaccinations for this event.

hold it because his hands were shaking, so she gave him the coffee and then made him pee on the bed because he couldn't get up. At lunch time she made him eat something and he fell sleep again. His wife was hanging around him all day and around 7:30pm she realized that he was cold, and his neck was sweating, she couldn't hear his heartbeat. So, she called emergency services and when they arrived, her husband's blood pressure went down until he died. Treatment for the events were not provided. Action taken with mRNA-1273 was not applicable. Patient was pronounced dead on 13 Feb 2021 20:00. The cause of death was not provided. The plans for an autopsy were not provided. The events of blood pressure went down until he died and couldn't hear his heartbeat were fatal. The outcome for the remaining events were unknown.; Reporter's Comments: This case concerns an 81 year old, male patient, who experienced a serious event of death among others, 2 days after receiving mRNA- 1273 (Lot# 007M20A). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

HYPERHIDROSIS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.

Influenza Virus Vaccines - Unknown date/type or brand

HYPERHIDROSIS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021	No prior vaccinations for this event.	
HYPERHIDROSIS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/9/21-Diaphoresis, O2 90%, respirations 22, increased weakness, wheezing bilaterally. Send to ER for evaluation and treatment. She was sent to ER, where she was admitted for 2 days, then expired there on 1/11/21	No prior vaccinations for this event.	
HYPERHIDROSIS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were	No prior vaccinations for this event.	

no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk

away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

HYPERHIDROSIS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident received the 2nd dose of the Covid vaccine approximately around 1105 by pharmacy through the pharmacy LTC partnership vaccination program. Resident had no adverse effects until around 8:00 pm she began complaining of body aches, and chills, Tylenol was given at this time. Around 9:30pm resident was sleeping in bed. Around 12:00 am the CNA called nurse into room to assess resident as the resident stated she did not feel good. Temperature at that time was 102.2, and vomiting. RN came to assess @ 1220 am She was noted to be vomiting, diaphoretic, pale and having trouble breathing. Temp was 97.3 after vomting, Pulse 53, Resp 20, o2 sats were 40-45%, unable to obtain Blood pressure, Applied 5 L of oxygen at this time and had LPN call 911 immediately. Resident was repsonsive and able to follow staff members instructions but was only answering yes or no simple questions at the time time of assessment. Paramedics arrived at 0040 and resident was sent to Hospital. @ 0130 ER nurse called to nursing facility to notify resident had coded in the ER and passed away @ 0110.	No prior vaccinations for this event.
HYPERHIDROSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal	No prior vaccinations for this event.

and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.		
	HYPERHIDROSIS	**COVID19 (COVID19 (UNKNOWN)) (1202)**
COVID 19 vaccine, unknown which company Chronically ill in a skilled nursing facility found diaphoretic, hypotensive, hypoxia to 85% arrived to Emergency dept in cardiac arrest Died within 65 minutes of nursing finding patient in distress Wife felt it may have been related to vaccine date of vaccination 1/6/20 hx covid 19 PNA in April 2020		No prior vaccinations for this event.
	HYPERKALAEMIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presents to ER with increased weakness, hypoxia, history of COPD, but not oxygen dependent., hypotension. Acute Kidney failure noted in labs, not previously diagnosed , new hyperkalemia. BP 73/39, HR 67. dopamine initiated, and switched to Levophed. Oxygen Sat 86%, requiring 10 L O2. Transferred from this critical access hospital to another Hospital. Expires later 2-13-2021		No prior vaccinations for this event.
	HYPERKALAEMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p		No prior vaccinations

multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	for this event.
HYPERNATRAEMIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.	No prior vaccinations for this event.
HYPERPHAGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Hx dementia, CVA, CAD. 2-3 year history of only consuming 25% of 1-2 meals daily. All meds d/c early 2020 because of refusing to eat or drink anything. Suddenly began drinking april/may, gained weight back. Vaccinated on 1/7/21 & 2/4/21. On 2/22/21 had significant changes in respiratory status. Passed away 2/23/21.	No prior vaccinations for this event.
HYPERSOMNIA	**COVID19 (COVID19 (MODERNA)) (1201)**
extreme fatigue. could not awaken for more than few seconds. When briefly awake she was coherent and not confused. slept deeply from 4pm and could not wake to eat or drink. No fever, bp normal, blood oxygen	No prior vaccinations

ok. Blood sugar at 11pm was 230. Gave her 15u lantus at 11pm (normally 25u). Was sleeping at 2:30am but had died at next check at 3:30am.		for this event.
	HYPERSOMNIA	**COVID19 (COVID19 (MODERNA)) (1201)**
I video chatted with her Thursday after receiving the vaccine. My mom was in poor health but she was talking in complete sentences and responded appropriately. She was upright in bed and made eye contact. She smiled and denied pain. By Sunday, she was extremely weak and unable to sip water with a straw. Her health had changed dramatically and rapidly. She moaned in pain and was very fatigued. Her condition continued to deteriorate over the week and she stopped talking and was constantly sleeping. They started antibiotics for the oozing cancer lesion and then morphine for pain and end of life care. She passed away on January 22nd which was 15 days post vaccination.		No prior vaccinations for this event.
	HYPERSOMNIA	**COVID19 (COVID19 (MODERNA)) (1201)**
On February 11, 2021 around 10:15 am, patient was given the Moderna brand COVID-19 vaccination. After his vaccination, he was instructed to wait around for 15 minutes after the administration of the vaccine. During this time, there were no reported issues with the patient. On February 15, 2021 around 9:15am, patient's wife called the pharmacy and spoke with the pharmacist informing her that patient had passed away in his sleep on Saturday evening. Patient's wife inquired about whether death may have been caused by an adverse reaction to the vaccine. During the call patient's wife mentioned that patient slept a lot the day of the vaccine and the day after. patient's wife mentioned that patient woke up Saturday to eat breakfast and lunch. She states that later that evening, she found patient asleep and cold which she then realized that he'd passed away.		No prior vaccinations for this event.
	HYPERSOMNIA	**COVID19 (COVID19**

(MODERNA)) (1201)

Blood pressure went down until he died; Couldn't hear his heartbeat; neck was sweating; He was cold; Couldn't get up; Death; Sick; immediately very tired; he was tired; Hands were shaking; Slept for too long; A spontaneous report was received on 18 Feb 2021 from a consumer concerning a 81-years-old, male patient who received Moderna's COVID-19 vaccine and developed immediately very tired, hands were shaking, neck was sweating, was cold, sick, couldn't get up, couldn't hear his heartbeat and blood pressure went down until he died. Patients' medical history, as provided by patient's spouse, was emergency room(ER) admission in November 2020 because he had a congested chest (he had fluid around his heart). At that time, they gave him pills for kidney function. Other concomitant medication reported was Coumadin, blood thinner. Two weeks before receiving the vaccine, patient's EKG was normal. On 11 Feb 2021, in the morning, patient received their first of two planned doses of mRNA-1273(BATCH/LOT # 007M20A) probably in the right arm for the prophylaxis of COVID-19 infection. On 11 Feb 2021, approximately after 15 minutes of receiving vaccine, they left and patient was immediately very tired, his hands were shaking. So, patient's spouse made them down sleep for too long. On Friday, 12 Feb 2021 she tried to pick him up, but he was tired, exhausted, and sick. On Saturday, 13 Feb 2021, she brought him a coffee and he couldn't hold it because his hands were shaking, so she gave him the coffee and then made him pee on the bed because he couldn't get up. At lunch time she made him eat something and he fell sleep again. His wife was hanging around him all day and around 7:30pm she realized that he was cold, and his neck was sweating, she couldn't hear his heartbeat. So, she called emergency services and when they arrived, her husband's blood pressure went down until he died. Treatment for the events were not provided. Action taken with mRNA-1273 was not applicable. Patient was pronounced dead on 13 Feb 2021 20:00. The cause of death was not provided. The plans for an autopsy were not provided. The events of blood pressure went down until he died and couldn't hear his heartbeat were fatal. The outcome for the remaining events were unknown.; Reporter's Comments: This case concerns an 81 year old, male patient, who experienced a serious event of death among others, 2 days after receiving mRNA-1273 (Lot# 007M20A). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

No prior vaccinations for this event.

HYPERTENSION	COVID19 (COVID19 (MODERNA)) (1201)
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.	No prior vaccinations for this event.

HYPERTENSION	COVID19 (COVID19 (MODERNA)) (1201)
Shortness of Breath, decreased oxygen saturation, irregular heart rhythm, hypertension, Positive for COVID, bilateral pneumonia	No prior vaccinations for this event.

HYPERTENSION	COVID19 (COVID19 (MODERNA)) (1201)
Brain aneurysm; Anaphylactic reaction; Collapsed; BP sky rocketed; Shortness of breath; A spontaneous report was received from a consumer concerning a 69-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced blood pressure skyrocketed, shortness of breath, loss of consciousness, massive anaphylactic reaction, and brain aneurysm. The patient's medical history, as provided by the reporter, included high blood pressure and arthritis. Products known to have been used by the patient, within two weeks prior to the event, included an antihypertensive. On 04 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. Twenty-two minutes later she had a massive anaphylactic reaction. She experienced shortness of breath, blood pressure skyrocketed, and loss of consciousness. She was taken to	No prior vaccinations for this event.

the emergency room. The patient had a brain aneurysm and never recovered. No treatment information was provided. The patient died on 04 Jan 2021. The cause of death was reported as brain aneurysm. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns a 69-year-old, female patient with a medical history of hypertension, who experienced fatal, serious, unexpected events of Anaphylactic reaction, hypertension, dyspnea, loss of consciousness and brain aneurysm. The events occurred 22 minutes after the first dose of mRNA-1273 was administered. No treatment information was provided. The patient never recovered and died. The cause of death was reported as brain aneurysm. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Additional information has been requested.; Reported Cause(s) of Death: Brain aneurysm		
HYPERTENSION		**COVID19 (COVID19 (MODERNA)) (1201)**
covid shot 2/2; feel bad 2/5; covid positive diagnosis - 2/8 s/s cough, fever, shortness of breath , hypertension, afib (in er) - admitted went into DIC per intensivist 2/11 patient died		No prior vaccinations for this event.
HYPERTENSION		**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccination at 14:20 2/26/21. Was observed until discharged at 15:15. Discharged per wheel chair to lobby in alert/stable condition, to wait on bus to take him home. At 18:00 his neighbor heard him fall, could not get patient to answer phone, found him unresponsive. Neighbor called 9-1-1, ambulance personnel could not revive patient. Coroner's office ruled his death as Natural Causes due to Hypertension, Cardiac disease, Diabetes, ESRD. There were no indication of anaphylactic reaction noted when I questioned the coroner's office. The Coroner's office/EMS were aware the patient had received the Moderna COVID 19 vaccination that day.		No prior vaccinations for this event.

	HYPERTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Dr. received an urgent request to call a local Justice of the peace regarding one of her patients who was found dead in her home today. At this time no foul play is suspected. Dr. said the patient was relatively healthy with no major issues other than some hypertension		No prior vaccinations for this event.
	HYPERTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient and her husband are elderly, but healthy and live independently. Patient took blood pressure medicine 'off and on' according to family. She was 5'2"", 120 pounds and slim and healthy and active, so was her husband, though he had pulmonary fibrosis so they had been staying home and not attending church etc, and masking when they did go out to protect against covid disease. They were both vaccinated with covid Pfizer vaccine (dose #1) on Thursday Feb 11. (02/11/2021) Thursday night as they went to bed they checked in with each other on how they each felt. Patient said she felt totally fine, and her husband said his arm was a bit sore. Patient woke before her husband on Friday Feb 12, went downstairs and, from what the family can tell, fixed herself a snack, then sat on the sofa. Patient's husband found her deceased on the sofa. He called 911 and they asked him to do CPR until the paramedics arrived. Because of proximity to covid vaccine, the ME wanted to examine the body in the home and also ordered an autopsy. Autopsy was completed on the same day as death, Feb 12, 2021"		No prior vaccinations for this event.
	HYPERTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer 1/22/2021. RNA+ 2/4/2021. S/S SOB, cough, confusion. COVID assoc. resp. failure,		No prior vaccinations for this

stage 4 lung cancer, COPD, HTN, former smoker. patient in hospice and died 2/10/2021.		event.
	HYPERTENSIVE CEREBROVASCULAR DISEASE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient with history advanced vascular dementia, hypertensive cerebrovascular disease and stroke, T2DM. Received her second dose of Pfizer COVID-19 vaccine at approximately 14:00 and was reported to have expired at home at 20:55. Dr. (Medical Director) spoke with patient's son/caregiver 2/4/21. Son reports that patient was in her usual health yesterday morning, deemed well enough by son to travel for vaccination. He reports she had no bothersome symptoms after either first or second vaccinations. Specifically denied rash, wheeze, and difficulty breathing. Son was with patient throughout the day. In the evening, when preparing for bed, he noted she became suddenly unresponsive in a similar fashion as she has done several times in past years. While in all previous such episodes she recovered within minutes, last evening she did not regain consciousness, experiences a brief period of labored breathing, and died. Patient's son called 911 and the patient's body was brought to the medical examiners. The medical examiner declined to proceed with autopsy. Patient's son is not interested in autopsy. Patient's son reports confidence that his mother's underlying hypertensive/diabetic cardiovascular disease is the natural cause of her death. Other Relevant Hx: Symptoms: & Death Treatment:		No prior vaccinations for this event.
	HYPERTENSIVE URGENCY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21		No prior vaccinations for this event.

HYPERVENTILATION

COVID19 (COVID19 (MODERNA)) (1201)

Death Narrative: Patient received Covid vaccine on 2/2/21, person reports his legs were more rigid with some sweating the day of the vaccination with leg rigidity that was slowly improving. No other adverse effects reported for following 7 days. Person states he had vomiting episode earlier this week, person states he had no other symptoms before or after the vomiting episodes. On morning of 2/12/21, person reports patient got up ready for breakfast with no issues. She says he asked for chorizo and oatmeal but she laughed and said don't you mean chorizo and eggs. He said yes. They got him into W/C and he was rolling himself into dining room got stuck in hallway. She says he took several breaths then 3 very deep breaths and passed away. She called 911 they took his VS but he has passed. She told them to leave him along no resuscitation.

No prior vaccinations for this event.

HYPOAESTHESIA

COVID19 (COVID19 (MODERNA)) (1201)

My dad got the Moderna Vaccine on Tuesday, January 12, 2021 in his left arm at the Mall injection site for the Health Department. He was told that the side effects could mean his arm hurting, tiredness, headache, and even a low grade fever. Additionally, the site informed us both (as I was with him to get the injection) that this was all normal and not to seek medical attention unless these symptoms last longer than 72 hours. That evening, my dad was experiencing all of those symptoms, and went to bed at 7pm. A little after 10am on Wednesday, January 13, 2021, when he awoke, my dad went to the bathroom vomiting. This was where he collapsed and went into cardiac arrest. Fire/Rescue was dispatched about 10:30am after my mom started CPR. County Fire Rescue EMTs and Paramedics continued CPR and other attempts at reviving him all the way to Hospital Emergency Department. He was pronounced dead at 12:14pm on Wednesday, January 13, 2021. We have no doubt my dad, following the instructions of the injection facility, thought he was just experiencing the side effects of the vaccine. He had no chance. Had this injection been done in the RIGHT arm, perhaps he could have recognized the arm numbness being that of an impending heart attack. We really miss Dad. He served this country with distinction for over 50 years, and we believe his country

No prior vaccinations for this event.

failed him.

	HYPOAESTHESIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal tunnel and sent her home. The morning or March 18th , 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.		No prior vaccinations for this event.
	HYPOCHROMASIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
	HYPOGLYCAEMIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever,		No prior vaccinations for this event.

and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

HYPOGLYCAEMIA

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

HYPOGLYCAEMIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Admitted 1/14/21: Patient is an elderly 93-year-old female with multiple medical problems including chronic combined CHF, P 80, diabetes mellitus, HTN, hyperlipidemia, CKD stage 3, has been complaining of generalized weakness, fatigue, decreased appetite for the past few days. She had an outpatient COVID-19 vaccine earlier today. Within 2 hr of admitting the patient to the hospital, condition clinically deteriorated. Patient elected to be DNR/DNI while in the ED. Patient was pronounced dead at 10:30 p.m. earlier today. Preliminary cause of death: Hypoglycemia induced lactic acidosis.	No prior vaccinations for this event.
HYPOGLYCAEMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident on Hospice. 1/18 Hand Shaky. 1/19- Covid +19. 1/20 Desat 85% on RA, provided 2L O2 supplement= 97% 1/20 congestive cough, 1/28- RR-28;1/29- Hypoglycemia 1/30-NPO. 1/30-resident passed away.	No prior vaccinations for this event.
HYPONATRAEMIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus	No prior vaccinations for this event.

ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

HYPOPERFUSION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up.

No prior vaccinations for this event.

CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

HYPOPHAGIA

COVID19 (COVID19 (MODERNA)) (1201)

Patient had mild hypotension, decreased oral intake, somnolence starting 3 days after vaccination and death 5 days after administration. He did have advanced dementia and was hospice eligible based on history of aspiration pneumonia.	No prior vaccinations for this event.
HYPOPHAGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Accelerated decline in condition with decreased input, decreased responsiveness, somnolence, and death	No prior vaccinations for this event.
HYPOPHAGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
This patient has been under hospice care for over 2 years at the nursing home. She has had a steady decline with gradual weight loss. She was totally dependent in her care needs. She received the vaccine on 1/2/2021 as part of the facility vaccination campaign. No adverse events noted initially. On 1/3/2021 at 6:06 pm, she was noted on vital sign checks (done every 4 hours for first 72 hours after vaccination) with BP 64/52 but otherwise asymptomatic. Subsequent BP improved. On 1/4/2021 at 4:45 am, pt found with respiratory rate of 30 with otherwise normal vital signs. Tachypnea persisted, so she received liquid morphine 2.5 mg without improvement. Supplemental oxygen was applied. Tachypnea persisted. She had poor oral intake after that point had persistent tachypnea and worsening hypoxemia despite clear lungs on exam. She remained under hospice care and comfort measures were continued. No blood testing or imaging tests were done. She required increasing amounts of oxygen, became hypotensive, and died peacefully on 1/8/2021 at 7:45 pm.	No prior vaccinations for this event.
HYPOPHAGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021and felt	No prior vaccinations

poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM CHLORIDE 1000 MG ONCE		for this event.
	HYPOPHAGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration		No prior vaccinations for this event.
	HYPOPHAGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was transferred from hospital for further evaluation and care by pulmonologist. He started having symptoms a week before with fatigue, emesis, decreased p.o. intake, shortness of breath, vomiting and diarrhea. The two previous takes before death required increasing oxygen and family wanted everything done including intubation. He was transferred to ICU.		No prior vaccinations for this event.
	HYPOPHAGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
EXTREME PAIN, STOPPED EATING/DRINKING -- STARTED MORPHINE		No prior vaccinations for this event.

HYPOPHAGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Client recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic. Client tested positive for COVID-19 by rapid testing on 1/21/21, with c/o hurting all over and loose stools. She became non-verbal on 1/23/21 with poor intake. On 1/24/21 at 0537 Client was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.		No prior vaccinations for this event.
HYPOPHAGIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic #1. Patient tested positive for COVID-19 by rapid testing on 1/6/21. She demonstrated poor appetite and fluid/food intake and an IV of Normal Saline was initiated on 1/7/21. Oxygen saturation was initiated on 1/12/21 at 4L per nasal cannula. for shortness of breath. On 1/22/21 at 0310 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.		No prior vaccinations for this event.
HYPOPHAGIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began to demonstrate a cough the evening of 1/5/2021, after receiving the COVID-19 vaccine earlier in the afternoon. A rapid COVID-19 test was performed and was positive. She began to demonstrate shortness of breath with exertion on 1/7/21, and lethargy on 1/12/21. Appetite and oral intake began to decline on 1/12/21, and Oxygen saturation dropped on 1/16/21 to 82%, and oxygen was initiated at 3L per nasal cannula. On 1/19/21 at 0414 patient was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.		No prior vaccinations for this event.

HYPOPNOEA		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had no symptoms or adverse events until the next evening after shot (1/29/21) where daughter reported her having heart palpitations. Family told her to rest and did not seek medical attention. Saturday afternoon (1/30/2021), patient started experiencing labored breathing. Daughter called 911 and before the ambulance arrived, the patient's breathing became more and more shallow. Patient was taken to the local hospital and passed away Saturday evening around 5:30 pm.		No prior vaccinations for this event.
HYPOPNOEA		**COVID19 (COVID19 (MODERNA)) (1201)**
ON 02/08/2021 AROUND 0600 RESIDENTCOMPLAINED OF MOUTH PAIN AND RECEIVED OXYCODONE. DURING THE COURSE OF THE MORNING, RESIDENT EXHIBITED A FEW EPISODES OF LABORED/SHALLOW BREATHING AND SOB AT RESTING. 0XYGEN SATURATION RATE WAS 93-98% ON ROOM AIR, LUNG SOUNDS CLEAR IN ALL LOBES AND PULSE AND TEMPERATURE WITHIN NORMAL RANGE. AS THE DAY PROGRESSED, VITAL SIGNS REMAINED STABLE BUT RESIDENT CONTINUED TO HAVE PERIODS OF SOB/LABORED BREATHING.FAMILY AND NURSE PRACTIONER UPDATED AND THE ORDER WAS RECEIVED TO SEND PATIENT TO MEDICAL CENTER ER FOR EVALUATION PER AMBULANCE. RESIDENT TRANSPORTED AT 1425. RESIDENT RETURNED FROM THE ER AT 1830 ON HOSPICE CARE WITH THE DIAGNOSIS OF: ACURE RESPIRATORY FAILURE WITH HYPOXIA AND END OF LIFE DECISION MAKING. RESIDENT WAS MADE COMFORTABLE AND MONITORED DURING THE NIGHT AND EXPIRED AT 0630 ON 02/09/2021.		No prior vaccinations for this event.
HYPOPNOEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications.		No prior vaccinations for

Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.	this event.
HYPOPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received vaccination on January 15, 2021. She was found unresponsive with shallow respirations on the morning of January 16, 2021 and was sent to ER via ambulance. The resident was admitted to medical center ICU where she passed away later that day.	No prior vaccinations for this event.
HYPOPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
view 2/5/2021 09:23 e Progress Note Note Text: Patient passed away in the facility this morning. view 2/5/2021 08:39 Orders - Administration Note Note Text: Resident passed. view 2/5/2021 08:33 Nurses Note Note Text: Body released to funeral home at this time. Personal effects sent with resident include: 1 pair of glasses, 1 yellow wedding band, 1silver spoon ring, 1 ring with black and clear stones. Resident has own teeth view 2/5/2021 08:32 Nurses Note Note Text: cause of death per CRNP failure to thrive. view 2/5/2021 07:44 Orders - Administration Note Note Text: Take and document temp & PO2 every 4 hours for MONITORING Resident passed. view 2/5/2021 06:49 Nurses Note Note Text: Son returned call and was	No prior vaccinations for this event.

updated of resident's passing this am view 2/5/2021 06:33 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Unknown Resident expired @ 0604 [linked] view 2/5/2021 06:06 Nurses Note Note Text: Res found without pulse or respirations. Pronounced at 0604. Updated. N/o's for RN to pronounce, release body to funeral home, dispose of medications per facility policy. Daughter updated. Funeral Home called to release body. view 2/5/2021 05:26 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Pulse ox 60% on O2 @ 5L/min via mask. Resps 44 per minute. view 2/5/2021 01:57 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/5/2021 00:52 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Residents resps are 40 per minute, pulse ox 76% on O2 @ 5L/min via mask. Resps are labored, shallow and rapid. view 2/5/2021 00:48 Nurses Note Note Text: Nonresponsive to verbal and tactile stimulation. Appears comfortable. view 2/4/2021 22:01 Nurses Note Note Text: Resident resting comfortably, breathing becoming increasingly shallow, wearing O2 via mask at 5L via mask, no dyspnea noted, feet are mottled, oral and peri care provided Q2H. No s/s of pain or discomfort. view 2/4/2021 21:40 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective [linked] view 2/4/2021 19:32 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger medicated for air hunger, RR 28 to 32/ min view 2/4/2021 19:22 Nurses Note Note Text: Daughter updated on N/O to increase Morphine Sulfate 20mg/mL 0.25mL to Q2H prn from Q6H prn. view 2/4/2021 18:06 Nurses Note Note Text: POA Daughter and daughter aware of residents current condition. view 2/4/2021 11:58 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/4/2021 11:13 Nurses Note Note Text: Pt. noted to be lethargic at this time. Does respond to verbal and tactile stimuli by opening her eyes but non verbal currently. Skin warm and dry. No mottling or apnea observed at this time. O2 sat 88% with O2 at 2 LPM via n/c. On increased to 3 LPM via mask as pt.

noted to be mouth breathing. Respirations 28. F/U O2 sat 93%. HOB elevated. Pt. medicated with morphine by LPN. Daughter updated on pt.'s condition. Does not want pt. sent out to hospital and would like comfort measures to continue. Daughter also in agreement with delay in d/c d/t pt.'s condition.CRNP updated on pt.'s condition, delay in d/c and daughter's wishes. No n/o's at this time. view 2/4/2021 10:56 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB Resident showing s/s of discomfort. SOB at this time and high respirations. Repositioned, changed for incontinence care and mouth care provided. view 2/4/2021 10:34 Progress Note Note Text: Spoke with RN regarding change in condition. Updated Sr Living regarding change. Recommendation to cancel d/c/transfer for today, see how resident does through the weekend and re-evaluate on Monday. Daughter updated on cancellation of d/c today. view 2/4/2021 10:04 Nurses Note Note Text: Daughter aware that resident's O2 sat was 88% on room air on 3-11 shift and that oxygen was applied via nasal cannula. view 2/4/2021 10:03 Nurses Note Note Text: N/O: Discharge 2/4/21 with scripts to Sr. Living. Daughter aware. view 2/4/2021 09:53 Nurses Note Note Text: Pt. to be d/c'd to another facility this am as per MD order. Pt. alert and responsive. Skin assessment done as per facility policy. No pressure areas noted at this time. No s/sx of pain or discomfort observed at this time. V.S. 97.0 67 20 O2 sat 95% with O2 at 2 LPM via n/c. view 2/4/2021 07:45 Nurses Note Note Text: Resident seen by Dr. for discharge. Orders pending at this time. view 2/4/2021 07:36 Nurses Note Note Text: CRNP and Dr. updated on O2 sat 88% on RA with f/u of 93% with O2 on at 2 LPM as well as rest of VS, 3-11 shift 2/3/21. No n/o's at this time. view 2/3/2021 21:17 Nurses Note Note Text: Resident Sp02 88% on RA. Pulse 124. Respirations 40. PRN morphine given and O2 applied via NC at 2L/min. After recheck pulse ox up to 93%, pulse 100, and respirations 22. Resident appears comfortable at this time. view 2/3/2021 20:05 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective [linked] view 2/3/2021 19:48 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN given for SOB after elevation of HOB not effective. view 2/3/2021 11:51 Nurses Note Note Text: CRNP updated rapid COVID test done for d/c tomorrow was negative. No n/o's at this time. view 2/3/2021 11:44 Nurses Note Note Text: Daughter notified of rapid covid swab being negative. view 2/3/2021 09:50 Orders - Administration Note Note Text: Obtain Rapid Covid test on 2/3/2021 for discharge.

Please give copy of results to Social Worker every day shift for covid testing for 1 Day Completed and negative. view 2/3/2021 08:45 Skilled Nursing Note Reason for skilled service: Therapy describe skilled service: Nursing, therapy assessment: V.S. 97.8 79 18 138/84 Orientation: Oriented to self only. Oxygen: O2 sat 94% on RA Edema: Trace edema noted BLE. Pedal pulses present. Pain: Denies pain or discomfort at this time. Nursing note: Pt. alert and responsive. Skin warm and dry. Lung sounds diminished. No respiratory distress observed at this time. Abdomen soft. BS+ in all 4 quads. Continent/Incontinent of B&B. 1 assist with ambulation, transfers. 1 assist with ADL's. Working with therapy on gait training, therapeutic exercise, therapeutic activities & neuromuscular reeducation. view 2/2/2021 14:37 Progress Note Note Text: Per health professional at Sr Living, prepared to accept patient to their Memory Care Unit 2/4. Transportation arranged for 11 AM per family request. Daughter (POA) updated on d/c time on 2/4/21. Facility requesting rapid COVID test completed prior to d/c and results sent to them. All other information sent for continuity of care.

HYPORESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

Accelerated decline in condition with decreased input, decreased responsiveness, somnolence, and death

No prior vaccinations for this event.

HYPORESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.

No prior vaccinations for this event.

HYPORESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

6 days after vaccine developed bloody diarrhea. Thought to have ischemic colitis but negative evaluation. became hypotensive bradycardic placed on ventilator. Subsequently was poorly responsive and

No prior vaccinations for

eventually coded once more and succumbed	this event.
HYPORESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No reactions immediately after vaccine was given. Resident has dementia, has had multiple hospitalizations related to a renal stone recently. Had a tooth that was bothering her, went to see her dentist and it was extracted on 1/6/21. On 1/10 they noted feet and ankles are dark purple with white splotches appears to be mottling. Minimally responsive to voice and touch. Not eating. Compassionate visit with family. Family did not want hospice, did not feel it was needed, said, what more could they do for her than you're already doing? On 1/11 at 1950 was determined to be deceased.	No prior vaccinations for this event.
HYPORESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21	No prior vaccinations for this event.

HYPOTENSION

COVID19 (COVID19 (MODERNA)) (1201)

Patient had mild hypotension, decreased oral intake, somnolence starting 3 days after vaccination and death 5 days after administration. He did have advanced dementia and was hospice eligible based on history of aspiration pneumonia.

No prior vaccinations for this event.

HYPOTENSION

COVID19 (COVID19 (MODERNA)) (1201)

This patient has been under hospice care for over 2 years at the nursing home. She has had a steady decline with gradual weight loss. She was totally dependent in her care needs. She received the vaccine on 1/2/2021 as part of the facility vaccination campaign. No adverse events noted initially. On 1/3/2021 at 6:06 pm, she was noted on vital sign checks (done every 4 hours for first 72 hours after vaccination) with BP 64/52 but otherwise asymptomatic. Subsequent BP improved. On 1/4/2021 at 4:45 am, pt found with respiratory rate of 30 with otherwise normal vital signs. Tachypnea persisted, so she received liquid morphine 2.5 mg without improvement. Supplemental oxygen was applied. Tachypnea persisted. She had poor oral intake after that point had persistent tachypnea and worsening hypoxemia despite clear lungs on exam. She remained under hospice care and comfort measures were continued. No blood testing or imaging tests were done. She required increasing amounts of oxygen, became hypotensive, and died peacefully on 1/8/2021 at 7:45 pm.

No prior vaccinations for this event.

HYPOTENSION

COVID19 (COVID19 (MODERNA)) (1201)

Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.

No prior vaccinations for this event.

HYPOTENSION

COVID19 (COVID19

	(MODERNA)) (1201)
Patient presented to the Emergency Department complaining of chest pain, pale, cool diaphoretic, and hypotensive. The patient was discovered to have a large saddle pulmonary embolism, went into cardiac arrest and expired. Of note, the patient received her second Moderna COVID vaccine on 1/23, which would place her first one approximately 12/25 if she received them at the appropriate interval. This information is from the patient's daughter and the ED record, the information is not available in CAIR. Per the daughter, the patient started feeling ill on 1/21, improved on 1/25, and then acutely worsened on 1/27, resulting in the ED visit.	No prior vaccinations for this event.
HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**
36 hours after vaccination, the patient had increased respiratory distress. He was placed on high flow nasal cannula oxygen with mild improvement. He then continued to be hypotensive requiring IV fluids and subsequently IV vasopressors. Patient's BP was stabilized with vasopresor, however he continued to deteriorate clinically with altered mental status and lethargy, concerned for bowel peroration based on physical exam by MD. He was then emergency intubated and placed on mechanical ventilation. He was then transferred to acute care hospital near by.	No prior vaccinations for this event.
HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**
6 days after vaccine developed bloody diarrhea. Thought to have ischemic colitis but negative evaluation. became hypotensive bradycardic placed on ventilator. Subsequently was poorly responsive and eventually coded once more and succumbed	No prior vaccinations for this event.
HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**

Patient awake at 0300. When going into the room to get him ready for dialysis he was cold to touch, unresponsive other than to sound, and nonverbal. O2 sat was 67 via finger probe. Oxygen immediately initiated and a venturi mask retrieved and initiated. When unable to arouse him via sternal rub this RN called 911. Send to ED. Febrile 39.2 and hypotensive 58/43. Admitted. unknown after that as patient expired in hospital.		No prior vaccinations for this event.
	HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Moderna Vaccine Lot 029K20A Patient received second dose of vaccine on 2/2/21. Within 30 minutes patient had a near syncopal episode. She felt lightheaded and shortly after had episode of nonbloody vomiting. Hypotensive 81/69 and started on levophed. Alert and orientated. Lungs clear, abdomen benign on admission. Patient had no reaction when received first dose of the vaccine. Patient developed worsening shortness of breath, tachypnea, Afib with RVR, hypotension and required intubation and multiple pressors.		No prior vaccinations for this event.
	HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient, who was a pharmacist, developed fatigue and shortness of breath hours after receiving vaccine. Two days later, on 01/28/2021, the patient went to local urgent care for worsening shortness of breath and was referred to Hospital for worsening dyspnea and hypoxia. The patient was admitted to the hospital We was found to have bilateral pulmonary infiltrates and treated for pneumonia with Rocephin and azithromycin. He was tested for COVID-19 multiple times, but each of the results were negative. Despite the negative results, there was high clinical suspicion for COVID-19 and the patient was started on Remdesivir and Decadron. The patient's oxygen requirements continued to worsen and the patient was transferred to another facility for higher level of care. There his hypoxia worsened and he required mechanical ventilation. Patient then developed hypotension and required vasopressors for blood pressure support. Furthermore, patient developed acute renal failure requiring hemodialysis. Despite mechanical ventilation with FiO2 100%, and for		No prior vaccinations for this event.

vasopressors, patient clinically deteriorated and family decided to palliatively extubate on 02/05/2021.

	HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presents to ER with increased weakness, hypoxia, history of COPD, but not oxygen dependent., hypotension. Acute Kidney failure noted in labs, not previously diagnosed , new hyperkalemia. BP 73/39, HR 67. dopamine initiated, and switched to Levophed. Oxygen Sat 86%, requiring 10 L O2. Transferred from this critical access hospital to another Hospital. Expires later 2-13-2021		No prior vaccinations for this event.

	HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**
1/31/2021 12:50 Nursing Note Note Text: Res had low BP, low O2 sats, 30 breaths per minute, eyes open wide, making confused utterances. Started supplemental oxygen via NC, 2L, then 3L. Sats went up to 93% for a while, Sprvsr called. Unable to auscultate Left lung sounds. Called to update Res daughter. Called to page NP, writer went back to assess Res and O2 sats were 88%, turned O2 to 4LPM, called 911 for transport to Hospital ED. Left around 1030. NP called back afterwards, was updated. Family updated that Res was sent to Hospital ED. Note Text: Received phone call from daughter as well as information from hospital. Resident has pneumonia with septic shock. She is on abx and had thoracentesis performed for large pleural effusion. [linked]		No prior vaccinations for this event.

	HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident tested NEGATIVE for COVID-19 last 1/25/2021. She was on monitoring for desaturation and low blood pressure on Jan. 27,2021		No prior vaccinations for this event.

HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.	No prior vaccinations for this event.
HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127	No prior vaccinations for this event.
HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**

Patient experienced an episode of emesis and loss of consciousness several hours after vaccine on 2/16/21. He was taken by EMS to the hospital and was noted to be hypoxic and hypotensive. He was admitted to the hospital and subsequently intubated. He was also found to have a small bowel obstruction and a nasogastric tube was placed to decompress the bowel. He required pressor support as well. He expired on 2/17/21.	No prior vaccinations for this event.	
HYPOTENSION		**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine was administered at Nursing Facility. Patient is an 89-year-old female with prior medical history of CVA with dysphagia, history of possible dementia, GERD, hyperlipidemia, and a pacemaker. She is a resident from town. She was sent for hypotension with a blood pressure of 90/52, tachypnea respirations of 54, possible aspiration pneumonia. Status post Covid vaccine earlier today. History is limited as patient is nonverbal on my exam. Death within 24 hours of vaccination	No prior vaccinations for this event.	
HYPOTENSION		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).	No prior vaccinations for this event.	
HYPOTENSION		**COVID19 (COVID19 (MODERNA)) (1201)**

"""Feeling Hot"" without fever and nausea 10 hours post vaccine and resolved within 1 hour. Seizure, Hypotension, Unresponsive followed shortly by cardiac arrest and pulseless electrical activity 21 hours post vaccine. Pronounced dead 22 hours post vaccine"	No prior vaccinations for this event.
HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**
loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated	No prior vaccinations for this event.

as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

HYPOTENSION

COVID19 (COVID19 (MODERNA)) (1201)

Blood pressure went down until he died; Couldn't hear his heartbeat; neck was sweating; He was cold; Couldn't get up; Death; Sick; immediately very tired; he was tired; Hands were shaking; Slept for too long; A spontaneous report was received on 18 Feb 2021 from a consumer concerning a 81-years-old, male patient who received Moderna's COVID-19 vaccine and developed immediately very tired, hands were shaking, neck was sweating, was cold, sick, couldn't get up, couldn't hear his heartbeat and blood pressure went down until he died. Patients' medical history, as provided by patient's spouse, was emergency room(ER) admission in November 2020 because he had a congested chest (he had fluid around his heart). At that time, they gave him pills for kidney function. Other concomitant medication reported was Coumadin, blood thinner. Two weeks before receiving the vaccine, patient's EKG was normal. On 11 Feb 2021, in the morning, patient received their first of two planned doses of mRNA-1273(BATCH/LOT # 007M20A) probably in the right arm for the prophylaxis of COVID-19 infection. On 11 Feb 2021, approximately after 15 minutes of receiving vaccine, they left and patient was immediately very tired, his hands were shaking. So, patient's spouse made them down sleep for too long. On Friday, 12 Feb 2021 she tried to pick him up, but he was tired, exhausted, and sick. On Saturday, 13 Feb 2021, she brought him a coffee and he couldn't hold it because his hands were shaking, so she gave him the coffee and then made him pee on the bed because he couldn't get up. At lunch time she made him eat something and he fell sleep again. His wife was hanging around him all day and around 7:30pm she realized that he was cold, and his neck was sweating, she couldn't hear his heartbeat. So, she called emergency services and when they arrived, her husband's blood pressure went down until he died. Treatment for the events were not provided. Action taken with mRNA-1273 was not applicable. Patient was pronounced

No prior vaccinations for this event.

dead on 13 Feb 2021 20:00. The cause of death was not provided. The plans for an autopsy were not provided. The events of blood pressure went down until he died and couldn't hear his heartbeat were fatal. The outcome for the remaining events were unknown.; Reporter's Comments: This case concerns an 81 year old, male patient, who experienced a serious event of death among others, 2 days after receiving mRNA-1273 (Lot# 007M20A). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

	HYPOTENSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.		No prior vaccinations for this event.
	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.		No prior vaccinations for this event.
	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event		No prior vaccinations for this event.

could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.

	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
At approximately 12:15 pm the resident had a brief unresponsive episode that resolved quickly. Her Vital signs were stable and her mentation was at baseline. Later that evening approximately 10 pm she had labored respirations, shortness of breath, lethargy with bilateral crackles, Oxygen desaturated to 76% on room air, tachycardia and hypotension. She expired at 6:30 a.m. the following day.		No prior vaccinations for this event.
	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per EMS, the patient was last seen walking and talking to wife 10 minutes prior to EMS arrival. EMS reports via patients wife, that patient was upstairs to change for his doctor appointment then patient's wife found him down. The patient received his COVID-19 vaccine on 1/25/21. EMS states they gave 5 rounds of EPI then patient moved into vfib then was shocked once but returned to asystole. In ED, the patient initially in asystole CPR was started immediately. The patient was given 3 rounds EPI, 1 round bicarb. The patient stayed in PEA throughout. Patient was given tPA. Patient continued to be in asystole and time of death was called at 11:35 am.		No prior vaccinations for this event.
	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was hospitalized for confusion, and hypotension and increased weakness; resident		No prior vaccinations for this

proceeded to have a NSTEMI and died on 5th day in hospital on 1/31/2021.		event.
	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient received vaccine on Jan 23, 2021. developed weakness on Jan 25, 2021. Sent to ED on Jan 27, 2021 with hypoxia requiring 6 L O2, low Bp, declining mental status. Per family request transitioned to hospice and passed away on Jan 30, 2021		No prior vaccinations for this event.
	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began with vomiting and diarrhea. C/O chest pain. Bradycardia. Hypotension. 2 seizures in 45 minutes after not having one in years. We gave fluids. Gave Zofran. Comfort measures. Pt passed at midnight. Was completely fine one day before. Had minimal issues with COVID though did have a pneumonia that was treated w ATB early on and resolved.		No prior vaccinations for this event.
	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Early in the shift on January 31 resident was noticed to be more tired than usual and was not eating well. Lung sounds were crackly and resident was found to be hypotensive. He was evaluated in emergency department. He was diagnosed with pneumonia. Received a loading dose of antibiotic and returned to facility.		No prior vaccinations for this event.
	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH))**

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or

No prior vaccinations for this event.

definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt with acute resp failure, COVID PNA, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior toa admit, then shortly after progressed with other covid symptoms and was admitted. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. Pt passed soon after(2/2).	No prior vaccinations for this event.

HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

New onset dizziness with hypotension, tachycardia, and vomiting blood. Sent to ER - told he went into cardiac arrest and died.	No prior vaccinations for this event.
HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt passed soon after; shortly after progressed with other covid symptoms and was admitted / acute resp failure, COVID pneumonia; acute resp failure, COVID pneumonia; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle.; This is a spontaneous report from a non-contactable Pharmacist. A 76-years-old non-pregnant female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE lot number EL3247), intramuscular on 19Jan2021 at single dose for COVID-19 immunisation. The patient medical history included COVID symptoms from 16Jan2021 and ongoing. Concomitant medications were not reported. The patient with acute resp failure, COVID pneumonia, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior to a admit, then shortly after progressed with other covid symptoms and was admitted on 25Jan2021. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. The patient died on 02Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on temporal association, the causal relationship between bnt162b2 and the events death, COVID-19 pneumonia, acute respiratory failure, hypotension, abdominal wall haematoma and abdominal wall haemorrhage cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate	No prior vaccinations for this event.

data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pt passed soon after		
	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO WITHDRAWL EXTRME MEASURES		No prior vaccinations for this event.
	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM		No prior vaccinations for this event.
	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-		No prior vaccinations for this event.

2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

	HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Presented to ED via EMS c/o increasing shortness of breath, O2 sat mid to high 80s on		No prior vaccinations for

4L. When EMS arrived , pt was in distress, intubated by EMS and transported to ED. Pt had a PEA arrest en route but resuscitated w/ return of spontaneous circulation after receiving a dose of epinephrine and chest compressions. Pt was hypotensive on arrival to ED. He was started on sepsis protocol , volume resuscitation and empiric antibiotics. Once stabilized, he was admitted to icu at hospital. Removed from respirator 2/22/21	this event.	
HYPOTENSION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccinated 2/20. At that time, had symptoms of incarcerated hernia, went to ED for evaluation. Not felt to warrant hospital admission. Returned two days later with agitation, altered mental status, and incarceration. Went to OR, uncomplicated hernia repair. Postoperatively, did not recover mental status. Went into arrythmias POD 4, hypotension ensued, had multiple interventions and evaluations without satisfying answers for clinical course.	No prior vaccinations for this event.	
HYPOTENSION		**COVID19 (COVID19 (UNKNOWN)) (1202)**
COVID 19 vaccine, unknown which company Chronically ill in a skilled nursing facility found diaphoretic, hypotensive, hypoxia to 85% arrived to Emergency dept in cardiac arrest Died within 65 minutes of nursing finding patient in distress Wife felt it may have been related to vaccine date of vaccination 1/6/20 hx covid 19 PNA in April 2020	No prior vaccinations for this event.	
HYPOTHERMIA		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt was hospitalized Jan 18, 2021 after he had fallen outside overnight and lay there approximately 12 hours until he was found. Hypothermic & rhabdomyolis diagnosis. Gradually improved w/ strength & mental status	No prior vaccinations for	

- was in swing bed @ hospital. He got his first Covid 19 shot on 2-8-21. Was fine @ 0300 on 2-9-21 and @ 0430 he was found unresponsive. Dx: probable arrythmia & pronounced dead @ 0454. Noted on pain scale @ 2/8/21 @ 21:11, clients pain was a 7/10 They offered pain med & he refused They repositioned & distracted him @ 2047 on 2/8/21 Pain had decreased to 3/10 and nothing given. Then @ 0300 check he was sleeping and @ 0430 unresponsive.		this event.
	HYPOTHERMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.		No prior vaccinations for this event.
	HYPOTHYROIDISM	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient fell the day after receiving the Moderna COVID-19 vaccine. She broke her hip in this fall. During surgery to correct the broken hip, she went in to sudden and unexpected cardiac arrest. The anesthetist did not notice any ST changes or A fib; dysrhythmia was very unexpected. The patient had a DNR. She died at 13:00 on 02/07/2021. Causes of death are listed as 1. Cardiac Arrest 2. Recent hip fracture with hip placement 3. History of Breast Cancer 4. Hypothyroid and 5. Dementia		No prior vaccinations for this event.
	HYPOTONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Staff walked into resident's room around 10:00am and noted resident's left side of his face was flaccid. Nurse		No prior vaccinations

was called and upon assessment resident noted to have an unequal hand grasp with left worse. He was able to talk but was mumbled and hard to understand. Physician, hospice, and family were notified. Resident had a stroke at 10:06 am on 1/8/2020. He lost all ability to use his left side. Resident passed away on 1/11/2020.	for this event.	
HYPOTONIA		**COVID19 (COVID19 (MODERNA)) (1201)**
The patient passed away today, 1/13/2021. She was a hospice patient. She showed no adverse effects after receiving the vaccine on 1/12/2021. This morning she woke up as normal and during her morning shower she had a bowel movement, went limp and was non-responsive. The patient passed away at 7:45 am.	No prior vaccinations for this event.	
HYPOXIA		**COVID19 (COVID19 (MODERNA)) (1201)**
51 year old M with h/o O2 dependent COPD, Severe pulmonary fibrosis became increasingly hypoxic around 1800hours 1/7/2021. He was transported to hospital for acute on chronic hypoxia respiratory failure. On 1/12/2021 he decompensated further, and after discussing with family and palliative care, He was changed to comfort care. He expired on 1/12/2021@2325 at medical center.	No prior vaccinations for this event.	
HYPOXIA		**COVID19 (COVID19 (MODERNA)) (1201)**
This patient has been under hospice care for over 2 years at the nursing home. She has had a steady decline with gradual weight loss. She was totally dependent in her care needs. She received the vaccine on 1/2/2021 as part of the facility vaccination campaign. No adverse events noted initially. On 1/3/2021 at 6:06 pm, she was noted on vital sign checks (done every 4 hours for first 72 hours after vaccination) with BP 64/52 but otherwise asymptomatic. Subsequent BP improved. On 1/4/2021 at 4:45 am, pt found with respiratory rate of 30 with otherwise normal vital signs. Tachypnea persisted, so she received liquid morphine 2.5 mg without improvement. Supplemental oxygen was applied. Tachypnea persisted. She had poor oral intake after that	No prior vaccinations for this event.	

point had persistent tachypnea and worsening hypoxemia despite clear lungs on exam. She remained under hospice care and comfort measures were continued. No blood testing or imaging tests were done. She required increasing amounts of oxygen, became hypotensive, and died peacefully on 1/8/2021 at 7:45 pm.

	HYPOXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
hypoxia, secretions,cough, dyspnea Narrative: ALS patient on hospice with ongoing history of aspiration pna, receiving tube feeds. Developed incr in secretions, hypoxeia, temp and with recently noted clogged feeding tube.		No prior vaccinations for this event.
	HYPOXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Congestion, Hypoxia, SOB, Tachycardia, Weakness. Started on O2 @ 3L, HOB elevated, Tylenol supp		No prior vaccinations for this event.
	HYPOXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient, who was a pharmacist, developed fatigue and shortness of breath hours after receiving vaccine. Two days later, on 01/28/2021, the patient went to local urgent care for worsening shortness of breath and was referred to Hospital for worsening dyspnea and hypoxia. The patient was admitted to the hospital We was found to have bilateral pulmonary infiltrates and treated for pneumonia with Rocephin and azithromycin. He was tested for COVID-19 multiple times, but each of the results were negative. Despite the negative results, there was high clinical suspicion for COVID-19 and the patient was started on Remdesivir and Decadron. The patient's oxygen requirements continued to worsen and the patient was transferred to another facility for higher level of care. There his hypoxia worsened and he required mechanical ventilation. Patient then developed hypotension and required vasopressors for blood pressure support. Furthermore, patient		No prior vaccinations for this event.

developed acute renal failure requiring hemodialysis. Despite mechanical ventilation with FiO2 100%, and for vasopressors, patient clinically deteriorated and family decided to palliatively extubate on 02/05/2021.

	HYPOXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the Moderna COVID vaccine 1/28/21. He was tested for COVID 19 on 1/29/31. Results were received 1/30/21, at which time he was evaluated and found to be hypoxic with tachycardia. He was sent to the local ER and returned this same day. On 2/2/21, he was evaluated by the provider, who sent him to the emergency room with acute respiratory distress and poor O2 sats		No prior vaccinations for this event.

	HYPOXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"		No prior vaccinations for this event.

	HYPOXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presents to ER with increased weakness, hypoxia, history of COPD, but not oxygen dependent., hypotension. Acute Kidney failure noted in labs, not previously diagnosed , new hyperkalemia. BP 73/39, HR 67. dopamine initiated, and switched to Levophed. Oxygen Sat 86%, requiring 10 L O2. Transferred from this		No prior vaccinations for this event.

critical access hospital to another Hospital. Expires later 2-13-2021

	HYPOXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.		No prior vaccinations for this event.

	HYPOXIA	**COVID19 (COVID19 (MODERNA)) (1201)**

Patient experienced an episode of emesis and loss of consciousness several hours after vaccine on 2/16/21. He was taken by EMS to the hospital and was noted to be hypoxic and hypotensive. He was admitted to the hospital and subsequently intubated. He was also found to have a small bowel obstruction and a nasogastric tube was placed to decompress the bowel. He required pressor support as well. He expired on 2/17/21.

No prior vaccinations for this event.

HYPOXIA

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with

No prior vaccinations for this event.

hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

	HYPOXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Hypoxia, Decreased responsiveness, Narrative: 86yo male with PMHx HTN, Afib not on AC after head trauma, CVA, and colon cancer who was brought to the ED by his family on 2/17. Per documentation the pt was in his usual state of health until 2/16. Received Moderna covid vaccine #2 on 2/16/21 at 0900, and was monitored for 15 minutes following immunization no noted issues. Later that night, had myalgias and took Tylenol. Per the family he slipped on the ice and fell on his butt. Overnight, had several dark stools and vomitus. was brought to the ED by his family because he was being less responsive. Pt arrived to the emergency department in extremis. No pulse identified. CPR immediately initiated for several rounds lasting about 25-30 minutes. ROSC unable to be achieved. Patient expired on 2/17 at 1941. Of note, per previous documentation had waxing and waning mental status at baseline. No symptoms noted with 1st dose of Moderna vaccine, which was administered on 1/16/21.		No prior vaccinations for this event.

	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident became SOB, congested and hypoxic requiring oxygen, respiratory treatments and suctioning. Stabilized after treatment and for the next 72 hours with oxygen saturations in the 90s. On 1/3/2021 was found without pulse and respirations. Resident was a DNR on Hospice.		No prior vaccinations for this event.

HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient developed hypoxia on 1/4/2021 and did not respond to maximal treatment and passed way on 1/5/2021	No prior vaccinations for this event.
HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.	No prior vaccinations for this event.
HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
REPORTING ONLY AS RESIDENT EXPIRED ON 1/17/2021 3 DAYS AFTER. S/S HYPOXIA/CONGESTED LUNG SOUNDS	No prior vaccinations for this event.
HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21	No prior vaccinations for this event.

	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (	No prior vaccinations for this event.

	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new	No prior vaccinations for this event.

periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on

admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
decedent had shortness of breath and hypoxia, cardiac arrested in front of the EMS crew, ACLS initiated, arrived in the Hospital ED asystole and pronounced dead		No prior vaccinations for this event.

	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient stated he wasn't feeling well on January 25, 2021, wasn't eating and complained of abdominal pain. Patient noted to have indigestion and was constipated. Meds provided and labs ordered. On morning of January 26, 2021, patient became weak, lethargic and hypoxic and was sent to emergency department around 0700 hours on January 26, 2021. At approximately 1100 hours, emergency physician notified this writer that patient was not going to overcome his illness and would be placed on comfort care. At approximately 1130 hours, this writer was notified that patient had passed away from multi-organ failure.		No prior vaccinations for this event.
	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of the COVID-19 Moderna vaccine on 1/19/2021 at an outside facility (no lot #, route, or site available to me in electronic charting). Pt began having hypoxia, SOB, and a dusky appearance of extremities on 1/29/2021 and was brought by EMS to our hospital. PT is a DNR and family had been looking into a hospice sign up due to dementia and general decline in the weeks prior to hospitalization. Pt tested positive on admission for COVID-19 via PCR test on 1/29/2021. Pt continued to have respiratory decline, was put on comfort care per wishes of family/advanced directives, and he passed away the evening of 1/30.		No prior vaccinations for this event.
	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient received vaccine on Jan 23, 2021. developed weakness on Jan 25, 2021. Sent to ED on Jan 27, 2021 with hypoxia requiring 6 L O2, low Bp, declining mental status. Per family request transitioned to		No prior vaccinations for this event.

hospice and passed away on Jan 30, 2021

	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.	

	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"	No prior vaccinations for this event.
HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
For the two days prior to presentation the patient had been complaining of chest pain, his breathing seemed to be labored Monday. He and the family thought the pain was due to shingles as he carried this diagnosis from a month ago. Patient had also received the COVID vaccine 2 days prior to presentation and assumed he was feeling unwell due to the vaccine. Family wanted to take him to the hospital yesterday and earlier	No prior vaccinations for this event.

today but he refused. She left him in his home earlier this afternoon prior to presentation and returned to check on him finding him unresponsive and apneic at which time EMS was activated. #cardiac arrest -- suspect primary cardiac given collateral from family at home, consider hypoxemia which was corrected with advanced airway and 100% FiO2, patient clinically euvolemic and with soft brown stool in diaper not suggestive of GI hemorrhage, attempt to address acidosis with CPR and bicarbonate, not hypoglycemia, on bedside ultrasound FAST neg and no pericardial effusion suggestive of tamponade and +lung sliding bil not spontaneous pneumothorax Assessment/Diagnosis: -cardiac arrest, cause unspecified

	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia		No prior vaccinations for this event.

	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.		No prior vaccinations for this event.

	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o		No prior vaccinations for

of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.		this event.
	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was hospitalized 15 days after receiving vaccine. Admission was not due to vaccine and was admitted for acute ascites and patient had reported fever and hypoxia. Patients admission resulted in death 7 days after being admitted to hospital.		No prior vaccinations for this event.
	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pale, Short of Breath, Hypoxic, Lethargic within minutes became unresponsive and died.		No prior vaccinations for this event.
	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He		No prior vaccinations for this event.

was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.

	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt fell within 24 hours after vaccine. was sent to hospital. pt was found to be hypoxic with multifocal opacities on CT scan		No prior vaccinations for this event.
	HYPOXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/21 - Resident complained of SOB. SPO2 66% on RA, vs 105/66-96-20 T98.2 O2 administered Pox 97% Binax test revealed (+) COVID results. Resident transferred to COVID wing. Family (HCP) updated and declined transfer to hospital Resident continued with fever, hypoxia and lethargy. Family elected CMO and Hospice notified. Resident died on 1/16/2021 @ 930AM.		No prior vaccinations for this event.
	HYPOXIA	**COVID19 (COVID19 (UNKNOWN)) (1202)**
COVID 19 vaccine, unknown which company Chronically ill in a skilled nursing facility found diaphoretic, hypotensive, hypoxia to 85% arrived to Emergency dept in cardiac arrest Died within 65 minutes of nursing finding patient in distress Wife felt it may have been related to vaccine date of vaccination 1/6/20 hx covid 19 PNA in April 2020		No prior vaccinations for this event.
	ILEUS	**COVID19 (COVID19**

		(MODERNA)) (1201)
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.	
ILLNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
per recipient spouse - vaccine recipient became ill during the night of 1/21/21 or early morning of 1/22/21 and was deceased in the morning of 1/22/21.	No prior vaccinations for this event.	
ILLNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
This is the patient who passed away 2d after his second COVID vaccine. Of note, the 2/8 telephone note makes it sound like he was hospitalized at time of death - that is incorrect. His daugther listed as EM contact works in the eye clinic here. He had mild illness, completed 10d isolation but missed his scheduled booster dose on 2/2 due to isolation. He was called on 2/5 when there was a booster visit cancellation and received his booster dose on that day. His daugther reported that he was doing fine and looking well on 2/7 AM, ate breakfast, shortly after stood up and just collapsed.	No prior vaccinations for this event.	
ILLNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
Was given without consent from POA patient got severely sick and never recovered later passed away only live 1 month POA did not allow second vaccine to be given just wanted to report this vaccine was given illegal without POA knowledge	Hives	

ILLNESS	COVID19 (COVID19 (MODERNA)) (1201)
Blood pressure went down until he died; Couldn't hear his heartbeat; neck was sweating; He was cold; Couldn't get up; Death; Sick; immediately very tired; he was tired; Hands were shaking; Slept for too long; A spontaneous report was received on 18 Feb 2021 from a consumer concerning a 81-years-old, male patient who received Moderna's COVID-19 vaccine and developed immediately very tired, hands were shaking, neck was sweating, was cold, sick, couldn't get up, couldn't hear his heartbeat and blood pressure went down until he died. Patients' medical history, as provided by patient's spouse, was emergency room(ER) admission in November 2020 because he had a congested chest (he had fluid around his heart). At that time, they gave him pills for kidney function. Other concomitant medication reported was Coumadin, blood thinner. Two weeks before receiving the vaccine, patient's EKG was normal. On 11 Feb 2021, in the morning, patient received their first of two planned doses of mRNA-1273(BATCH/LOT # 007M20A) probably in the right arm for the prophylaxis of COVID-19 infection. On 11 Feb 2021, approximately after 15 minutes of receiving vaccine, they left and patient was immediately very tired, his hands were shaking. So, patient's spouse made them down sleep for too long. On Friday, 12 Feb 2021 she tried to pick him up, but he was tired, exhausted, and sick. On Saturday, 13 Feb 2021, she brought him a coffee and he couldn't hold it because his hands were shaking, so she gave him the coffee and then made him pee on the bed because he couldn't get up. At lunch time she made him eat something and he fell sleep again. His wife was hanging around him all day and around 7:30pm she realized that he was cold, and his neck was sweating, she couldn't hear his heartbeat. So, she called emergency services and when they arrived, her husband's blood pressure went down until he died. Treatment for the events were not provided. Action taken with mRNA-1273 was not applicable. Patient was pronounced dead on 13 Feb 2021 20:00. The cause of death was not provided. The plans for an autopsy were not provided. The events of blood pressure went down until he died and couldn't hear his heartbeat were fatal. The outcome for the remaining events were unknown.; Reporter's Comments: This case concerns an 81 year old, male patient, who experienced a serious event of death among others, 2 days after receiving mRNA-1273 (Lot# 007M20A). Very limited information regarding this event has been provided at this time. Further	No prior vaccinations for this event.

information has been requested.; Reported Cause(s) of Death: Unknown cause of death

IMAGING PROCEDURE	**COVID19 (COVID19 (MODERNA)) (1201)**
Lethargy/altered level of consciousness lead to hospital admission. Multiple interventions during hospitalization. Final hospital diagnoses: Acute respiratory failure with hypercapnia, acute pansinusitis.	No prior vaccinations for this event.
IMAGING PROCEDURE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient family had been noticing onset confusion for a few weeks prior to vaccine and event. Patient was taken to ED when found unconscious and died of a subdural hemorrhage a few days after vaccine clinic at retirement home.	No prior vaccinations for this event.
IMAGING PROCEDURE ARTIFACT	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	No prior vaccinations for this event.
IMMATURE GRANULOCYTE COUNT INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH))**

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or

No prior vaccinations for this event.

definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

IMMATURE GRANULOCYTE PERCENTAGE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
IMMEDIATE POST-INJECTION REACTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
right arm swelling immediately after injection. followed by bilateral lower leg edema, chills and body aches	No prior vaccinations

that continued daily at 2 weeks post immunization admin 2/4/21 treated with dexamethasone 6mg PO x 7 days- this resolved his s/s 2/13/21 patient passed away at facility

for this event.

IMMOBILE

COVID19 (COVID19 (MODERNA)) (1201)

began itching within 24 hours, within 5 days couldn't move on her own, by 6th day was having respiratory issues, by day 7 unresponsive, by day 8 dead

No prior vaccinations for this event.

IMMOBILE

COVID19 (COVID19 (MODERNA)) (1201)

Patient became immobile on 1/25/21 (4 days after receiving Moderna COVID-19 vaccine). He died on 1/27/21

No prior vaccinations for this event.

IMMUNE THROMBOCYTOPENIA

COVID19 (COVID19 (MODERNA)) (1201)

patient developed autoimmune thrombocytopenia No prior vaccinations for this event.

IMMUNOGLOBULIN THERAPY **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full

No prior vaccinations for this event.

viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

IMMUNOGLOBULIN THERAPY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.

IMMUNOGLOBULIN THERAPY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's	No prior vaccinations for this event.

wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.

IMMUNOGLOBULIN THERAPY	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.	Influenza Vaccine

IMPAIRED WORK ABILITY	COVID19 (COVID19 (MODERNA)) (1201)
"Client came to nursing station about 2pm to report she ""was not feeling well"". Nurses took vital signs, then referred her to the vaccination clinic that was onsite. She was observed by vaccination team for a period of time. She reported shoulder pain radiating into shoulder blade in arm vaccine was received. Vaccination team offered ice pack to her, observed for a period of time, and released back to work. About 10pm that evening, she sent a text to another coworker that her pain was ""off the charts"" and that she had pain covering her whole left side of her body. She did not come to work in the morning and did not contact work. Well being check was performed at approximately 9am on 2/2/2021 and she was found dead in her home. 911 was immediately called and authorities took over the scene."	No prior vaccinations for this event.

	INCARCERATED HERNIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccinated 2/20. At that time, had symptoms of incarcerated hernia, went to ED for evaluation. Not felt to warrant hospital admission. Returned two days later with agitation, altered mental status, and incarceration. Went to OR, uncomplicated hernia repair. Postoperatively, did not recover mental status. Went into arrythmias POD 4, hypotension ensued, had multiple interventions and evaluations without satisfying answers for clinical course.		No prior vaccinations for this event.
	INCOHERENT	**COVID19 (COVID19 (MODERNA)) (1201)**
She had pain in the injection site Tuesday night and then during Tuesday she got worse with nausea and some fever. By Wednesday she was complaining that she could not pee even though she was drinking a lot of fluids. She continued to complain it was the worst she ever felt and then at 0600 Thursday morning she woke us up and said she needed to go to the hospital. We arrived at the hospital just before 0700 and she immediately threw up in the trash can. We went into a treatment room and they took blood and started fluids as she became incoherent. She said she had taken Tylenol so they started a drug to counter that but her liver function was all wrong and they started to look for a hospital that could transplant a liver. She was air evade about 0930 to Medical center and just over 30 hours latter she was dead. There is a pending autopsy. She was a healthy 39 year old mother who got the shots because she worked as a surgical tech and she was the single mother of a 9 year old little girl.		No prior vaccinations for this event.
	INCONTINENCE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24		No prior vaccinations

hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021	for this event.	
INCREASED BRONCHIAL SECRETION		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident expired on 2/5/21 at 03:35pm, about 25 hours after second dose of vaccine. At breakfast, resident was spitting a lot of secretions, coughing up liquids from nose and phlegm, facial swelling, which were all symptoms that he was struggling with prior to both doses of COVID vaccine, but had increased more than prior incidences on 2/5/21. Gurgling noted in upper airways, hyscolamine given, bath given to loosen secretions, morphine given. Family notified and came into facility for compassionate care visit around 1300. 1400 HR was 3 and RR was 2, but increased back to 60 and 12 within 20 minutes. Then resident expired at 1535.	No prior vaccinations for this event.	
INFLAMMATION		**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation	No prior vaccinations for this event.	
INFLAMMATORY MARKER INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a	No prior vaccinations for	

71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death	this event.
INFLAMMATORY MARKER INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from	No prior vaccinations for this event.

facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note:

""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

INFLAMMATORY MARKER TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since	No prior vaccinations for

receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.	this event.
INFLUENZA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21	No prior vaccinations for this event.
INFLUENZA A VIRUS TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
CARDIAC ARREST THAT LEAD TO DEATH - IT WAS REPORTED BY EMS THAT THE PT HAD RECEIVED THE VACCINE ABOUT 30 MINS PRIOR. HE ARRIVED HOME, BECAME SHORT OF BREATH & COLLAPSED. 911 WAS CALLED AND HE WAS TRANSPORTED VIA EMS TO HOSPITAL (16:17) WHERE HE LATER EXPIRED (23:01).	No prior vaccinations for this event.
INFLUENZA A VIRUS TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**

Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29	No prior vaccinations for this event.
INFLUENZA A VIRUS TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
INFLUENZA A VIRUS TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.	No prior vaccinations for this event.
INFLUENZA A VIRUS TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Jan 3 vaccine administered, jan 4 started headaches, vomiting, pain in the back of the neck, Headaches, chills, loss of speech,	No prior vaccinations for this event.	
INFLUENZA B VIRUS TEST		**COVID19 (COVID19 (MODERNA)) (1201)**
CARDIAC ARREST THAT LEAD TO DEATH - IT WAS REPORTED BY EMS THAT THE PT HAD RECEIVED THE VACCINE ABOUT 30 MINS PRIOR. HE ARRIVED HOME, BECAME SHORT OF BREATH & COLLAPSED. 911 WAS CALLED AND HE WAS TRANSPORTED VIA EMS TO HOSPITAL (16:17) WHERE HE LATER EXPIRED (23:01).	No prior vaccinations for this event.	
INFLUENZA B VIRUS TEST		**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29	No prior vaccinations for this event.	
INFLUENZA B VIRUS TEST		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.	
INFLUENZA B VIRUS TEST		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.

No prior vaccinations for this event.

INFLUENZA LIKE ILLNESS

COVID19 (COVID19 (MODERNA)) (1201)

Patient reported mild flu like symptoms from vaccination later that evening. Next morning LTCF staff found pt deceased

No prior vaccinations for this event.

INFLUENZA LIKE ILLNESS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.

No prior vaccinations for this event.

INFLUENZA LIKE ILLNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per Patients Wife - Same day - Flu like symptoms, Nausea, Headache. Restless that night. Next day - Weak, shortness of breath. Wife called squad to get him out of his wheelchair but patient refused hospital as it gets him agitated. Patient passed away around 11 AM the day after vaccination.	No prior vaccinations for this event.
INFLUENZA VIRUS TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 10 minutes after receiving the COVID- 19 vaccine resident displayed seizure activity, staring straight ahead and strong allover muscle jerking of both the up and lower extremities, color became gray, activity lasted approximately 3 minutes, resident then became relaxed, color returned to normal, BP-140/80, 97.8, 60, 16, sleeping the remainder of the shift,. Resident continued to decline until resident CTB on 1/19/21	No prior vaccinations for this event.
INFLUENZA VIRUS TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today.	No prior vaccinations for this event.

Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics

	INFLUENZA VIRUS TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
CARDIAC ARREST THAT LEAD TO DEATH - IT WAS REPORTED BY EMS THAT THE PT HAD RECEIVED THE VACCINE ABOUT 30 MINS PRIOR. HE ARRIVED HOME, BECAME SHORT OF BREATH & COLLAPSED. 911 WAS CALLED AND HE WAS TRANSPORTED VIA EMS TO HOSPITAL (16:17) WHERE HE LATER EXPIRED (23:01).		No prior vaccinations for this event.
	INFLUENZA VIRUS TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face,		No prior vaccinations for this event.

increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

INFLUENZA VIRUS TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29

No prior vaccinations for this event.

INFLUENZA VIRUS TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Started feeling unwell; Headaches; Body aches; Chest pain; Didn't had wishes to eat; Diarrhea; COVID-19 pneumonia; A spontaneous report was received from a consumer concerning a 69-year-old male patient

No prior vaccinations for this event.

who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced COVID-19 pneumonia, feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea The patient's medical history high blood pressure which was controlled with medication. Concomitant product use included nifedipine and fenofibrate. On 20-JAN-2021, approximately a week and a half or two prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number 030L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. A week and a half or two later the patient stated feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea for which patient was hospitalized on 06-FEB-2021. Since everything seemed to be fine the patient was discharged on an unknown date in FEB-2021 however, patient's family was not notified that it was a late reaction to the vaccine's first dose. Later, due to shortness of breath he was hospitalized again on 08-FEB-2021 and was diagnosed for pneumonia and was intubated on the same day. Due to COVID-19 situation patient's family could not be in the facilities and that there wasn't any follow up of the patient given to the family, so family did not have much information. During the first hospitalization(06-FEB-2021) the patient had a blood test which showed a normal result and was tested for COVID-19 and Influenza, both were negative. During second hospitalization (08-FEB-2021) the hospital said that the patient was stable. The patient's family did not know the results of the tests conducted at the time. The action taken with the vaccine in response to the events is not applicable. The outcome of COVID-19 pneumonia was fatal. The patient died on 14 Feb 2021 The cause of death was reported as COVID-19 related pneumonia. The autopsy was not done.; Reporter's Comments: Very limited information regarding this event has been provided at this time. The cause of death was reported as COVID-19 related pneumonia. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the events are assessed as unlikely related. Further information has been requested.; Reported Cause(s) of Death: COVID-19 pneumonia

INFLUENZA VIRUS TEST NEGATIVE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. No prior vaccinations for

Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.

this event.

INFLUENZA VIRUS TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to

No prior vaccinations for this event.

initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

INFLUENZA VIRUS TEST NEGATIVE

COVID19 (COVID19 (UNKNOWN)) (1202)

Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2 diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline

No prior vaccinations for

health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated) then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and was intubated. Transported to hospital. SARS CoV-2 and influenza negative.	this event.	
INFREQUENT BOWEL MOVEMENTS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/22/2021 10:09 pm resident reported 1 episode of being nauseous and having dry heaves, no temperature, MD notified and nurse was told to continue to monitor, no new orders, daughter made aware. Vital signs being done every 4 hours. 2/23/2021 3:04am resident complains of nausea, scant BM amount x 2, MD notified and no new orders, continue to monitor and encourage fluids, vital signs continue every 4 hours.	No prior vaccinations for this event.	
INFUSION		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be	No prior vaccinations for this event.	

the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

INJECTION SITE DISCOMFORT **COVID19 (COVID19 (MODERNA)) (1201)**

2nd dose of Moderna at 9:00am. No side effect (except pinch at injection site) throughout the day and evening. At ~9:45pm, my wife suddenly fell unconscious. Immediate CPR & with Paramedic were not able to revive her. SHE PASSED AWAY at home. We believe it may be triggered by the vaccine. Did not have a chance to go to hospital or emergency room - it was too sudden. A sad day for us. No prior vaccinations for this event.

INJECTION SITE PAIN **COVID19 (COVID19 (MODERNA)) (1201)**

Headache, pain in the injection site, threw up. A few hours later she died. No prior vaccinations for this event.

INJECTION SITE PAIN **COVID19 (COVID19 (MODERNA)) (1201)**

Death Narrative: Patient received the first COVID-19 dose on 12/23. Afterwards, patient complained of localized pain on L deltoid area where the vaccine was administered; his temperature was 98.1 F. On 12/26-27, staff reported that patient appeared more fatigued than usual and was shivering on 12/27, which seized No prior vaccinations for this event.

after blanket was given. On 12/28, patient presented with fever (Tmax 100.2 F) and acetaminophen was administered for alleviation of fever. ADR was reported for the fever on 12/29. Patient continued to decline and was placed back on hospice care on 12/29; on 12/30. the symptoms reported on nursing note include erythema and pain on whole L arm. Lidocaine was applied. Patient's family and provider mutually agreed not to administer the second dose of vaccine. He continued to decline and was started on end-of-life care around 1/4 and passed on 1/20 1417.

	INJECTION SITE PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
"Client came to nursing station about 2pm to report she ""was not feeling well"". Nurses took vital signs, then referred her to the vaccination clinic that was onsite. She was observed by vaccination team for a period of time. She reported shoulder pain radiating into shoulder blade in arm vaccine was received. Vaccination team offered ice pack to her, observed for a period of time, and released back to work. About 10pm that evening, she sent a text to another coworker that her pain was ""off the charts"" and that she had pain covering her whole left side of her body. She did not come to work in the morning and did not contact work. Well being check was performed at approximately 9am on 2/2/2021 and she was found dead in her home. 911 was immediately called and authorities took over the scene."		No prior vaccinations for this event.
	INJECTION SITE PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
On 2/1/2021, the patients daughter, who claims is a nurse, reported this incident to me. She stated that the evening after the patient received the vaccine, she felt some mild injection site pain. The morning after, the patient reported severe abdominal pain, diarrhea and vomiting. The patients daughter then called her physician to report these symptoms and attributed them as an adverse reaction to the vaccine at that time. These symptoms were intermittent for one week and no other adverse reactions were noted. In the early morning hours of 1/27/2021, the patient was toileting and had expired while doing so. An ambulance was		No prior vaccinations for this event.

called and cause of death was not found. An autopsy was not performed.

	INJECTION SITE PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
She had pain in the injection site Tuesday night and then during Tuesday she got worse with nausea and some fever. By Wednesday she was complaining that she could not pee even though she was drinking a lot of fluids. She continued to complain it was the worst she ever felt and then at 0600 Thursday morning she woke us up and said she needed to go to the hospital. We arrived at the hospital just before 0700 and she immediately threw up in the trash can. We went into a treatment room and they took blood and started fluids as she became incoherent. She said she had taken Tylenol so they started a drug to counter that but her liver function was all wrong and they started to look for a hospital that could transplant a liver. She was air evade about 0930 to Medical center and just over 30 hours latter she was dead. There is a pending autopsy. She was a healthy 39 year old mother who got the shots because she worked as a surgical tech and she was the single mother of a 9 year old little girl.		No prior vaccinations for this event.

	INJECTION SITE PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Toileting and had expired while doing so; Severe abdominal pain; Diarrhea; Vomiting; Mild injection site pain; A spontaneous report was received from a healthcare professional concerning an 88-year-old , female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced the events, toileting and had expired while doing so (death), mild injection site pain, severe abdominal pain, diarrhea, and vomiting. The patient's medical history was not provided. No relevant concomitant medications were reported. On 20 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 029L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 20 Jan 2021, the patient felt mild pain at the injection site after receiving the vaccine. On 21 Jan 2021, the patient reported severe abdominal pain, diarrhea and vomiting. These symptoms were intermittent for a week and no other adverse events were		No prior vaccinations for this event.

noted. On 27 Jan 2021, the patient passed away while toileting. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 27 Jan 2021. The cause of death was unknown. An autopsy was not performed.; Reporter's Comments: The gastrointestinal events were consistent with increased risk associate with elderly age of patient. The cause of death was unknown. Autopsy was not performed. Very limited information regarding the events is available at this time. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Reported Cause(s) of Death: unknown cause of death

INJECTION SITE PAIN		**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away; Slight soreness in arm; A regulatory report was received from a pharmacist concerning a 72-year-old male patient who received Moderna covid-19 vaccine and death occurred 4 days after the vaccine and also experienced soreness in his arm after the vaccine administration. The patient's medical history includes diabetes mellitus, Hypertension, Hypercholesterolemia, CVD, previous stroke and Depression. No relevant concomitant medications were reported. No information on allergies. On 4-FEB-2021 at 10:43 am, prior to the onset of events, the patient received his first of two planned doses of covid-19 vaccine for the prophylaxis of covid-19 infection. He had soreness in his arm the day following the shot, but he had no other symptoms. He passed away on 08-FEB-2021 at 10 am. As per his wife, they never made it to the hospital, and he had poor health prior to vaccination. Action taken with 2nd dose of Moderna Covid-19 vaccine was not applicable. The outcome of the event death is fatal.; Reporter's Comments: This is a 72 year old male with hx of diabetes mellitus, hypertension, hypercholesterolemia, and CVD who died 4 days after the vaccine was administered. No autopsy report provided. No further information is expected in this regulatory report case.; Reported Cause(s) of Death: Unknown cause of death	No prior vaccinations for this event.	
INJECTION SITE PAIN		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"Patient's wife called this morning stating that her husband has passed away last night. After receiving first dose of Pfizer COVID-19 vaccine at around 0830, patient remained in the Immunizations Department for the 15-minute monitoring period. Per wife, patient's only complaint was pain at the injection site. At 1300, wife states that patient complaint of dizziness which ""dissipated after a few minutes"" followed by a headache which ""dissipated after a few minutes"" as well. Then patient complained of nausea, no vomiting and ""couldn't relax."" Per wife, from around 1400/1500, patient stayed on his recliner while still having a conversation with her--""he didn't get up to eat."" Last conversation they had was around 2000/2100. Per wife, at around 2100/2200, patient was quiet and when she checked on him, ""he wasn't responding anymore."" Wife then called 911, ""but they couldn't revive him.""""	No prior vaccinations for this event.	
INJECTION SITE PAIN		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom only had site soreness after her covid vaccine on 1/21 which resolved within a couple days. However, she died in the early morning hours of 1/25, she was fine the day before, no sign of injury. We found her collapsed on the ground and although we tried cpr she was already dead. She had gone to the hospital on 12/28 for shortness of breath, angina and symptomatic anemia, her ekg was unchanged and blood work normal except for anemia. The cardiologist did not think a cardiac cath was needed. Her shortness of breath improved with a blood transfusion and a dose of lasix (no heart failure).	No prior vaccinations for this event.	
INJECTION SITE PAIN		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/23 - Mild injection site discomfort. Appetite loss compared to previous day. Beginning loss of mental acuity compared to previous day. 1/24 - Continued loss of appetite. Near complete loss of ability to move. Continued decline of mental acuity. Very little speaking. 1/25 - Stopped speaking completely. Loss of bowel	No prior vaccinations for this event.	

control in the evening and continued until death. Complete loss of appetite. 1/26 - Near complete loss of ability to swallow. Moved to hospice 4:00pm. 1/27 - Died 4:00am

	INJECTION SITE PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death Narrative: 86 year old MALE with PMH of Afib s/p AICD/PPM, HFrEF (EF< 20% 10/2019), DM2, HTN, HLD, BPH, Depression. Was stable and feeling well when he was administered Covid-19 vaccine on 02/17/2021- Pfizer COVID-19 Vaccine 0.3 ml IM. MVX (Manuf); PFR; Lot#; EL9267; Exp Date:05/31/2021 Administration Anatomic site: Right Deltoid; Pt was monitored for 30 minutes after administration and had no adverse effects. He was called later in the day and reports he feels well and has had no adverse reactions, he endorsed his arm is a little sore at injection site. ON 02/19/2021- his dghter found him on the floor, next to his bed, dead. She reported on 2/19/2021- that she was out with him to dinner on 2/18/2021, and he stated he did not feel well, that his insides did not feel right. He proceeded to have dinner and 2 drinks. HE was doing ok, when she took him home.		No prior vaccinations for this event.

	INJECTION SITE RASH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.

INJURY		**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene when EMS arrived. Autopsy showed a left temporal subdural hematoma.		No prior vaccinations for this event.
INSOMNIA		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna COVID-19 vaccination administered in left arm at her assisted living facility by Pharmacist at 1153 on 2/19/2021. Pt was monitored for vaccine reaction with no known adverse reaction. Approximately 18 hours post-vaccine, she was found deceased in her sleep at 0540 on 2/20/21. Per circumstances/pt history, it is presumed that the patient aspirated while sleeping, perhaps secondary to a seizure. Coroner was notified and declined as coroner's case. VAERS notification being made due to pt death within 24 hours of receiving a vaccine.		No prior vaccinations for this event.
INSOMNIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1-12-21 Resident is complaining of heart pain. Resident blood pressure is 228/105. 1-22-21 Dx UTI 1-13-21 His nurse called MD at approximately 0645, reported to him that it was reported to this nurse that resident has not slept in 2 days and night, has an increased blood pressure, reports severe pain in lower back, and appears to be uncomfortable Resident is able to verbalize his pain and where it is at, but is unable to explain the quality of the pain or give a number on the 0/10 pain scale.		No prior vaccinations for this event.

INTENSIVE CARE

COVID19 (COVID19 (MODERNA)) (1201)

Patient received her first dose of the Moderna COVID-19 Vaccination on Saturday January 16th 2021 at approximately 12pm. She completed all necessary screening forms and was deemed to be at low risk for serious allergic reactions. She tolerated the vaccination well, and no complications or immediate adverse events occurred. She was observed for a full 15 mins per CDPHE/CDC guidelines and left the Clinic in stable condition after her observation period was complete. On the morning of Tuesday, January 19th, 2021, the patient was found unconscious and unresponsive by her husband. She was transferred by Ambulance to Hospital shortly thereafter. She was diagnosed with a brain bleed that was determined to be inoperable. She was transferred to other Hospital for higher level care. She was seen by neurosurgery and diagnosed with a ruptured aneurysm. She was treated in the ICU for 24 hours, at which point her team determined that the severity of her brain bleed would not respond to treatment. Supportive cares were withdrawn on Wednesday Jan 20th, and she passed away shortly thereafter.

No prior vaccinations for this event.

INTENSIVE CARE

COVID19 (COVID19 (MODERNA)) (1201)

about 20+ hours after vaccination resident was having hard time breathing, 911 was called. Resident coded multiple times at the facility after CPR she was taken to ICU. She coded again and was placed on life support. Due to her choice to not be on life support she passed on 11/26/2021.

No prior vaccinations for this event.

INTENSIVE CARE

COVID19 (COVID19 (MODERNA)) (1201)

Pt likely presented to vaccine appt with asymptomatic/early infection of COVID-19, as he presented 2 days post-vaccination and tested positive for COVID-19 on rapid and PCR test. He was hospitalized where he eventually died of complications from COVID-19 while in ICU. Date of death was 1/15/2021.

No prior vaccinations for this event.

	INTENSIVE CARE	**COVID19 (COVID19 (MODERNA)) (1201)**
pt received vaccine on 2/3. early on 2/4 developed chest pain, dyspnea, and was seen in ED and diagnosed with acute exacerbation of CHF and NSTEMI type 2, and anemia. on 2/5 transfusion was started and pt developed worsening dyspnea and then PEA arrest. Pt achieved ROSC and was transferred to the cardiac intensive care unit where he required vasopressor support. he subsequently declined and died on 2/7		No prior vaccinations for this event.
	INTENSIVE CARE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient went into new-onset atrial fibrillation, resulting in a catastrophic stroke. Patient passed away on 2/11 as a result of the stroke.		No prior vaccinations for this event.
	INTENSIVE CARE	**COVID19 (COVID19 (MODERNA)) (1201)**
jaundice->hemolytic anemia-> hemorrhagic shock->multi organ failure->death pt admitted to ICU 2/16 with Hgb=3.4, treated with steroids, supportive care , pressors, pt died 2/20/21		No prior vaccinations for this event.
	INTENSIVE CARE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was transferred from hospital for further evaluation and care by pulmonologist. He started having symptoms a week before with fatigue, emesis, decreased p.o. intake, shortness of breath, vomiting and diarrhea. The two previous takes before death required increasing oxygen and family wanted everything done including intubation. He was transferred to ICU.		No prior vaccinations for this event.

INTENSIVE CARE	COVID19 (COVID19 (MODERNA)) (1201)
loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE,	No prior vaccinations for this event.

no acute PE.

INTENSIVE CARE

COVID19 (COVID19 (MODERNA)) (1201)

Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse

No prior vaccinations for this event.

INTENSIVE CARE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

The patient had an apparent cardiac arrest on 12/23/20 and was admitted to the ICU. He was taken off of life support on 12/30/20. He had known cardiac disease.

No prior vaccinations for this event.

INTENSIVE CARE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."	No prior vaccinations for this event.
INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.	No prior vaccinations for this event.
INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Cardiac arrest within 1 hour Patient had the second vaccine approximately 2 pm on Tuesday Jan 12th He works at the extended care community and was in good health that morning with no complaints. He waited	No prior vaccinations for this event.

10-15 minutes at the vaccine admin site and then told them he felt fine and was ready to get back to work. He then was found unresponsive at 3 pm within an hour of the 2nd vaccine. EMS called immediately worked on him 30 minutes in field then 30 minutes at ER was able to put him on life support yet deemed Brain dead 1-14-21 and pronounced dead an hour or so later		
	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received vaccination on January 15, 2021. She was found unresponsive with shallow respirations on the morning of January 16, 2021 and was sent to ER via ambulance. The resident was admitted to medical center ICU where she passed away later that day.		No prior vaccinations for this event.
	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21		No prior vaccinations for this event.
	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue		No prior vaccinations for

embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight this event.

1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.		No prior vaccinations for this event.
	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021.		No prior vaccinations for this event.
	INTENSIVE CARE	**COVID19 (COVID19**

	(PFIZER-BIONTECH)) (1200)
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"	No prior vaccinations for this event.
INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD,	No prior vaccinations for

CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."	this event.
INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt with acute resp failure, COVID PNA, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior toa admit, then shortly after progressed with other covid symptoms and was admitted. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated.	No prior vaccinations for this event.

Pt passed soon after(2/2).

	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
She started having breathing problems/heart attack appearance. on 1/22/21 and went to the ER. Upon admittance was told it was an anaphylactic shock from the Covid shot. They kept her in ICU and released her 1/23/21. At 12:45 am on 1/24/21 she passed out and we called the ambulance. Hospital admitted her and worked through multiple organ failure issues and thought her numbers were under control. She was released on 1/27/21 and was driving on 1/28/21 around 4:15 pm and appears to have had heart failure and had a wreck. She passed away that day.		No prior vaccinations for this event.

	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO WITHDRAWL EXTRME MEASURES		No prior vaccinations for this event.

	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My dad received the Pfizer vaccination on 2/5/21. He was admitted into the hospital the next day for C-Diff bacterial infection. He had been on dialysis treatments for kidney failure treatment since 2017 and had recently been diagnosed with stage 3 colon cancer in June 2020. He had completed his final treatment of chemotherapy on 2/4/21 and several weeks prior had been determined cancer free. On Tuesday 2/9/21 he		No prior vaccinations for this event.

was released from the hospital and went home. Early Thursday morning 2/11/21 @ approximately 1:30 am CST his eyes rolled back in head and he stopped breathing and was non responsive. My mother called 911 and attempted CPR. Paramedics arrived and were able to successfully get a pulse then transferred him to the hospital. He was put on a ventilator @ the hospital and then transferred to a different hospital a few hours later. He lost pulse/heartbeat several times @ the 2nd hospital he was transferred to. We were not allowed to travel with him or see him b/c of all of the COVID restrictions. We were communicating with the ICU doctor by phone who ultimately communicated to us that there was nothing further that could be done to save his life. He subsequently passed away @ approximately 8:55 am CST on 2/11/21.		
	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.		No prior vaccinations for this event.
	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
within 24 hours after her second injection she developed chills, had a syncopal episode and had, difficulty breathing. this progressed over the next day when she had a second syncopal episode and her dyspnea and confusion worsened EMT was called and she was brought to the hospital. she was in flash pulmonary		No prior vaccinations for this event.

edema and with her history of severe aortic stenosis she was admitted to the cardiac icu. she had no prior history up to that time of pulmonary edema and was functioning without distress in her home. she had a history of covid in early april, manifesting primarily as severe confusion, from which she recovered.		
	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Presented to ED via EMS c/o increasing shortness of breath, O2 sat mid to high 80s on 4L. When EMS arrived , pt was in distress, intubated by EMS and transported to ED. Pt had a PEA arrest en route but resuscitated w/ return of spontaneous circulation after receiving a dose of epinephrine and chest compressions. Pt was hypotensive on arrival to ED. He was started on sepsis protocol , volume resuscitation and empiric antibiotics. Once stabilized, he was admitted to icu at hospital. Removed from respirator 2/22/21		No prior vaccinations for this event.
	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Pt he reports he developed chills SOB body aches the same night as receiving the COVID vaccine on 1.26.2021-pt is currently reporting CheSt tightness and SOB Admitted to hosp: ICU with Bilateral Pulmonary Emboli, LLE DVT, NSTEMI, Arrhythmia.		No prior vaccinations for this event.
	INTENSIVE CARE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath		No prior vaccinations

61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the for this event. patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-

evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

INTERLEUKIN LEVEL

COVID19 (COVID19 (MODERNA)) (1201)

High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown)

No prior vaccinations for this event.

intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

INTERNAL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mother died suddenly on February 3rd. She went into shock/cardiac arrest and appeared to have internal bleeding. No autopsy has been performed. Unsure if it was related to the COVID vaccine.	No prior vaccinations for this event.
INTERNATIONAL NORMALISED RATIO	**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away; UTI; Abnormal bleeding; A spontaneous report was received from a healthcare professional concerning a patient who received the Moderna COVID-19 Vaccine (mRNA-1273) and experienced abnormal bleeding, UTI, and passed away. The patient's medical history included a long term history of anticoagulation therapy. Concomitant product use included anticoagulation therapy. On 31Jan2021 prior to the onset of the events the patient recieved their first dose of mRNA-1273 (Lot number:not reported) intramuscularly for prophylaxis of COVID-19 infection. On 07Feb2021, the patient complained of abnormal bleeding. Patient was	No prior vaccinations for this event.

seen at clinic on 10Feb2021 and was diagnosed with a UTI and given antibiotics. An INR was also completed that day due to patient having a long term history of anticoagulation therapy. Results of that showed the INR to be 12. Prior to vaccination, patient's INR was normal and no changes to medications and diet were made after vaccination and prior to complaint starting. On 12Feb2021 the patient passed away. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12Feb2021. The cause of death was unknown. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns an 82 year old male patient, with history of long term anticoagulation therapy (unknown indication), who experienced a fatal event of death and abnormal hemorrhage, 13 days after receiving second dose of mRNA-1273 (Lot# Unknown). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

INTERNATIONAL NORMALISED RATIO INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Pt started complaining of chest heaviness and shortness of breath on the afternoon of 1/21/21. EMS was called to the patients home and she was found to have an O2 sat in the 70's. She was admitted to hospital and found to have a proBNP of 5000. She tested negative for Covid-19. She was determined to be in acute-on-chronic heart failure and was referred for hospice care. She passed away on the evening of 1/24/21.

No prior vaccinations for this event.

INTERNATIONAL NORMALISED RATIO INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

INTERNATIONAL NORMALISED RATIO INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient received the vaccine on 1/31/2021. Patient complained of bleeding 2/7/2021. Went to clinic where labs were conducted. Patient had an INR of 12. Previous INR results were normal prior to vaccination. Patient was also diagnosed with UTI and given antibiotics. Patient was encouraged to go to ER. Patient died on 2/12/2021.

No prior vaccinations for this event.

INTERNATIONAL NORMALISED RATIO INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

INTERNATIONAL NORMALISED RATIO INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated.

No prior vaccinations for this event.

ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

INTERNATIONAL NORMALISED RATIO INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO WITHDRAWL EXTRME MEASURES

No prior vaccinations for this event.

INTERNATIONAL NORMALISED RATIO INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM

No prior vaccinations for this event.

INTERNATIONAL NORMALISED RATIO INCREASED

COVID19 (COVID19 (UNKNOWN)) (1202)

5 days after receiving his COVID vaccination the patient had a spontaneous (nontraumatic) subarachnoid hemorrhage which was fatal. The patient had previously been stable on his coumadin dosing with therapeutic INRs for the past several months per his wife. At time of presentation his blood pressure in the

No prior vaccinations for this event.

ER was elevated to 223/94 and his INR was risen to 3.1

	INTERSTITIAL LUNG DISEASE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.		No prior vaccinations for this event.
	INTESTINAL DILATATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was an 87 y/o female admitted for septic shock. She was started on and eventually maxed on 3 pressors. CT abd showed colonic obstruction with dilatation of large and small bowel. Patient was made DNR in the ED. Palliative care consulted on case. Family opted for comfort care. Patient was asystole on monitor. No spontaneous breath/cardiac sounds ausculted. Patient did not withdraw to pain. Pupils fixed and dilated. She was pronounced and 1230 on 1/28/21		No prior vaccinations for this event.
	INTESTINAL INFARCTION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented with spontaneous IVH of small vessel origin with essentially no past medical history. She		No prior vaccinations

then acutely developed mesenteric ischemia. Died due to all dead small bowel which also appeared to be small vessel disease and not embolic/thrombotic. This process started one week after	for this event.
INTESTINAL ISCHAEMIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented with spontaneous IVH of small vessel origin with essentially no past medical history. She then acutely developed mesenteric ischemia. Died due to all dead small bowel which also appeared to be small vessel disease and not embolic/thrombotic. This process started one week after	No prior vaccinations for this event.
INTESTINAL ISCHAEMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration	No prior vaccinations for this event.

pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

INTESTINAL ISCHAEMIA

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Received Pfizer Covid Vaccine in the AM on 2/9/21. Arrived to emergency department later the same day complaining of nausea, weakness, fatigue, Vomiting, Diarrhea. Post operative diagnosis, Ischemic colon/toxic megacolon.	No prior vaccinations for this event.
INTESTINAL OBSTRUCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Grandmother had trouble breathing the night she got the vaccine. She went to the hospital. They found pneumonia and a partial bowel obstruction. The obstruction cleared but she died from the pneumonia on 2/16/21.	No prior vaccinations for this event.
INTESTINAL PERFORATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
bowel perforation; pain in her upper abdomen; This is a spontaneous report from a contactable consumer. An 86-year-old female patient received the 2nd dose of bnt162b2 (BNT162B2) at single dose on 13Jan2021 for Covid-19 immunisation, administerd at nursing home/senior living facility Medical history included dementia, arthritis. No known allergies. Patient was not pregnant. Patient had not COVID prior vaccination. Concomitant medication in 2 weeks included: memantine (manufacturer unknown) 10 mg BID, diclofenac (manufacturer unknown) BID, carbidopa, levodopa (manufacturer unknown) 25-100 mg TID, quetiapine (manufacturer unknown) 12.5 mg q HS, escitalopram oxalate (LEXAPRO) 10 mg q HS, paracetamol (TYLENOL) 650 mg BID, glucosamine (manufacturer unknown) drink. The patient received the 1st dose of bnt162b2 (BNT162B2) at single dose on 24Dec2020 for Covid-19 immunisation. No other vaccine received in 4 weeks. The patient experienced bowel perforation and pain in her upper abdomen on 18Jan2021 07:30. The events resulted in Emergency room/department or urgent care, Life threatening illness (immediate risk of death from the event),	No prior vaccinations for this event.

and death. On 18Jan2021 07:30 AM, less than a week after the second shot, she had pain in her upper abdomen and was taken to the ER on 18Jan2021. CT showed a bowel perforation in the small bowel. She had never had bowel surgery or diverticulitis. She had been healthy other than her dementia and arthritis. Patient received treatment for the events: hospice and pain management. COVID-19 was not tested post vaccination. The cause of death was bowel perforation. An autopsy was not performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: bowel perforation

INTRACRANIAL ANEURYSM	**COVID19 (COVID19 (MODERNA)) (1201)**
At approximately, 1855, I was alerted by caregiver, resident was not responding. Per caregiver, she was doing her rounds and found resident in bed, unresponsive, mouth open, observed gurgling noises and tongue hanging out of mouth. This primary caregiver observed resident at baseline and ambulating after dinner at approximately, 1800 less than an hour prior to incident. This PCG called 911 for EMS and gave report of incident. Resident was taken to Medical Center Emergency Department. At ER, CT scan and X-ray was performed. Per report from ER RN, CT scan and x-ray revealed an intracranial aneurysm and fluid in the lungs. Per RN, resident was still unresponsive and was admitted to Medical Center for observation and comfort measures. This primary caregiver reported to RN, resident recently received the first dose of COVID-19 vaccine on 1/2/21. Primary caregiver received a call from Castle RN at 0700, resident expired at 0615.	No prior vaccinations for this event.
INTRACRANIAL ANEURYSM	**COVID19 (COVID19 (MODERNA)) (1201)**
Brain aneurysm; Anaphylactic reaction; Collapsed; BP sky rocketed; Shortness of breath; A spontaneous report was received from a consumer concerning a 69-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced blood pressure skyrocketed, shortness of breath, loss of consciousness, massive anaphylactic reaction, and brain aneurysm. The patient's medical history, as provided by the reporter, included high blood pressure and arthritis. Products known to have been used by the	No prior vaccinations for this event.

patient, within two weeks prior to the event, included an antihypertensive. On 04 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. Twenty-two minutes later she had a massive anaphylactic reaction. She experienced shortness of breath, blood pressure skyrocketed, and loss of consciousness. She was taken to the emergency room. The patient had a brain aneurysm and never recovered. No treatment information was provided. The patient died on 04 Jan 2021. The cause of death was reported as brain aneurysm. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns a 69-year-old, female patient with a medical history of hypertension, who experienced fatal, serious, unexpected events of Anaphylactic reaction, hypertension, dyspnea, loss of consciousness and brain aneurysm. The events occurred 22 minutes after the first dose of mRNA-1273 was administered. No treatment information was provided. The patient never recovered and died. The cause of death was reported as brain aneurysm. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Additional information has been requested.; Reported Cause(s) of Death: Brain aneurysm

INTRACRANIAL ANEURYSM **COVID19 (COVID19 (MODERNA)) (1201)**

Four days later, my father had a severe brain aneurysm. No prior vaccinations for this event.

INTRACRANIAL ANEURYSM **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - anuerism lead to death approximately 14 hours after initial symptoms.

No prior vaccinations for this event.

INTRACRANIAL ANEURYSM **COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

No prior vaccinations for this event.

INTRACRANIAL PRESSURE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH))
(1200)

"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and

No prior vaccinations

released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

for this event.

INTRAOSSEOUS ACCESS PLACEMENT

COVID19 (COVID19 (MODERNA)) (1201)

Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to

No prior vaccinations for this event.

asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.

INTRAOSSEOUS ACCESS PLACEMENT	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Few minutes post vaccination, after moving to observation area via wheelchair, the patient complained of dizziness. She took glucose tabs she had brought with her. Staff wheeled her to Triage # 1. Her eyes rolled back in her head and she lost consciousness. Staff (paramedics on site) transferred her to gurney and started compressions. AED placed, V- Fib was rhythm, Shock # 1 given, CPR resumed. Shocked again. Fire truck and additional EMT arrived on site and took over care. Epinephrine was given 3 times via intra-osseous route, Amiodarone given intra-osseous route. Additional defibrillation with on site AED for a total of 6-7 times. Patient had good chest rise with ambu-bag, no airway obstruction or peri-oral edema noted. Code called at 12:40 PM.	No prior vaccinations for this event.

INTRAVENTRICULAR HAEMORRHAGE	COVID19 (COVID19 (MODERNA)) (1201)
Patient presented with spontaneous IVH of small vessel origin with essentially no past medical history. She then acutely developed mesenteric ischemia. Died due to all dead small bowel which also appeared to be small vessel disease and not embolic/thrombotic. This process started one week after	No prior vaccinations for this event.

INTRAVENTRICULAR HAEMORRHAGE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out	No prior vaccinations for this event.

and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

INVESTIGATION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Stroke; This is a spontaneous report from a contactable consumer. A 94-year-old female patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 16Jan2021, at single dose, for COVID-19 immunisation. Medical history included ongoing hypertension (took medication). Patient did not have COVID-19 prior to vaccination. Concomitant included unspecified medication for hypertension. The patient experienced stroke on 31Jan2021. The patient was brought to the emergency room and hospitalized due to the event on 31Jan2021. No therapeutic measures were taken as a result of the event. The patient underwent lab tests and procedures	No prior vaccinations for this event.

which included COVID-19 virus test: negative in Feb2021 (a week before report); investigation: brain bleed and discovered she had a stroke (on unknown date in 2021). The patient died on 03Feb2021 due to stroke and old age. An autopsy was not performed. Patient's family did not attribute her death to the vaccine at all. The information on the Lot/Batch number has been requested.; Reported Cause(s) of Death: stroke; Old age		
	IRREGULAR BREATHING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient noted to have irregular breathing in bed and unable to arouse. Provided life saving measures in the field x 30 minutes and transferred to hospital. Noted to have heart arrhythmia which suspected to cause cardiac arrest.		No prior vaccinations for this event.
	ISCHAEMIC CARDIOMYOPATHY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient did not have any adverse reaction to the COVID vaccine, but we were asked by our health dept to submit a VAERS report since the patient died between his first and second dose. Received Pfizer Dose #1 12/17/2020. No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Date of death 12/23/2020 from aspiration pneumonia complicated by end-stage heart failure and ischemic cardiomyopathy. Death was anticipated and not sudden.		No prior vaccinations for this event.
	ISCHAEMIC HEPATITIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of		No prior vaccinations

for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

for this event.

ISCHAEMIC STROKE

COVID19 (COVID19 (MODERNA)) (1201)

Massive ischemic stroke with aspiration, unable to arouse on the morning of 1/21/2021 and placed on Hospice with death 1/24/2021

No prior vaccinations for this event.

ISCHAEMIC STROKE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient admitted to hospital evening of 2/7/21 with acute ischemic stroke and received tenectaplase. Diagnosis Left MCA stroke. Reporting event given was just over 24 hours after first COVID vaccine dose.	No prior vaccinations for this event.

JAUNDICE	COVID19 (COVID19 (MODERNA)) (1201)
jaundice->hemolytic anemia-> hemorrhagic shock->multi organ failure->death pt admitted to ICU 2/16 with Hgb=3.4, treated with steroids, supportive care , pressors, pt died 2/20/21	No prior vaccinations for this event.

JOINT INJURY	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to	No prior vaccinations for this event.

comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."

	JOINT SWELLING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.		No prior vaccinations for this event.
	KLEBSIELLA INFECTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis.		No prior vaccinations for this event.

Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

LABORATORY TEST	COVID19 (COVID19 (MODERNA)) (1201)
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.	No prior vaccinations for this event.

LABORATORY TEST	COVID19 (COVID19 (MODERNA)) (1201)
cough congestive heart failure death	No prior vaccinations for this event.

LABORATORY TEST	COVID19 (COVID19 (MODERNA)) (1201)	
Patient presented to the Emergency Department complaining of chest pain, pale, cool diaphoretic, and hypotensive. The patient was discovered to have a large saddle pulmonary embolism, went into cardiac arrest and expired. Of note, the patient received her second Moderna COVID vaccine on 1/23, which would place her first one approximately 12/25 if she received them at the appropriate interval. This information is from the patient's daughter and the ED record, the information is not available in CAIR. Per the daughter, the patient started feeling ill on 1/21, improved on 1/25, and then acutely worsened on 1/27, resulting in the ED visit.		No prior vaccinations for this event.

LABORATORY TEST	COVID19 (COVID19 (MODERNA)) (1201)
Lethargy/altered level of consciousness lead to hospital admission. Multiple interventions during hospitalization. Final hospital diagnoses: Acute respiratory failure with hypercapnia, acute pansinusitis.	No prior vaccinations for this event.

LABORATORY TEST	COVID19 (COVID19 (MODERNA)) (1201)
Resident passed away unexpectedly on 01/19/21 after developing acute hypoxic respiratory failure on morning of 01/19/21. She was transferred to hospital via EMS where she was intubated, coded, and ultimately expired with uncertain underlying cause, potentially ACS.	No prior vaccinations for this event.

LABORATORY TEST	COVID19 (COVID19 (MODERNA)) (1201)
2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient	No prior vaccinations for this event.

POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.

LABORATORY TEST	COVID19 (COVID19 (MODERNA)) (1201)
"Patient had COVID vaccination on 2/3 with no adverse s/s before leaving unit. Upon coming to treatment Friday 2/5 he reported to the RN that he had fallen on thursday 2/4 due to ""getting up fast"" did not hit head or hurt anything per RN discussion. Began treatment without difficulty. About 3/4 way through treatment was talking with staff and became unresponsive - code was called and pt expired after 30 minute resuscitation efforts."	No prior vaccinations for this event.

LABORATORY TEST	COVID19 (COVID19 (MODERNA)) (1201)
Resident yelling for assistance in apartment. Nursing personnel found resident on floor at 6:10 AM on 2/18/2021. Resident was transported to Hospital on 2/18/2021. Status update on 2/18/2021 from son, resident CT & X-rays were done all normal. Labs done and WBC count was elevated and awaiting results. Resident stable and admitted to hospital for observation. Resident passed away on 2.21.2021.	No prior vaccinations for this event.

LABORATORY TEST	COVID19 (COVID19 (MODERNA)) (1201)
High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient	No prior vaccinations for this event.

received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

LABORATORY TEST

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause

No prior vaccinations for this event.

for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

LABORATORY TEST	COVID19 (COVID19 (MODERNA)) (1201)
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation	No prior vaccinations for this event.

LABORATORY TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.	No prior vaccinations for this event.

LABORATORY TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
On Saturday, 1/16/2021, Patient went to the grocery store. Upon her return, she indicated she was experiencing N/V and some throat swelling. Patient subsequently collapsed and expired before she could be brought to an emergency room. During investigation by Coroners Office, it has been reported that Patient may have gotten some takeout food while she was out. Labs are pending and the Coroners	No prior vaccinations for this event.

investigation is ongoing. Spouse believes that her death was caused by the vaccine.

LABORATORY TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Approximately 10 minutes after receiving the COVID- 19 vaccine resident displayed seizure activity, staring straight ahead and strong allover muscle jerking of both the up and lower extremities, color became gray, activity lasted approximately 3 minutes, resident then became relaxed, color returned to normal, BP-140/80, 97.8, 60, 16, sleeping the remainder of the shift,. Resident continued to decline until resident CTB on 1/19/21	No prior vaccinations for this event.

LABORATORY TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Patient woke up on the morning of 2/6 with symptoms of a stroke. Rushed to hospital where clot found in brain. Recovered from initial stroke but then had another major stroke on 2/8 and never recovered.	No prior vaccinations for this event.

LABORATORY TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.

LABORATORY TEST ABNORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had Covid-19 in October of 2020. He recovered. He received the vaccination on 12/30/2020 with no complaints. On 01-05-2021 it was noted to he was incontinent of urine and bilateral lower extremity edema. Lab work was completed showed acute kidney injury. He had decreased blood pressure and oxygen saturations on 01-06-2021 He was admitted to the hospital with rapid progression of symptoms and suggested multi-system failure. He had a long cardiac history. On 01-14-2021 he passed away with a diagnosis of Cardiomyopathic CHF, A.Fib contributory.		No prior vaccinations for this event.
LABORATORY TEST ABNORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
Admitted to hospital with sob upon exertion that started prior to vaccine. Hx COPD, HTN, CKD, hyperlipidemia, bladder cancer in remission. Stated he has been taking Eliquis and Xarelto between renal doctor and cardiologist Dr. Anticipating going home 2/5/21 but then turned blue and stopped breathing under a DNR. COVID test negative. Labs show acute on chronic renal failure with an elevated troponin likely from demand ischemia.		No prior vaccinations for this event.
LABORATORY TEST ABNORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident had severe CAD, DM type 2, and hx of RBKA and left 5 digits on foot amputation. Hx of osteomyelitis post surgical. After last surgery, resident did not have a good appetite, more restless, increased confusion with dementia. Significant other passed away on 12/30/20, resident began refusing meals, decreased eating. Vaccinated on 1/13/21. On 1/25/21 Resident labs showed kidney failure. Dr. spoke with family and transitioned to Comfort care, on 2/5/21 went hospice. Patient passed away on 2/13/2021.		No prior vaccinations for this event.

LABORATORY TEST ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Three days after second COVID-19 vaccine, patient became lethargic. Due to advance directive that instructed that no life saving interventions to take place, patient continued to decline and expired on 29 January 2021.	No prior vaccinations for this event.
LABORATORY TEST NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient recieved vaccine 1 of covid 19 i 1/19/2021. She felt poorly on 1/20/2021. She felt dizzy and fell at 3 AM on 1/23/2021. She felt poorly and did not know her son's name which was not normal. She went to ER on 1/24. She was assessed as not having fractures. She was going to be transferred to a skilled nursing facility. She was not having respiratory complaints. She was awaiting transfer when her O2 levels started dropping substantially. She declined aggressive intervention and she died within a few hours.	No prior vaccinations for this event.
LABORATORY TEST NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show	No prior vaccinations for this event.

no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

LABORATORY TEST NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Death Narrative: Patient received the first COVID-19 dose on 12/23. Afterwards, patient complained of localized pain on L deltoid area where the vaccine was administered; his temperature was 98.1 F. On 12/26-27, staff reported that patient appeared more fatigued than usual and was shivering on 12/27, which seized after blanket was given. On 12/28, patient presented with fever (Tmax 100.2 F) and acetaminophen was administered for alleviation of fever. ADR was reported for the fever on 12/29. Patient continued to decline and was placed back on hospice care on 12/29; on 12/30. the symptoms reported on nursing note include erythema and pain on whole L arm. Lidocaine was applied. Patient's family and provider mutually agreed not to administer the second dose of vaccine. He continued to decline and was started on end-of-life care around 1/4 and passed on 1/20 1417.

No prior vaccinations for this event.

LABORATORY TEST NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

On January 1, 2021, patient was admitted to Medical Center with COVID. Tested positive on January 2, 2021. Spent 10 days in hospital. Once recovered from pneumonia and fever gone, on January 10, 2021, she was transferred to Rehabilitation Center for continued treatment. She spent 16 days there. She developed UTI and CDIF infections and was on/off oxygen. She started physical therapy. She was

No prior vaccinations for this event.

scheduled to be released to go home on January 27, 2021. On January 26, 2021, the day before going home, Rehabilitation Center gave her the Moderna vaccine. On January 27, the day she went home, she started feeling very weak and couldn't walk. My dad tried lifting her and they both fell to the ground. My dad called 911 and she was taken to Medical Center, with high fever and possible stroke symptoms (which later was negative). Two days later, she had difficulty breathing and was put on a ventilator. She was on a ventilator for about three days. They took it off and she slowly started recovering. The doctors did all kinds of tests (blood clot in lung, heart, etc.) and all was negative. The only thing they could trace it to was an adverse reaction to the vaccine. After spending 11 days at hospital and treating her for various infections, her heart stopped and she passed away suddenly.		
LABORATORY TEST NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.		No prior vaccinations for this event.
LACTIC ACIDOSIS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Admitted 1/14/21: Patient is an elderly 93-year-old female with multiple medical problems including chronic combined CHF, P 80, diabetes mellitus, HTN, hyperlipidemia, CKD stage 3, has been complaining of generalized weakness, fatigue, decreased appetite for the past few days. She had an outpatient COVID-19 vaccine earlier today. Within 2 hr of admitting the patient to the hospital, condition clinically deteriorated.		No prior vaccinations for this event.

Patient elected to be DNR/DNI while in the ED. Patient was pronounced dead at 10:30 p.m. earlier today. Preliminary cause of death: Hypoglycemia induced lactic acidosis.

LARGE INTESTINAL OBSTRUCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was an 87 y/o female admitted for septic shock. She was started on and eventually maxed on 3 pressors. CT abd showed colonic obstruction with dilatation of large and small bowel. Patient was made DNR in the ED. Palliative care consulted on case. Family opted for comfort care. Patient was asystole on monitor. No spontaneous breath/cardiac sounds ausculted. Patient did not withdraw to pain. Pupils fixed and dilated. She was pronounced and 1230 on 1/28/21	No prior vaccinations for this event.
LARYNGEAL MASK AIRWAY INSERTION	**COVID19 (COVID19 (MODERNA)) (1201)**
Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.	No prior vaccinations for this event.
LEFT ATRIAL DILATATION	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased	No prior vaccinations for

shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.	this event.
LEFT VENTRICULAR DYSFUNCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	No prior vaccinations for this event.
LEFT VENTRICULAR FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	No prior vaccinations for this event.
LEFT VENTRICULAR HYPERTROPHY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p	No prior vaccinations for

multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.		this event.
	LEGIONELLA TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.		No prior vaccinations for this event.
	LETHARGY	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received vaccine on 1/4/2021. He was in Hospice for CHF and renal failure, but was able to get up in his wheelchair and eat and take medications and talk. On 1/5/2021 am, he was noted to be very lethargic an could only mumble, could not swallow. No localizing neurologic findings. He was too lethargic to get up in chair.		No prior vaccinations for this event.
	LETHARGY	**COVID19 (COVID19 (MODERNA)) (1201)**

"On 1/15/2021 at 1800, resident noted to be lethargic and shaking, stating ""I don't care."" repeatedly. C/O head and neck pain. T100.6. Given Tylenol with no relief of pain. Order received for Aleve and administered.. Assisted to bed as usual in evening. Monitored during night shift and noted to be resting comfortably/sleeping.. Noted agonal breathing at 4:10 AM 1/16/2021 , T 99.4, Absence of vital signs at 4:15AM 1/16/21 and death pronounced at 4:40AM 1/16/21."

No prior vaccinations for this event.

LETHARGY

COVID19 (COVID19 (MODERNA)) (1201)

Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.

No prior vaccinations for this event.

LETHARGY

COVID19 (COVID19 (MODERNA)) (1201)

Resident became lethargic and reports of blood coming from resident's nose and mouth on the morning of 1/13/21. Resident went out to ER for eval, and came back to facility with dx of pneumonia and recommendations for resident to be placed on hospice. Resident deceased on 1/14/21. Unknown if vaccine related, but with timeline of events I was advised to report this per medical director of facility, as well as Pharmacy who administered the vaccine.

No prior vaccinations for this event.

LETHARGY

COVID19 (COVID19 (MODERNA)) (1201)

36 hours after vaccination, the patient had increased respiratory distress. He was placed on high flow nasal cannula oxygen with mild improvement. He then continued to be hypotensive requiring IV fluids and subsequently IV vasopressors. Patient's BP was stabilized with vasopresor, however he continued to deteriorate clinically with altered mental status and lethargy, concerned for bowel peroration based on physical exam by MD. He was then emergency intubated and placed on mechanical ventilation. He was then

No prior vaccinations for this event.

transferred to acute care hospital near by.

	LETHARGY	**COVID19 (COVID19 (MODERNA)) (1201)**
Lethargy/altered level of consciousness lead to hospital admission. Multiple interventions during hospitalization. Final hospital diagnoses: Acute respiratory failure with hypercapnia, acute pansinusitis.		No prior vaccinations for this event.

	LETHARGY	**COVID19 (COVID19 (MODERNA)) (1201)**
2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.		No prior vaccinations for this event.

	LETHARGY	**COVID19 (COVID19 (MODERNA)) (1201)**
Within a few days, my mother started reporting profound fatigue and shortness of breath while conducting routine household activities. She no longer had to energy for her daily exercise walks and became increasingly lethargic. She died in her sleep while taking an afternoon nap on Thursday, February 4th. I am highly concerned this could be a vaccine related.		No prior vaccinations for this event.

	LETHARGY	**COVID19 (COVID19 (MODERNA)) (1201)**

30 hours after the first Covid vaccination, the resident was lethargic, non responsive with shortness of breathe.		No prior vaccinations for this event.
	LETHARGY	**COVID19 (COVID19 (MODERNA)) (1201)**
Beginning in the evening 2/19/21, fever/chills/fatigue; worsening of symptoms 2/20/21 with lethargy/lack of appetite/weakness; unable to arouse on 2/21/21 then breathing stopped, patient's spouse called 911 performed CPR, EMS continued for 15 min then while in ambulance to hospital where he was pronounced dead. Official time of death 2:20pm		No prior vaccinations for this event.
	LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine given on 12/29/20 by Pharmacy. On 1/1/21, resident became lethargic and sluggish and developed a rash on forearms. He was a Hospice recipient and doctor and Hospice ordered no treatment, just to continue to monitor. When no improvement of codition reported, doctor and Hospice ordered comfort meds (Morphine, Ativan, Levsin). Resident expired on 1/4/2021		No prior vaccinations for this event.
	LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics		No prior vaccinations for this event.

arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.

LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.	No prior vaccinations for this event.

LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.	Influenza Virus Vaccines - Unknown date/type or brand

LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
At approximately 12:15 pm the resident had a brief unresponsive episode that resolved quickly. Her Vital signs were stable and her mentation was at baseline. Later that evening approximately 10 pm she had labored respirations, shortness of breath, lethargy with bilateral crackles, Oxygen desaturated to 76% on room air, tachycardia and hypotension. She expired at 6:30 a.m. the following day.	No prior vaccinations for this event.

	LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient stated he wasn't feeling well on January 25, 2021, wasn't eating and complained of abdominal pain. Patient noted to have indigestion and was constipated. Meds provided and labs ordered. On morning of January 26, 2021, patient became weak, lethargic and hypoxic and was sent to emergency department around 0700 hours on January 26, 2021. At approximately 1100 hours, emergency physician notified this writer that patient was not going to overcome his illness and would be placed on comfort care. At approximately 1130 hours, this writer was notified that patient had passed away from multi-organ failure.		No prior vaccinations for this event.
	LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient noted to have a change in status at 11:23PM that night. Her oxygen saturation had dropped from normal on room air to 82% and required oxygen. She was also noted to be lethargic with altered mental status and not responding verbally. She then began to mottle. Her oxygen saturation worsened to 51% on 4Liters of oxygen by the next day and she expired on 1/14/21.		No prior vaccinations for this event.
	LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began to demonstrate a cough the evening of 1/5/2021, after receiving the COVID-19 vaccine earlier in the afternoon. A rapid COVID-19 test was performed and was positive. She began to demonstrate shortness of breath with exertion on 1/7/21, and lethargy on 1/12/21. Appetite and oral intake began to decline on 1/12/21, and Oxygen saturation dropped on 1/16/21 to 82%, and oxygen was initiated at 3L per nasal cannula. On 1/19/21 at 0414 patient was unresponsive and without vital signs. Orders were for DNR,		No prior vaccinations for this event.

and CPR was not initiated.

LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The patient was observed to be lethargic on 1/29/21 at 1515. BP-80/50, P-75, RR-27, T-100.1. He was given a bolus of NS 150 mlx2. and Rocephin 1 gram IM.	No prior vaccinations for this event.
LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
view 2/5/2021 09:23 e Progress Note Note Text: Patient passed away in the facility this morning. view 2/5/2021 08:39 Orders - Administration Note Note Text: Resident passed. view 2/5/2021 08:33 Nurses Note Note Text: Body released to funeral home at this time. Personal effects sent with resident include: 1 pair of glasses, 1 yellow wedding band, 1silver spoon ring, 1 ring with black and clear stones. Resident has own teeth view 2/5/2021 08:32 Nurses Note Note Text: cause of death per CRNP failure to thrive. view 2/5/2021 07:44 Orders - Administration Note Note Text: Take and document temp & PO2 every 4 hours for MONITORING Resident passed. view 2/5/2021 06:49 Nurses Note Note Text: Son returned call and was updated of resident's passing this am view 2/5/2021 06:33 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Unknown Resident expired @ 0604 [linked] view 2/5/2021 06:06 Nurses Note Note Text: Res found without pulse or respirations. Pronounced at 0604. Updated. N/o's for RN to pronounce, release body to funeral home, dispose of medications per facility policy. Daughter updated. Funeral Home called to release body. view 2/5/2021 05:26 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Pulse ox 60% on O2 @ 5L/min via mask. Resps 44 per minute. view 2/5/2021 01:57 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml	No prior vaccinations for this event.

by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/5/2021 00:52 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Residents resps are 40 per minute, pulse ox 76% on O2 @ 5L/min via mask. Resps are labored, shallow and rapid. view 2/5/2021 00:48 Nurses Note Note Text: Nonresponsive to verbal and tactile stimulation. Appears comfortable. view 2/4/2021 22:01 Nurses Note Note Text: Resident resting comfortably, breathing becoming increasingly shallow, wearing O2 via mask at 5L via mask, no dyspnea noted, feet are mottled, oral and peri care provided Q2H. No s/s of pain or discomfort. view 2/4/2021 21:40 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective [linked] view 2/4/2021 19:32 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger medicated for air hunger, RR 28 to 32/ min view 2/4/2021 19:22 Nurses Note Note Text: Daughter updated on N/O to increase Morphine Sulfate 20mg/mL 0.25mL to Q2H prn from Q6H prn. view 2/4/2021 18:06 Nurses Note Note Text: POA Daughter and daughter aware of residents current condition. view 2/4/2021 11:58 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/4/2021 11:13 Nurses Note Note Text: Pt. noted to be lethargic at this time. Does respond to verbal and tactile stimuli by opening her eyes but non verbal currently. Skin warm and dry. No mottling or apnea observed at this time. O2 sat 88% with O2 at 2 LPM via n/c. On increased to 3 LPM via mask as pt. noted to be mouth breathing. Respirations 28. F/U O2 sat 93%. HOB elevated. Pt. medicated with morphine by LPN. Daughter updated on pt.'s condition. Does not want pt. sent out to hospital and would like comfort measures to continue. Daughter also in agreement with delay in d/c d/t pt.'s condition.CRNP updated on pt.'s condition, delay in d/c and daughter's wishes. No n/o's at this time. view 2/4/2021 10:56 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB Resident showing s/s of discomfort. SOB at this time and high respirations. Repositioned, changed for incontinence care and mouth care provided. view 2/4/2021 10:34 Progress Note Note Text: Spoke with RN regarding change in condition. Updated Sr Living regarding change. Recommendation to cancel d/c/transfer for today,

see how resident does through the weekend and re-evaluate on Monday. Daughter updated on cancellation of d/c today. view 2/4/2021 10:04 Nurses Note Note Text: Daughter aware that resident's O2 sat was 88% on room air on 3-11 shift and that oxygen was applied via nasal cannula. view 2/4/2021 10:03 Nurses Note Note Text: N/O: Discharge 2/4/21 with scripts to Sr. Living. Daughter aware. view 2/4/2021 09:53 Nurses Note Note Text: Pt. to be d/c'd to another facility this am as per MD order. Pt. alert and responsive. Skin assessment done as per facility policy. No pressure areas noted at this time. No s/sx of pain or discomfort observed at this time. V.S. 97.0 67 20 O2 sat 95% with O2 at 2 LPM via n/c. view 2/4/2021 07:45 Nurses Note Note Text: Resident seen by Dr. for discharge. Orders pending at this time. view 2/4/2021 07:36 Nurses Note Note Text: CRNP and Dr. updated on O2 sat 88% on RA with f/u of 93% with O2 on at 2 LPM as well as rest of VS, 3-11 shift 2/3/21. No n/o's at this time. view 2/3/2021 21:17 Nurses Note Note Text: Resident Sp02 88% on RA. Pulse 124. Respirations 40. PRN morphine given and O2 applied via NC at 2L/min. After recheck pulse ox up to 93%, pulse 100, and respirations 22. Resident appears comfortable at this time. view 2/3/2021 20:05 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective [linked] view 2/3/2021 19:48 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN given for SOB after elevation of HOB not effective. view 2/3/2021 11:51 Nurses Note Note Text: CRNP updated rapid COVID test done for d/c tomorrow was negative. No n/o's at this time. view 2/3/2021 11:44 Nurses Note Note Text: Daughter notified of rapid covid swab being negative. view 2/3/2021 09:50 Orders - Administration Note Note Text: Obtain Rapid Covid test on 2/3/2021 for discharge. Please give copy of results to Social Worker every day shift for covid testing for 1 Day Completed and negative. view 2/3/2021 08:45 Skilled Nursing Note Reason for skilled service: Therapy describe skilled service: Nursing, therapy assessment: V.S. 97.8 79 18 138/84 Orientation: Oriented to self only. Oxygen: O2 sat 94% on RA Edema: Trace edema noted BLE. Pedal pulses present. Pain: Denies pain or discomfort at this time. Nursing note: Pt. alert and responsive. Skin warm and dry. Lung sounds diminished. No respiratory distress observed at this time. Abdomen soft. BS+ in all 4 quads. Continent/Incontinent of B&B. 1 assist with ambulation, transfers. 1 assist with ADL's. Working with therapy on gait training, therapeutic exercise, therapeutic activities & neuromuscular reeducation. view 2/2/2021 14:37 Progress Note Note Text: Per health

professional at Sr Living, prepared to accept patient to their Memory Care Unit 2/4. Transportation arranged for 11 AM per family request. Daughter (POA) updated on d/c time on 2/4/21. Facility requesting rapid COVID test completed prior to d/c and results sent to them. All other information sent for continuity of care.

	LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.		No prior vaccinations for this event.

	LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.		

	LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Ongoing decline overall. Remained on Hospice with increased lethargy documented on 1/20/21 and progressively worsening thereafter.		No prior vaccinations for this event.

	LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
pt became lethargic, stopped eating. No fever; no nausea No prior vaccinations for this event.		

	LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x		No prior vaccinations for

2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21- N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

LETHARGY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pale, Short of Breath, Hypoxic, Lethargic within minutes became unresponsive and died.

No prior vaccinations for this event.

LETHARGY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Three days after second COVID-19 vaccine, patient became lethargic. Due to advance directive that instructed that no life saving interventions to take place, patient continued to decline and expired on 29 January 2021.	No prior vaccinations for this event.
LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/21 - Resident complained of SOB. SPO2 66% on RA, vs 105/66-96-20 T98.2 O2 administered Pox 97% Binax test revealed (+) COVID results. Resident transferred to COVID wing. Family (HCP) updated and declined transfer to hospital Resident continued with fever, hypoxia and lethargy. Family elected CMO and Hospice notified. Resident died on 1/16/2021 @ 930AM.	No prior vaccinations for this event.
LETHARGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No known side effects; however, on 1/20 the decedent suffered lethargy. On 2/12/2021, the decedent had a possible seizure and was transported to emergency department where shortly after arrival, he was pronounced dead.	No prior vaccinations for this event.
LEUKAEMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite	Influenza Virus Vaccines - Unknown date/type or brand

from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.

	LEUKOCYTOSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
	Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face, increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have	No prior vaccinations for this event.

been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

LEUKOCYTOSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"	No prior vaccinations for this event.
LIFE SUPPORT	**COVID19 (COVID19 (MODERNA)) (1201)**
about 20+ hours after vaccination resident was having hard time breathing, 911 was called. Resident coded multiple times at the facility after CPR she was taken to ICU. She coded again and was placed on life support. Due to her choice to not be on life support she passed on 11/26/2021.	No prior vaccinations for this event.
LIFE SUPPORT	**COVID19 (COVID19 (MODERNA)) (1201)**
My Mother was given the Covid Vaccine (1st Dose) on 12/28/2020. Later that night we received a call from the nursing facility that my Mother was having uncontrollable seizures and had to be transported to the nearby hospital. The ER doctor confirmed that my Mother had tested positive to Covid. She was treated for Covid and was on life support. A few days later we received a call that my Mother had a major stroke. She passed away on January 4, 2021	No prior vaccinations for this event.

LIFE SUPPORT

COVID19 (COVID19 (MODERNA)) (1201)

Received Covid vaccine in am. Last seen by family at 17:30 pm and observed to be well. About an hour later he collapsed, unresponsive. A 911 call was initiated at 18:29. Paramedics arrived to find the patient in cardiac arrest. CPR/ACLS was initiated, but resuscitation was unsuccessful. Pt. was transported to MC where he was pronounced dead at 19:32. There was no sing of an injection site reaction, nor of allergic reaction..

No prior vaccinations for this event.

LIFE SUPPORT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Cardiac arrest within 1 hour Patient had the second vaccine approximately 2 pm on Tuesday Jan 12th He works at the extended care community and was in good health that morning with no complaints. He waited 10-15 minutes at the vaccine admin site and then told them he felt fine and was ready to get back to work. He then was found unresponsive at 3 pm within an hour of the 2nd vaccine. EMS called immediately worked on him 30 minutes in field then 30 minutes at ER was able to put him on life support yet deemed Brain dead 1-14-21 and pronounced dead an hour or so later

No prior vaccinations for this event.

LIFE SUPPORT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received the vaccine at an outside healthcare facility on 2/11/21. At approximately 1 pm she screamed out and fell out of her chair. EMS was called and patient was found to be in Vfib. ACLS was performed for approximately 42 minutes prior to arrival at ED. At that time the patient had been pulseless for 25 minutes. Patient received 450 mg of amiodarone, epinephrine x7, sodium bicarbonate x2, and 7 AED shocks. In the ED 3 more doses of epinephrine were given, one more dose of sodium bicarbonate, and 5 additional shocks.

No prior vaccinations for this event.

ROSC was not achieved and time of death was called at 1416.

LIMB DISCOMFORT	COVID19 (COVID19 (MODERNA)) (1201)
Passed away; tired; nonresponsive; cold; difficulty breathing; swelling; sore arm; feeling weird and funny; A spontaneous report (United States) was received from a consumer concerning a 63 year old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and the patient experienced limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal and the patient passed away . Medical history included treatment for tuberculosis and dialysis. Concomitant medication included calcium acetate, Renvela, glipizide, omeprazole, aspirin, vitamin D, losartan, furosemide, rifampin, and Sensipar. On 14 Jan 2021, the patient received the first of their first planned doses of mRNA-1273 (lot number 030L20A) for prophylaxis of COVID-19 infection. On 13 Jan2021, the patient tested negative for COVID-19). On 16 Jan 2021, the patient experienced a sore arm, and feeling weird/funny. On 17Jan2021, the patient experienced difficulty breathing and swelling. On 18 Jan 2021, the patient declined dialysis, was tired and wanted to lay down. At 8 am, the patient was found nonresponsive and cold and is believed to have passed away around 4 am. The coroner tested the deceased for COVID-19 and the test was positive. No autopsy was reported. No death certificate was issued at the time of the report but the reporter believes it will list cause of death as COVID complications. Action taken with the mRNA-1273 was not applicable. The outcome of the events of limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal, was fatal. On 18 Jan 2021, the patient was died. Cause of death was COVID-19. Autopsy details were not provided.; Reporter's Comments: The events developed on four days after first dose of mRNA-1372. Dyspnea, unresponsive to stimuli, and death were consistent with infection in pandemic set up confounded by age of patient and refusal of dialysis Cause of death was reported as COVID-19. Autopsy details were not provided. Based on reporter's causality the events are assessed as unlikely related to mRNA-1273.; Reported Cause(s) of Death: COVID-19	No prior vaccinations for this event.

	LIMB DISCOMFORT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"The resident received is vaccine around 11:00 am and tolerated it without any difficulty or immediate adverse effects. He was at therapy from 12:36 pm until 1:22 pm when he stated he was too tired and could not do anymore. The therapist took him back to his room at that time and he got into bed himself but stated his legs felt heavy. At 1:50 pm the CNA answered his call light and found he had taken himself to the bathroom. She stated that when he went to get back into the bed it was ""abnormal"" how he was getting into it so she assisted him. At that time he quit breathing and she called a RN into the room immediately. He was found without a pulse, respirations, or blood pressure at 1:54 pm. He was a DNR."		No prior vaccinations for this event.
	LIMB DISCOMFORT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
tired; legs felt heavy; stopped breathing; This is a spontaneous report from a Pfizer-sponsored program a non-contactable consumer. A 93-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 11:00 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Patient received vaccine around 11:00 a.m. About two hours later, he said he was tired and couldn't continue with the physical therapy he was doing. He was taken back to his room, where he said his legs felt heavy. Soon after, he stopped breathing. A nurse declared a do-not-resuscitate order. The patient died on 04Jan2021. It was not reported if an autopsy was performed. Outcome of stopped breathing was fatal. Outcome of tired and legs felt heavy was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: stopped breathing		No prior vaccinations for this event.
	LIMB INJURY	**COVID19 (COVID19**

	(PFIZER-BIONTECH)) (1200)
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.	No prior vaccinations for this event.
LIMB MASS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.	No prior vaccinations for this event.
LIP BLISTER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"The day after the 2nd shot, patient developed blisters on his lips and mouth. The care facility said that he had a nut allergy -- but he had never been allergic to nuts. He stopped eating and drinking and his BP had dropped to 60/40. By Jan 16th they called to say he was dying and he passed away on 1/18/21. Patient had COVID19 from Oct 29th - early November. By Nov 21st he had lost 40 lbs. He	Shingles - Glaxo 8/22/2020, resulted in hospitalization and LTC.

was 6'3"" and had gone from 189lbs to 149 lbs with COVID. By Nov 21st when we could visit, he had recovered from COVID, but was very thin and weak. He could not bathroom alone and kept falling. He didn't seem to have a bad reaction to the 1st COVID shot, But he immediately reacted to the 2nd shot and passed away within 6 days."

LIPASE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status:

No prior vaccinations for this event.

SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

LISTLESS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

24 hours after shot had high fever 101, chills, weakness, became listless, family called 911, client became unresponsive and died in the Emergency room.

No prior vaccinations for this event.

LIVEDO RETICULARIS

COVID19 (COVID19 (MODERNA)) (1201)

"Pt. woke up the next morning after vaccination and ""didn't feel well"", described by wife as fatigue, no energy. At approximately 2 PM, he vomited. His wife checked on him at 4:20 PM and he wasn't breathing sitting in his chair. EMS squad was called but when they arrived he was asystole and mottling present. Did not start CPR since he was already gone too long. Pronounced by coroner on scene."	No prior vaccinations for this event.	
LIVEDO RETICULARIS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No adverse effects from vaccination seen on 1/2/21. On 1/6/21 resident was seen by Dr and her baclofen pump was refilled with 20 ml Baclofen 4,000mcg/ml. ITB Rate increased by 6% to 455.5 mcg/day simple continuous rate over 3 days. On 1/8/21 at 0615 resident was shaking, lower extremities mottled, Sa02 70%, pulse 45. Oxygen started at 2 L/m per NC. At 0715 her primary physician was notified as well as her daughter. Oxygen increased to 4 L/min, sats at 83%. SOA noted, reported all over pain. At 0850 when they attempted to reposition the resident, she was not responsive. Licensed nurse assessed her and no heartbeat heard or pulse found.	No prior vaccinations for this event.	
LIVEDO RETICULARIS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No reactions immediately after vaccine was given. Resident has dementia, has had multiple hospitalizations related to a renal stone recently. Had a tooth that was bothering her, went to see her dentist and it was extracted on 1/6/21. On 1/10 they noted feet and ankles are dark purple with white splotches appears to be mottling. Minimally responsive to voice and touch. Not eating. Compassionate visit with family. Family did not want hospice, did not feel it was needed, said, what more could they do for her than you're already doing? On 1/11 at 1950 was determined to be deceased.	No prior vaccinations for this event.	

LIVEDO RETICULARIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient noted to have a change in status at 11:23PM that night. Her oxygen saturation had dropped from normal on room air to 82% and required oxygen. She was also noted to be lethargic with altered mental status and not responding verbally. She then began to mottle. Her oxygen saturation worsened to 51% on 4Liters of oxygen by the next day and she expired on 1/14/21.	No prior vaccinations for this event.
LIVER FUNCTION TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.	No prior vaccinations for this event.
LIVER FUNCTION TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total	No prior vaccinations for this event.

bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

LIVER FUNCTION TEST ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

She had pain in the injection site Tuesday night and then during Tuesday she got worse with nausea and some fever. By Wednesday she was complaining that she could not pee even though she was drinking a lot of fluids. She continued to complain it was the worst she ever felt and then at 0600 Thursday morning she woke us up and said she needed to go to the hospital. We arrived at the hospital just before 0700 and she immediately threw up in the trash can. We went into a treatment room and they took blood and started fluids as she became incoherent. She said she had taken Tylenol so they started a drug to counter that but her liver function was all wrong and they started to look for a hospital that could transplant a liver. She was air evade about 0930 to Medical center and just over 30 hours latter she was dead. There is a pending autopsy. She was a healthy 39 year old mother who got the shots because she worked as a surgical tech and she was the single mother of a 9 year old little girl.

No prior vaccinations for this event.

LIVER FUNCTION TEST ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.	No prior vaccinations for this event.
LIVER FUNCTION TEST ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	No prior vaccinations for this event.
LIVER FUNCTION TEST INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.	No prior vaccinations for this event.

LIVER FUNCTION TEST NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."		No prior vaccinations for this event.
LOCALISED OEDEMA		**COVID19 (COVID19 (MODERNA)) (1201)**
Redness and warmth with edema to right side of neck and under chin. Resident was on Hospice services and expired on 1.1.21		No prior vaccinations for this event.
LOSS OF CONSCIOUSNESS		**COVID19 (COVID19**

(MODERNA)) (1201)

Patient received her first dose of the Moderna COVID-19 Vaccination on Saturday January 16th 2021 at approximately 12pm. She completed all necessary screening forms and was deemed to be at low risk for serious allergic reactions. She tolerated the vaccination well, and no complications or immediate adverse events occurred. She was observed for a full 15 mins per CDPHE/CDC guidelines and left the Clinic in stable condition after her observation period was complete. On the morning of Tuesday, January 19th, 2021, the patient was found unconscious and unresponsive by her husband. She was transferred by Ambulance to Hospital shortly thereafter. She was diagnosed with a brain bleed that was determined to be inoperable. She was transferred to other Hospital for higher level care. She was seen by neurosurgery and diagnosed with a ruptured aneurysm. She was treated in the ICU for 24 hours, at which point her team determined that the severity of her brain bleed would not respond to treatment. Supportive cares were withdrawn on Wednesday Jan 20th, and she passed away shortly thereafter.

No prior vaccinations for this event.

LOSS OF CONSCIOUSNESS

COVID19 (COVID19 (MODERNA)) (1201)

Rapid decline in health status, Elevated BP&P, posturing, loss of consciousness, Glasgow coma Scale 4 starting 2/1/2021, Deceased 2/3/21

No prior vaccinations for this event.

LOSS OF CONSCIOUSNESS

COVID19 (COVID19 (MODERNA)) (1201)

Brain aneurysm; Anaphylactic reaction; Collapsed; BP sky rocketed; Shortness of breath; A spontaneous report was received from a consumer concerning a 69-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced blood pressure skyrocketed, shortness of breath, loss of consciousness, massive anaphylactic reaction, and brain aneurysm. The patient's medical history, as provided by the reporter, included high blood pressure and arthritis. Products known to have been used by the patient, within two weeks prior to the event, included an antihypertensive. On 04 Jan 2021, prior to the onset

No prior vaccinations for this event.

of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. Twenty-two minutes later she had a massive anaphylactic reaction. She experienced shortness of breath, blood pressure skyrocketed, and loss of consciousness. She was taken to the emergency room. The patient had a brain aneurysm and never recovered. No treatment information was provided. The patient died on 04 Jan 2021. The cause of death was reported as brain aneurysm. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns a 69-year-old, female patient with a medical history of hypertension, who experienced fatal, serious, unexpected events of Anaphylactic reaction, hypertension, dyspnea, loss of consciousness and brain aneurysm. The events occurred 22 minutes after the first dose of mRNA-1273 was administered. No treatment information was provided. The patient never recovered and died. The cause of death was reported as brain aneurysm. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. Additional information has been requested.; Reported Cause(s) of Death: Brain aneurysm

LOSS OF CONSCIOUSNESS

COVID19 (COVID19 (MODERNA)) (1201)

Patient found down at home with agonal respirations and per EMS asystole, received 2 rounds of epi at her house with return of spontaneous pulses, lost pulse again in route to ER and another round of epi was given, CPR in progress when arrived at hospital. Prior to this patient's husband states he heard her fall in the bathroom but did not immediately check on her as he states that this has happened before. He checked on her 10 min later and that's when he found her unconscious. Daughter called 911 and she began CPR. No previous complaints of headache, chest pain, back pain, fever or chills. Husband states patient was drinking that evening which is not unusual for her. Patient died at hospital.

No prior vaccinations for this event.

LOSS OF CONSCIOUSNESS

COVID19 (COVID19 (MODERNA)) (1201)

2/10: Fever, fatigue, tylenol 2/11 @ 1300: pt made DNR, hospice consulted 2/11 @ 1800 decreased LOC, increased RR, fever, chills - 1/5L NS bolus IV, rectal tylenol. Refusing to eat/drink, PO morphine 2/12 @ 16:30, deceased at facility **resident was not doing well prior to vaccination	No prior vaccinations for this event.
LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient family had been noticing onset confusion for a few weeks prior to vaccine and event. Patient was taken to ED when found unconscious and died of a subdural hemorrhage a few days after vaccine clinic at retirement home.	No prior vaccinations for this event.
LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was at a gym watching his daughter. He slumped over unconscious. EMS was called. He was found to be in fine ventricular fibrillation and resuscitation efforts failed. He was brought to Hospital ED where he was pronounced dead. He had underlying cardiac disease but his family requested I report this event as possibly related to the recent COVID vaccination.	No prior vaccinations for this event.
LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was found unconscious without a pulse. Patient remained in asystole without pulse or respirations despite CPR.	No prior vaccinations for this event.
LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient called son around 6:30am on 2/18/21. When son tried to contact patient around 8:30am, he was not	No prior vaccinations

able to get a hold of patient. Son sent someone over to check on patient. They found patient on the floor. He was coherent at first but then lost consciousness. It believed he experienced a stroke sometime around 8:30-9:00am of 2/18/21. Patient was taken to hospital and then transferred to another hospital. He was put in a medically induced coma. He passed between 4:00 and 4:30 pm on 02/19/21.	for this event.
LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient experienced an episode of emesis and loss of consciousness several hours after vaccine on 2/16/21. He was taken by EMS to the hospital and was noted to be hypoxic and hypotensive. He was admitted to the hospital and subsequently intubated. He was also found to have a small bowel obstruction and a nasogastric tube was placed to decompress the bowel. He required pressor support as well. He expired on 2/17/21.	No prior vaccinations for this event.
LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away; Found unconscious; Coma; Lack of oxygen to the brain; A spontaneous report was received from a consumer, concerning his mother, a 71-year-old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and passed away, prior to death, patient experienced lack of oxygen to the brain and was found unconscious and went to coma. The patient's medical history reported included seizures. Concomitant medications included phenobarbital, lamotrigine and levetiracetam. On 27 Jan 2021, approximately six days prior to the onset of events, the patient received their first of two planned doses of mRNA-1273 (lot number: 030L20A) intramuscularly for prophylaxis of COVID-19 infection. On 01 Feb 2021 at 4 am, the patient was found to be unconscious on the couch, hence she was rushed to the hospital with lack of oxygen to the brain. Later, she went into a coma, hence she was in hospital for 30 hours and then was transferred to a different hospital for a second opinion on 06-Feb-2021, where she was passed away at 02:20 PM. Treatment information was not provided Action taken with mRNA-1273 in response to the events were not applicable. The outcome of events, lack of oxygen to the brain, found unconscious and coma were	No prior vaccinations for this event.

considered unknown. The outcome of event passed away was fatal as she died on 06 Feb 2021 at 2:20 pm. The cause of death was not provided. Plans for an autopsy were unknown.; Reporter's Comments: This is a case of 71-year-old female subject with a history of seizures who died 6 days after receiving first dose of vaccine. Very limited information has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Passed away		
LOSS OF CONSCIOUSNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
I am the patient's daughter as well as an RN-BSN. My mother was given the Moderna vaccine on Feb 11, 2021 and on Feb 15, 2021 she had a CVA and MI. She was found on her apt. floor unconscious. She was transferred to the Hospital by ambulance where a CT scan and other tests were done. It was determined she had a stroke and heart attack. My mother was in great health, took no medications, and lived alone in her apt. before this incident. The medical professionals determined she would not recover so she was admitted to hospice and died on Feb. 21, 2021. I believe there is a relationship between the vaccine and the CVA and MI.		No prior vaccinations for this event.
LOSS OF CONSCIOUSNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
2nd dose of Moderna at 9:00am. No side effect (except pinch at injection site) throughout the day and evening. At ~9:45pm, my wife suddenly fell unconscious. Immediate CPR & with Paramedic were not able to revive her. SHE PASSED AWAY at home. We believe it may be triggered by the vaccine. Did not have a chance to go to hospital or emergency room - it was too sudden. A sad day for us.		No prior vaccinations for this event.
LOSS OF CONSCIOUSNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
Beginning in the evening 2/19/21, fever/chills/fatigue; worsening of symptoms 2/20/21 with lethargy/lack of appetite/weakness; unable to arouse on 2/21/21 then breathing stopped, patient's spouse called 911		No prior vaccinations for

performed CPR, EMS continued for 15 min then while in ambulance to hospital where he was pronounced dead. Official time of death 2:20pm		this event.
	LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.		No prior vaccinations for this event.
	LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021		No prior vaccinations for this event.
	LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

loss of consciousness; respiratory distress Narrative: Patient tolerated his 1st dose of the COVID-19 vaccine well, on 12/16/2020, and received his 2nd dose on 1/6/2021. Patient had some mild clinical decline the past few days prior to 2nd vaccination, with a decreased appetite and some increased fatigue per nursing report, but no significant changes. He experienced nausea on the evening of 1/6/21, which was effectively managed, but by early morning he spiked a fever of 102.9 with a sat of 86.1%. He continued to deteriorate from that point on and died 1/7/21 @13:20. Clinically, the presentation was most consistent with an aspiration pneumonia.	No prior vaccinations for this event.	
LOSS OF CONSCIOUSNESS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient with history advanced vascular dementia, hypertensive cerebrovascular disease and stroke, T2DM. Received her second dose of Pfizer COVID-19 vaccine at approximately 14:00 and was reported to have expired at home at 20:55. Dr. (Medical Director) spoke with patient's son/caregiver 2/4/21. Son reports that patient was in her usual health yesterday morning, deemed well enough by son to travel for vaccination. He reports she had no bothersome symptoms after either first or second vaccinations. Specifically denied rash, wheeze, and difficulty breathing. Son was with patient throughout the day. In the evening, when preparing for bed, he noted she became suddenly unresponsive in a similar fashion as she has done several times in past years. While in all previous such episodes she recovered within minutes, last evening she did not regain consciousness, experiences a brief period of labored breathing, and died. Patient's son called 911 and the patient's body was brought to the medical examiners. The medical examiner declined to proceed with autopsy. Patient's son is not interested in autopsy. Patient's son reports confidence that his mother's underlying hypertensive/diabetic cardiovascular disease is the natural cause of her death. Other Relevant Hx: Symptoms: & Death Treatment:	No prior vaccinations for this event.	
LOSS OF CONSCIOUSNESS		**COVID19 (COVID19 (PFIZER-BIONTECH))**

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all

No prior vaccinations for this event.

above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Few minutes post vaccination, after moving to observation area via wheelchair, the patient complained of dizziness. She took glucose tabs she had brought with her. Staff wheeled her to Triage # 1. Her eyes rolled back in her head and she lost consciousness. Staff (paramedics on site) transferred her to gurney and started compressions. AED placed, V- Fib was rhythm, Shock # 1 given, CPR resumed. Shocked again. Fire truck and additional EMT arrived on site and took over care. Epinephrine was given 3 times via intra-osseous route, Amiodarone given intra-osseous route. Additional defibrillation with on site AED for a total of 6-7 times. Patient had good chest rise with ambu-bag, no airway obstruction or peri-oral edema noted. Code called at 12:40 PM.	No prior vaccinations for this event.

LOSS OF CONSCIOUSNESS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
She started having breathing problems/heart attack appearance. on 1/22/21 and went to the ER. Upon admittance was told it was an anaphylactic shock from the Covid shot. They kept her in ICU and released her 1/23/21. At 12:45 am on 1/24/21 she passed out and we called the ambulance. Hospital admitted her and worked through multiple organ failure issues and thought her numbers were under control. She was released on 1/27/21 and was driving on 1/28/21 around 4:15 pm and appears to have had heart failure and had a wreck. She passed away that day.		No prior vaccinations for this event.
LOSS OF CONSCIOUSNESS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.		No prior vaccinations for this event.
LOSS OF CONSCIOUSNESS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an		No prior vaccinations for this event.

unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in

the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second

COVID-19 Vaccine.; Reported Cause(s) of Death: Death

	LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM		No prior vaccinations for this event.
	LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
02/07/21 through 2/13/21 slightly fatiqued, took all his prescribed medications, ate breakfast, lunch and dinner was drinking eight 10 oz bottles of water. On 02/14/21 was very tired had a difficult time breathing after taking the normal meds. He took a breathing treatment with his prescribed Ipratropium Bromide and Albuterol Sulfate via home nebulizer. This did not improve his breathing. He was very weak and breathing was labored. 911 was called by wife. 911EMTchecked pulse and breathing. Informed him they would give him a breathing treatment.He started to go limp. EMT's got him to Ambulance and to Medical Center to the ER. Heroics done. He died. Pulmonary and Cardiac Arrest		No prior vaccinations for this event.
	LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Extreme difficulty breathing upon exertion, collapsed shortly after walking started, loss of		No prior vaccinations for this event.

conciousness, and death

	LOSS OF CONSCIOUSNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion; On 21Feb he went to the ER after vomiting and passing out; On 21Feb he went to the ER after vomiting and passing out; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; fever; headache; stomach upset; This is a spontaneous report from a contactable consumer reporting for the father: A 75-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EL3428) at single dose at left arm on 03Feb2021 for Covid-19 immunisation. Medical history included type 2 diabetes mellitus. No known allergies. The patient had not experienced Covid-19 prior vaccination. Concomitant medication in 2 weeks included amitriptyline hydrochloride (manufacturer unknown) 10 mg, atorvastatin (manufacturer unknown) 20 mg, dutasteride (manufacturer unknown) 0.5 mg, linaclotide (LINZESS) 290 mcg, gabapentin (manufacturer unknown) 300 mg, montelukast (manufacturer unknown) 10 mg, ramipril (manufacturer unknown) 5 mg, insulin degludec (TRESIBA) 100 unit/ml, liraglutide (VICTOZA) 18 mg/3ml solution. No other vaccine in 4 weeks. The patient experienced cardiac arrest due to pericardial effusion on 21Feb2021 14:15, fever on 13Feb2021, headache on 13Feb2021, stomach upset on 13Feb2021, on 19feb, he began to feel ill again with a fever, he felt worse on 20feb on 19Feb2021, on 21feb he went to the ER after vomiting and passing out on 21Feb2021. Events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of cardiac arrest due to pericardial effusion. Course of events: In Feb2021, 10 days after his 1st injection, the patient developed fever, headache, and stomach upset. He went for a rapid Covid-19 test (nasal swab) and it was negative on 11Feb2021. The doctor told him he might be having a delayed reaction to the vaccination. After a couple of days, he improved. On 19Feb2021, he began to feel ill again with a fever. He felt worse on 20Feb2021. On 21Feb2021 he went to the ER after vomiting and passing out and received treatment: IV fluids, diagnostic testing at ER. Rapid Covid test (nasal swab) at ER came back negative again on 21Feb2021. His heart arrested suddenly and he could not be resuscitated. CT scan results, that came back	No prior vaccinations for this event.

after death, showed Covid like pneumonia and pericardial effusion. The patient died on 21Feb2021 14:15. Cause of death was cardiac arrest due to pericardial effusion. An autopsy was not performed. The outcome of cardiac arrest due to pericardial effusion was fatal, of fever, headache, stomach upset was recovering, of he began to feel ill again with a fever, he felt worse was not recovered, of he went to the ER after vomiting and passing out was unknown.; Reported Cause(s) of Death: cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion

LOSS OF CONSCIOUSNESS	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Day After - severe headache, 2 days after headache continues, itchy scalp, day 3 rash visible at hair line headache continues, more confusion than normal, day 4 on site nurses check rash and think it is dermatitis, day 5 continues to get work nurse practitioner was to visit next day, day 6 NP thinks that she has UTI and sends her to hospital (2/11/21). Hospital determines - Rash is Shingles, UTI present, - MRSA is now present in shingles which is on right back of head and right neck and face. Next Sepsis is diagnosed. Since 2/11/21 patient was not conscious. 2/20/21 famiy is notified that she should be moved to Hospice. Moved to hospice on 2/20/21. The patient, my mother, died on 2/23/21 official cause of death is UTI.	No prior vaccinations for this event.

LOSS OF CONSCIOUSNESS	COVID19 (COVID19 (UNKNOWN)) (1202)
Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2 diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated) then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and was	No prior vaccinations for this event.

intubated. Transported to hospital. SARS CoV-2 and influenza negative.

LOSS OF CONSCIOUSNESS	COVID19 (COVID19 (UNKNOWN)) (1202)
Received first SARS-CoV2 vaccination yesterday at local store Experienced new symptoms of chills, nausea as well as worsening from baseline dyspnea at night. Wife states he had rough morning breathing and had sudden loss of consciousness and unresponsiveness and failed to respond to bystander CPR. He expired at his home.	No prior vaccinations for this event.

LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver failure, pneumonia, and DIC>"	No prior vaccinations for this event.

LOW DENSITY LIPOPROTEIN NORMAL	COVID19 (COVID19 (MODERNA)) (1201)
While at counseling appointment on February 17 patient had witnessed sudden cardiac arrest and was not able to be resuscitated. She was pronounced dead at 12:09. At the time of death her glucose was about 500.	No prior vaccinations for this event.

LOWER URINARY TRACT SYMPTOMS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."		No prior vaccinations for this event.

LUNG CARCINOMA CELL TYPE UNSPECIFIED STAGE IV		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer 1/22/2021. RNA+ 2/4/2021. S/S SOB, cough, confusion. COVID assoc. resp. failure, stage 4 lung cancer, COPD, HTN, former smoker. patient in hospice and died 2/10/2021.		No prior vaccinations for this event.

LUNG CONSOLIDATION		**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.
LUNG CONSOLIDATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.		No prior vaccinations for this event.
LUNG DISORDER		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC

No prior vaccinations for this event.

pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

LUNG INFILTRATION

COVID19 (COVID19 (MODERNA)) (1201)

12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate

No prior vaccinations for this event.

resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics

	LUNG INFILTRATION	**COVID19 (COVID19 (MODERNA)) (1201)**
UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless and breathless and was pronounced. Autopsy currently pending.		No prior vaccinations for this event.
	LUNG INFILTRATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.		No prior vaccinations for this event.
	LUNG INFILTRATION	**COVID19 (COVID19**

Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face, increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

No prior vaccinations for this event.

	LUNG INFILTRATION	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient, who was a pharmacist, developed fatigue and shortness of breath hours after receiving vaccine. Two days later, on 01/28/2021, the patient went to local urgent care for worsening shortness of breath and was referred to Hospital for worsening dyspnea and hypoxia. The patient was admitted to the hospital We was found to have bilateral pulmonary infiltrates and treated for pneumonia with Rocephin and azithromycin. He was tested for COVID-19 multiple times, but each of the results were negative. Despite the negative results, there was high clinical suspicion for COVID-19 and the patient was started on Remdesivir and Decadron. The patient's oxygen requirements continued to worsen and the patient was transferred to another facility for higher level of care. There his hypoxia worsened and he required mechanical ventilation. Patient then developed hypotension and required vasopressors for blood pressure support. Furthermore, patient developed acute renal failure requiring hemodialysis. Despite mechanical ventilation with FiO2 100%, and for vasopressors, patient clinically deteriorated and family decided to palliatively extubate on 02/05/2021.		No prior vaccinations for this event.

	LUNG INFILTRATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.		No prior vaccinations for this event.

	LUNG INFILTRATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in		No prior vaccinations for this event.

triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

LUNG INFILTRATION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient developed 104.4 temp approximately 48 hours after being given the vaccine. I treated him with antibiotics, IV fluids, cooling methods. CXR does show a new right perihilar infiltrate. However, his fever came down within the next 24-48 hours. Unfortunately, he suffered a cardiac arrest on 1/21/21 in the early morning and expired.

No prior vaccinations for this event.

LUNG INFILTRATION

COVID19 (COVID19

(PFIZER-BIONTECH))
(1200)

"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel

No prior vaccinations for this event.

can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the

steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

LUNG INFILTRATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"	No prior vaccinations for this event.

	LUNG INFILTRATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.		No prior vaccinations for this event.
	LUNG INFILTRATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.		No prior vaccinations for this event.
	LUNG INFILTRATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.	No prior vaccinations for this event.
LUNG INFILTRATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric	No prior vaccinations for this event.

treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his

stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

LUNG NEOPLASM MALIGNANT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
coughing up blood, significant hemoptysis -- > cardiac arrest. started day after vaccine but likely related to ongoing progression of lung cancer	No prior vaccinations for this event.
LUNG NEOPLASM MALIGNANT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
As per patient daughter - patient had some minor chills on the day of the vaccination - Friday 1/15/21; felt well next day -Saturday, than she was found slumped and lifeless on the couch on Sunday 1/17. Cause of death on death certificate was reportedly put as COPD, Lung Ca and ASHD.	No prior vaccinations for this event.
LUNG OPACITY	**COVID19 (COVID19 (MODERNA)) (1201)**
UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless	No prior vaccinations for this event.

and breathless and was pronounced. Autopsy currently pending.

	LUNG OPACITY	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.
	LUNG OPACITY	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.		No prior vaccinations for this event.
	LUNG OPACITY	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with		No prior vaccinations for this event.

improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

LUNG OPACITY

COVID19 (COVID19 (MODERNA)) (1201)

Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

No prior vaccinations for this event.

LUNG OPACITY	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a	No prior vaccinations for this event.

possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced

pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

	LUNG OPACITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.		No prior vaccinations for this event.
	LUNG OPACITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific		No prior vaccinations for this event.

conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.

LUNG OPACITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

emesis bright yellow in color, liquid BM, increased respirations No prior vaccinations for this event.

LUNG OPACITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis	No prior vaccinations for this event.

involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

LUNG OPACITY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."	No prior vaccinations for this event.
LUNG OPACITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.	No prior vaccinations for this event.
LUNG OPACITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.	No prior vaccinations for this event.
LUNG OPACITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with	No prior vaccinations for this event.

labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

LUNG OPACITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since	No prior vaccinations for

receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.	this event.
LUNG OPACITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt fell within 24 hours after vaccine. was sent to hospital. pt was found to be hypoxic with multifocal opacities on CT scan	No prior vaccinations for this event.
LUNG OPACITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
LYMPHOCYTE COUNT	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
LYMPHOCYTE COUNT	**COVID19 (COVID19 (MODERNA)) (1201)**

From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	No prior vaccinations for this event.
LYMPHOCYTE COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
LYMPHOCYTE COUNT DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.	No prior vaccinations for this event.

LYMPHOCYTE COUNT DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021		No prior vaccinations for this event.
LYMPHOCYTE COUNT INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."		No prior vaccinations for this event.
LYMPHOCYTE COUNT NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and		No prior vaccinations for this event.

had fixed unreactive pupils. He was pronounced at 16:13.

LYMPHOCYTE COUNT NORMAL	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild	No prior vaccinations for this event.

patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

LYMPHOCYTE PERCENTAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
LYMPHOCYTE PERCENTAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported	No prior vaccinations

left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.

for this event.

LYMPHOCYTE PERCENTAGE DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021

No prior vaccinations for this event.

LYMPHOCYTE PERCENTAGE DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her

No prior vaccinations for this event.

stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

LYMPHOCYTE PERCENTAGE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death on 1/31/2021 multiple comorbidities No prior vaccinations for this event.

LYMPHOCYTE PERCENTAGE DECREASED COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.	No prior vaccinations for this event.

LYMPHOCYTE PERCENTAGE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death on same day as vaccination | No prior vaccinations for this event.

LYMPHOCYTE PERCENTAGE INCREASED COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13. | No prior vaccinations for this event.

MAGNETIC RESONANCE IMAGING | **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient woke up on the morning of 2/6 with symptoms of a stroke. Rushed to hospital where clot found in brain. Recovered from initial stroke but then had another major stroke on 2/8 and never recovered. | No prior vaccinations for this event.

MAGNETIC RESONANCE IMAGING ABNORMAL | **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Day after receiving the vaccine, the patient complained of abdominal pain which worsened over the day. She went to the ED and was hospitalized. Abdominal pain complaints increased and continued, she decompensated rapidly, was intubated and subsequently died 3 days later. Imaging results showed, progressive ovarian cancer in the bowels. Blood culture revealed that she had E.Coli in her blood. It is thought that this is NOT related to the vaccine. | No prior vaccinations for this event.

MAGNETIC RESONANCE IMAGING ABNORMAL | **COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal tunnel and sent her home. The morning or March 18th , 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.

No prior vaccinations for this event.

MAGNETIC RESONANCE IMAGING BRAIN ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

No prior vaccinations for this event.

	MAGNETIC RESONANCE IMAGING BRAIN ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - anuerism lead to death approximately 14 hours after initial symptoms.		No prior vaccinations for this event.
	MAGNETIC RESONANCE IMAGING BRAIN ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal tunnel and sent her home. The morning or March 18th , 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.		No prior vaccinations for this event.
	MAGNETIC RESONANCE IMAGING BRAIN NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's		No prior vaccinations for this event.

wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.

MAGNETIC RESONANCE IMAGING BRAIN NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.	Influenza Vaccine	

MAGNETIC RESONANCE IMAGING NECK		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.	No prior vaccinations for this event.	

MALAISE

COVID19 (COVID19 (MODERNA)) (1201)

Patient did not report any signs or symptoms of adverse reaction to vaccine. Patient suffered from several comorbidities (diabetes and renal insufficiency). Patient reported not feeling well 01/06/2021 and passed away that day.

No prior vaccinations for this event.

MALAISE

COVID19 (COVID19 (MODERNA)) (1201)

The resident resides in an independent living facility/apartment. The reporter at the center was informed by his daughter he was not feeling well on 1/1/2021 (specific symptoms could not be ascertained). He reportedly went to be COVID tested on 1/1/2020 and observed to be deceased in his apartment on 1/2/2020. I do not have confirmation of his COVID results, although the reporter indicates his daughter reports his test was positive.

No prior vaccinations for this event.

MALAISE

COVID19 (COVID19 (MODERNA)) (1201)

1/13/21 pt came into clinic for vaccine. Had difficulty remembering age. Called me Mon. 1/18/21 stating she was sick. When asked what her sx were, she stated fatigue. She was well the night of the shot, Thur. and Fri. but became tired on Sat. and Sun. I went through other sx with her such as h/a, fever, n/v, muscle aches, weakness and she said she experienced none of those. I questioned her about eating and drinking and she said she ate and drank water. She seemed fine so I told her to call her doctor if she was worse or the fatigue persisted or call 911. She agreed. Two staff from clinic called her Mon. and Tues, (1/18 and 1/19). On Tues. she may have had sl slurred speech. She was found deceased on

No prior vaccinations for this event.

MALAISE

COVID19 (COVID19

(MODERNA)) (1201)

"Pt. woke up the next morning after vaccination and ""didn't feel well"", described by wife as fatigue, no energy. At approximately 2 PM, he vomited. His wife checked on him at 4:20 PM and he wasn't breathing sitting in his chair. EMS squad was called but when they arrived he was asystole and mottling present. Did not start CPR since he was already gone too long. Pronounced by coroner on scene."

No prior vaccinations for this event.

MALAISE

COVID19 (COVID19 (MODERNA)) (1201)

Patient was feeling dizzy and under the weather after the vaccination. The following day he died in his sleep during a nap.

No prior vaccinations for this event.

MALAISE

COVID19 (COVID19 (MODERNA)) (1201)

Patient received the vaccine on 12/29/20 and presented at the ER at the Hospital on 12/30/20 stating that he wasn't feeling well. It is stated that his health had declined over the past few weeks and currently on hospice. Visit was unremarkable. Patient stated that wanted to stop dialysis. Patient passed away on 01/02/2021.

No prior vaccinations for this event.

MALAISE

COVID19 (COVID19 (MODERNA)) (1201)

Patient complained to wife of not feeling well in evening after the vaccination and expired at home during the night.

No prior vaccinations for this event.

MALAISE

COVID19 (COVID19 (MODERNA)) (1201)

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.	No prior vaccinations for this event.	
MALAISE		**COVID19 (COVID19 (MODERNA)) (1201)**
"Client came to nursing station about 2pm to report she ""was not feeling well"". Nurses took vital signs, then referred her to the vaccination clinic that was onsite. She was observed by vaccination team for a period of time. She reported shoulder pain radiating into shoulder blade in arm vaccine was received. Vaccination team offered ice pack to her, observed for a period of time, and released back to work. About 10pm that evening, she sent a text to another coworker that her pain was ""off the charts"" and that she had pain covering her whole left side of her body. She did not come to work in the morning and did not contact work. Well being check was performed at approximately 9am on 2/2/2021 and she was found dead in her home. 911 was immediately called and authorities took over the scene."	No prior vaccinations for this event.	
MALAISE		**COVID19 (COVID19 (MODERNA)) (1201)**
Client lives alone and had dinner at his home with family members after the 4:40 appointment. Client stated that in general he did not feel well but did not give any specific symptom. Family states they asked the client to go to the ER and the client refused. Family states they helped the client to his chair in the living room and then left to go home. Family states that the client was found in his bedroom the next morning at 7:54 a.m. deceased.	No prior vaccinations for this event.	
MALAISE		**COVID19 (COVID19 (MODERNA)) (1201)**
chills 1 day after vaccine administration; found dead by family 1/18/2021 Narrative: Per patient family report, patient said the next day after vaccination that he didn't feel well because of chills. Patient was found dead at	No prior vaccinations	

home by his family on January 18th. He was a 74yo man with castrate resistant prostate cancer and liver and bone metastases with rising PSA, status post intravenous chemotherapy 1/7/21		for this event.
	MALAISE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received his second dose of Moderna COVID vaccine on 2/6 at 12:40PM. Patient was observed for 15 minutes post-vaccination with no adverse events. On the evening of 2/6 (time unknown) the patient began to develop dry cough and fatigue. He was checked by a physician at that time (who was a family member). Patient continued to feel unwell into Sunday. His lungs were clear when checked Sunday afternoon (time unknown). At approximately 5:30pm on 2/7 the patient began experiencing sudden onset shortness of breath. A pulse ox was conducted at that time and it was 92%, and again shortly thereafter and it was 90% (as reported by family member). 9-1-1 was contacted at this time. CPR was initiated when he arrived at the emergency department, pulse ox was 60% (as reported by family member). The patient passed away shortly thereafter on 2/8/2021.		No prior vaccinations for this event.
	MALAISE	**COVID19 (COVID19 (MODERNA)) (1201)**
He had not been feeling well after his second Covid vaccination (on 01/23/2021) and was found unresponsive in his room at the nursing home (late evening on 02/02/2021). He was taken to a hospital where they did tests and he had pneumonia and kidney failure, but he was being transferred to a larger hospital when he arrested and died (02/03/2021)		No prior vaccinations for this event.
	MALAISE	**COVID19 (COVID19 (MODERNA)) (1201)**
"death. Per son pt was not feeling well after the vaccination ""like her legs were weak."" Son found		No prior vaccinations for this

the mom in her bed 1am on 2/12/2021 unresponsive."		event.
	MALAISE	**COVID19 (COVID19 (MODERNA)) (1201)**
Two days later passed away; difficulty breathing, shortness of breath; difficulty breathing, gurgling; Not feeling well; Achiness; Severe fever; Chills; A spontaneous report was received from a physician concerning a 56-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed fever, chills, achiness, shortness of breath, gurgling and unresponsive. The patient's medical history was not provided. Concomitant product use was not provided. On 19 Jan 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Lot 042L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. After receiving the vaccine on 19 Jan 2021, the patient experienced fever, chills, shortness of breath, gurgling and achiness. On 21 Jan 2021, the patient was found unresponsive. Emergency medical services were called to perform life saving measures however, they were unsuccessful. No further treatment information was provided. The patient died on 21 Jan 2021. The cause of death was reported as unknown. An autopsy was planned.; Reporter's Comments: This case concerns a 56-year-old, female, who experienced a serious event of death, with many other events after receiving second dose of mRNA-1273 (Lot# 042L20A). Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death		No prior vaccinations for this event.
	MALAISE	**COVID19 (COVID19 (MODERNA)) (1201)**
She had pain in the injection site Tuesday night and then during Tuesday she got worse with nausea and some fever. By Wednesday she was complaining that she could not pee even though she was drinking a lot of fluids. She continued to complain it was the worst she ever felt and then at 0600 Thursday morning she woke us up and said she needed to go to the hospital. We arrived at the hospital just before 0700 and she immediately threw up in the trash can. We went into a treatment room and they took blood and started fluids		No prior vaccinations for this event.

as she became incoherent. She said she had taken Tylenol so they started a drug to counter that but her liver function was all wrong and they started to look for a hospital that could transplant a liver. She was air evade about 0930 to Medical center and just over 30 hours latter she was dead. There is a pending autopsy. She was a healthy 39 year old mother who got the shots because she worked as a surgical tech and she was the single mother of a 9 year old little girl.

MALAISE		**COVID19 (COVID19 (MODERNA)) (1201)**
"The patient came to the Emergency Room at approx 3:30 am on 02/03/2021 with pain in right arm (same arm the COVID vaccine had been administered in approx 12 hours earlier) and feeling generally unwell. Patient was concerned about possibility of gout flare or that something was wrong with her arm. Elevated blood pressure was noted; this was attributed to anxiety. She was evaluated, given 500 mg Tylenol, and discharged since the pain was decreasing and blood pressure was stabilized. Patient instructed to follow-up with physician. The next day, on 02/04/2021, the patient arrived at the Emergency Room by ambulance; cardiac arrest was the chief complaint. The patient's daughter stated the patient had been ""feeling generally poor and then suddenly collapsed."" Daughter described ""gurgling respirations"" and being unresponsive. 911 was called, police arrived within 5 minutes and initiated CPR. Epinephrine, atropine, lidocaine and bicarb administered after arrival to Emergency Room. Shockable rhythm never demonstrated. Patient never recovered spontaneous respiration or movement. The death was called at 23:04. Coronary artery disease with cardiac arrest is the cause from the ER records; the coroner is putting COVID-19 vaccination in Part 1 of the death certificate."		No prior vaccinations for this event.

MALAISE		**COVID19 (COVID19 (MODERNA)) (1201)**
Per family, patient has been feeling sick since he was vaccinated, patient went to ER on 02/15/2021, and after few hours at ER patient passed away.		No prior vaccinations for this event.

MALAISE	COVID19 (COVID19 (MODERNA)) (1201)
Started feeling unwell; Headaches; Body aches; Chest pain; Didn't had wishes to eat; Diarrhea; COVID-19 pneumonia; A spontaneous report was received from a consumer concerning a 69-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced COVID-19 pneumonia, feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea The patient's medical history high blood pressure which was controlled with medication. Concomitant product use included nifedipine and fenofibrate. On 20-JAN-2021, approximately a week and a half or two prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number 030L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. A week and a half or two later the patient stated feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea for which patient was hospitalized on 06-FEB-2021. Since everything seemed to be fine the patient was discharged on an unknown date in FEB-2021 however, patient's family was not notified that it was a late reaction to the vaccine's first dose. Later, due to shortness of breath he was hospitalized again on 08-FEB-2021 and was diagnosed for pneumonia and was intubated on the same day. Due to COVID-19 situation patient's family could not be in the facilities and that there wasn't any follow up of the patient given to the family, so family did not have much information. During the first hospitalization(06-FEB-2021) the patient had a blood test which showed a normal result and was tested for COVID-19 and Influenza, both were negative. During second hospitalization (08-FEB-2021) the hospital said that the patient was stable. The patient's family did not know the results of the tests conducted at the time. The action taken with the vaccine in response to the events is not applicable. The outcome of COVID-19 pneumonia was fatal. The patient died on 14 Feb 2021 The cause of death was reported as COVID-19 related pneumonia. The autopsy was not done.; Reporter's Comments: Very limited information regarding this event has been provided at this time. The cause of death was reported as COVID-19 related pneumonia. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the events are assessed as unlikely related. Further information has been requested.; Reported Cause(s) of Death: COVID-19 pneumonia	No prior vaccinations for this event.

	MALAISE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506		No prior vaccinations for this event.
	MALAISE	**COVID19 (COVID19 (MODERNA)) (1201)**
1-25-2021- Phone call: pt had cold and cough prior to vaccine. cough worsened 1-28-2021 Phone call: pt requesting provider visit, cough is same and taking tessalon pearls 1-29-2021 Provider in office visit: pt complain of cough and SOB for 6 days. Getting worse. Temp 101.2, pulse ox 87%, BP 128/70. level of distress- leaning forward to breath. appeared ill. diffuse rales throughout both lung fields, more at bases. Diagnosis Pneumonia due to COVID 19 virus. Sent to ER		No prior vaccinations for this event.

MALAISE

COVID19 (COVID19 (MODERNA)) (1201)

DEATH Narrative: Son stated that patient was doing well, still working and driving places. He stated that he called his son and stated that he wasn't feeling well and died shortly after that.

No prior vaccinations for this event.

MALAISE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Fever, Malaise No prior vaccinations for this event.

MALAISE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was okay, but he was very agitated; reported as not like this prior to the vaccine. The patient

No prior vaccinations for this event.

was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away

MALAISE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 1/11/21 noted with headache, nausea/vomiting, severe melaise. On 1/12/21 resident expired.

No prior vaccinations for this event.

MALAISE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A

No prior vaccinations for this event.

STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.

MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient became sick 3 hours after the vaccine and was found deceased 1 day after his vaccination. He passed away in his sleep.	No prior vaccinations for this event.
MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient stated he wasn't feeling well on January 25, 2021, wasn't eating and complained of abdominal pain. Patient noted to have indigestion and was constipated. Meds provided and labs ordered. On morning of January 26, 2021, patient became weak, lethargic and hypoxic and was sent to emergency department around 0700 hours on January 26, 2021. At approximately 1100 hours, emergency physician notified this writer that patient was not going to overcome his illness and would be placed on comfort care. At approximately 1130 hours, this writer was notified that patient had passed away from multi-organ failure.	No prior vaccinations for this event.
MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient passed su hospital on 23Jan2021 stopped breathing; complained of not feeling well; had an inflamed gall bladder; This is a spontaneous report from a contactable consumer. A 98-year-old female patient received bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL8982 and	No prior vaccinations for this event.

expiry date unknown), via an unspecified route of administration on 16Jan2021 at single dose for covid-19 immunisation. The patient medical history was not reported. The patient concomitant medication reported as has received other medications (unspecified) within 2 weeks. The patient passed in hospital on 23Jan2021 with stopped breathing. Day after vaccine on 17Jan2021, the patient complained of not feeling well, went to hospital where was told she had an inflamed gall bladder. The events caused patient hospitalization for 4 days. The cause of death reported as stopped breathing. It was unknown if autopsy done. Prior to vaccination, the patient not diagnosed with COVID-19. The outcome of the event breathing arrested was fatal, outcome of the other events was unknown.; Reported Cause(s) of Death: Stopped breathing		
	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/29/21 patient began not feeling well and saw her provider. The doctor gave her fluids and tramadol for pain. They noticed increased confusion, but thought that could have been due to the tramadol. They also increased her gabapentin as she was experiencing nerve pain. Patient also developed a rash and was diagnosed with shingles on 2/1/21. Patient died on 2/3/21		No prior vaccinations for this event.
	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient's primary care provider received a death certificate to be signed for this patient. He spoke with the patient's husband and son, who reported that the patient had pain and swelling at the vaccine administration site after receiving the vaccine and was feeling unwell after receiving the vaccine. The patient's family reported that they found her unresponsive on 2/2/21 and called 9-1-1. The patient was pronounced dead upon arrival of emergency responders.		No prior vaccinations for this event.

	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient expired. Per Emergency MD note: ""This is a 72-year-old male with what sounds like diabetes, atrial fibrillation, and hypertension who presents via EMS in cardiac arrest. It sounds like he received his Covid vaccine last week. Initially he had some mild effects from it. However over the last day or so he has felt very unwell. He apparently called his wife today and told her that he was not feeling well and so she returned home. Shortly thereafter he attempted to get up from his chair. He then collapsed and fell forward onto his face. Sounds like his wife had some difficulty rolling him over to perform CPR. When EMS arrived they found him in PEA. He received a total of 5 rounds of epinephrine. At some point they did have return of spontaneous circulation. However just prior to arriving in the emergency department they lost pulses again. The patient was intubated with an 8 oh endotracheal tube prior to arrival."""		No prior vaccinations for this event.
	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated at 11:30am. By 7pm he started presenting symptoms of fatigue, chest pain. Patient urinated and defecated in himself. Was not feeling well. Patient died at 10:30pm.		No prior vaccinations for this event.
	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver		No prior vaccinations for this event.

failure, pneumonia, and DIC>"

	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated	No prior vaccinations for this event.

ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

MALAISE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

For the two days prior to presentation the patient had been complaining of chest pain, his breathing seemed to be labored Monday. He and the family thought the pain was due to shingles as he carried this diagnosis from a month ago. Patient had also received the COVID vaccine 2 days prior to presentation and assumed he was feeling unwell due to the vaccine. Family wanted to take him to the hospital yesterday and earlier today but he refused. She left him in his home earlier this afternoon prior to presentation and returned to

No prior vaccinations for this event.

check on him finding him unresponsive and apneic at which time EMS was activated. #cardiac arrest -- suspect primary cardiac given collateral from family at home, consider hypoxemia which was corrected with advanced airway and 100% FiO2, patient clinically euvolemic and with soft brown stool in diaper not suggestive of GI hemorrhage, attempt to address acidosis with CPR and bicarbonate, not hypoglycemia, on bedside ultrasound FAST neg and no pericardial effusion suggestive of tamponade and +lung sliding bil not spontaneous pneumothorax Assessment/Diagnosis: -cardiac arrest, cause unspecified

	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/7/21 resident complainted of not feeling well, nausea, vomiting and weakness sent to ER passed away.	No prior vaccinations for this event.	

	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/4/21, at around 3:00pm he began feeling very tired and he began burping in the evening. The following morning, he woke up early and was still burping and not feeling well. At around 5:00am, he collapsed. My mother called 9-1-1 and began giving CPR. The parademics arrived and tried to revive him, and transported him to the hospital but at 6:11am, he was pronounced dead of a heart attack. He was healthy.	No prior vaccinations for this event.	

	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was into the clinic on the afternoon of 2/23/21 for a COVID-19 vaccine. He had a podiatry clinic visit after his vaccine same day. It was reported by the patients family physician that patient stated he didn't feel	No prior vaccinations for	

well and suddenly collapsed at home at approximately 4:45 pm. Emergency medical personnel were not able to revive him. Patient died at approximately 4:45 pm on 2/23/21.		this event.
	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient felt achy, tired starting the day after the vaccine. Per his wife, he was very tired and ""losing stamina"". On 2/13/21, he woke up feeling dizzy and weak. His wife asked him if he wanted to go to the doctor and he declined. He ate breakfast and went to rest in his easy chair. He passed away an hour later."		No prior vaccinations for this event.
	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.		No prior vaccinations for this event.
	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal		No prior vaccinations for

tunnel and sent her home. The morning or March 18th , 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.		this event.
	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death Narrative: 86 year old MALE with PMH of Afib s/p AICD/PPM, HFrEF (EF< 20% 10/2019), DM2, HTN, HLD, BPH, Depression. Was stable and feeling well when he was administered Covid-19 vaccine on 02/17/2021- Pfizer COVID-19 Vaccine 0.3 ml IM. MVX (Manuf); PFR; Lot#; EL9267; Exp Date:05/31/2021 Administration Anatomic site: Right Deltoid; Pt was monitored for 30 minutes after administration and had no adverse effects. He was called later in the day and reports he feels well and has had no adverse reactions, he endorsed his arm is a little sore at injection site. ON 02/19/2021- his dghter found him on the floor, next to his bed, dead. She reported on 2/19/2021- that she was out with him to dinner on 2/18/2021, and he stated he did not feel well, that his insides did not feel right. He proceeded to have dinner and 2 drinks. HE was doing ok, when she took him home.		No prior vaccinations for this event.
	MALAISE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion; On 21Feb he went to the ER after vomiting and passing out; On 21Feb he went to the ER after vomiting and passing out; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; fever; headache; stomach upset; This is a spontaneous report from a contactable consumer reporting for the father: A 75-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EL3428) at single dose at left arm on 03Feb2021 for Covid-19 immunisation. Medical		No prior vaccinations for this event.

history included type 2 diabetes mellitus. No known allergies. The patient had not experienced Covid-19 prior vaccination. Concomitant medication in 2 weeks included amitriptyline hydrochloride (manufacturer unknown) 10 mg, atorvastatin (manufacturer unknown) 20 mg, dutasteride (manufacturer unknown) 0.5 mg, linaclotide (LINZESS) 290 mcg, gabapentin (manufacturer unknown) 300 mg, montelukast (manufacturer unknown) 10 mg, ramipril (manufacturer unknown) 5 mg, insulin degludec (TRESIBA) 100 unit/ml, liraglutide (VICTOZA) 18 mg/3ml solution. No other vaccine in 4 weeks. The patient experienced cardiac arrest due to pericardial effusion on 21Feb2021 14:15, fever on 13Feb2021, headache on 13Feb2021, stomach upset on 13Feb2021, on 19feb, he began to feel ill again with a fever, he felt worse on 20feb on 19Feb2021, on 21feb he went to the ER after vomiting and passing out on 21Feb2021. Events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of cardiac arrest due to pericardial effusion. Course of events: In Feb2021, 10 days after his 1st injection, the patient developed fever, headache, and stomach upset. He went for a rapid Covid-19 test (nasal swab) and it was negative on 11Feb2021. The doctor told him he might be having a delayed reaction to the vaccination. After a couple of days, he improved. On 19Feb2021, he began to feel ill again with a fever. He felt worse on 20Feb2021. On 21Feb2021 he went to the ER after vomiting and passing out and received treatment: IV fluids, diagnostic testing at ER. Rapid Covid test (nasal swab) at ER came back negative again on 21Feb2021. His heart arrested suddenly and he could not be resuscitated. CT scan results, that came back after death, showed Covid like pneumonia and pericardial effusion. The patient died on 21Feb2021 14:15. Cause of death was cardiac arrest due to pericardial effusion. An autopsy was not performed. The outcome of cardiac arrest due to pericardial effusion was fatal, of fever, headache, stomach upset was recovering, of he began to feel ill again with a fever, he felt worse was not recovered, of he went to the ER after vomiting and passing out was unknown.; Reported Cause(s) of Death: cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion

MALAISE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received the vaccine around 11 am. He hadn't been feeling well (headache, dizziness) per report and initially called in to work. He then decided to come to work and was found down in a patient bathroom during his shift on our Facility while taking care of a patient (he was a nurse aid). Patient was coded and the team and was transferred to our Facility ED. He expired 3/3 2112	No prior vaccinations for this event.
MASTICATION DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21- N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm	No prior vaccinations for this event.

and noted she was not breathing. Supervisor called and pronounced resident deceased.

MATERNAL EXPOSURE DURING PREGNANCY	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Maternal exposure during pregnancy; Fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected; This is a spontaneous report from a contactable consumer (parent). This consumer reported information for both mother and fetus. This is a fetus report. A patient of unspecified age and gender (fetus) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269), transplacental on 04Feb2021 at 14:00 at single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medication included ergocalciferol (VIT D), folic acid (FOLATE), ascorbic acid/betacarotene/calcium sulfate/colecalciferol/cyanocobalamin/ferrous fumarate/folic acid/ nicotinamide/pyridoxine hydrochloride/retinol acetate/riboflavin/thiamine mononitrate/tocopheryl acetate/zinc oxide (PRENATAL VITAMINS) and sertraline hydrochloride (ZOLOFT) at 25 mg, all transplacental. It was reported that OB exam on 03Feb21 showed healthy baby at 7weeks 5days heartbeat detected 152 bpm; no abnormalities identified via ultrasound; labs and hormone levels all within normal ranges. No issues detected. Mother received 1st dose of vaccine on 04Feb2021. Per ultrasound on 20Feb2021, fetus stopped growing on 09Feb2021 (8 weeks 4 days); no heartbeat detected. Miscarriage occurred on 22Feb2021. The fetus died on 22Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021204433 same drug and reporter, different patient and event; Reported Cause(s) of Death: Fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected; Mother received 1st dose of vaccine 04Feb21. Per ultrasound on 20Feb21, fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected. Miscarriage occurred 22Feb21.	No prior vaccinations for this event.

MEAN CELL HAEMOGLOBIN	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
MEAN CELL HAEMOGLOBIN CONCENTRATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
MEAN CELL HAEMOGLOBIN CONCENTRATION DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.		No prior vaccinations for this event.
MEAN CELL HAEMOGLOBIN CONCENTRATION DECREASED		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

No prior vaccinations for this event.

MEAN CELL HAEMOGLOBIN CONCENTRATION DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.

No prior vaccinations for this event.

MEAN CELL HAEMOGLOBIN CONCENTRATION DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L

No prior vaccinations for this event.

of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

MEAN CELL HAEMOGLOBIN CONCENTRATION NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
MEAN CELL HAEMOGLOBIN CONCENTRATION NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	No prior vaccinations for this event.
MEAN CELL HAEMOGLOBIN DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.	No prior vaccinations for this event.

MEAN CELL HAEMOGLOBIN DECREASED	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.

MEAN CELL HAEMOGLOBIN NORMAL	COVID19 (COVID19 (MODERNA)) (1201)
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.

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From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	No prior vaccinations for this event.

MEAN CELL HAEMOGLOBIN NORMAL	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.

MEAN CELL HAEMOGLOBIN NORMAL	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.

MEAN CELL HAEMOGLOBIN NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200

No prior vaccinations for this event.

IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

MEAN CELL VOLUME	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
MEAN CELL VOLUME DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.
MEAN CELL VOLUME INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.

MEAN CELL VOLUME INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200

No prior vaccinations for this event.

IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

MEAN CELL VOLUME NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

MEAN CELL VOLUME NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage

No prior vaccinations for this event.

layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021

MEAN CELL VOLUME NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
MEAN PLATELET VOLUME INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
MEAN PLATELET VOLUME NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1	No prior vaccinations for this event.

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MEAN PLATELET VOLUME NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
MEAN PLATELET VOLUME NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without	No prior vaccinations for this event.

a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

MECHANICAL VENTILATION

COVID19 (COVID19 (MODERNA)) (1201)

36 hours after vaccination, the patient had increased respiratory distress. He was placed on high flow nasal

No prior vaccinations

cannula oxygen with mild improvement. He then continued to be hypotensive requiring IV fluids and subsequently IV vasopressors. Patient's BP was stabilized with vasopresor, however he continued to deteriorate clinically with altered mental status and lethargy, concerned for bowel peroration based on physical exam by MD. He was then emergency intubated and placed on mechanical ventilation. He was then transferred to acute care hospital near by.		for this event.
MECHANICAL VENTILATION		**COVID19 (COVID19 (MODERNA)) (1201)**
6 days after vaccine developed bloody diarrhea. Thought to have ischemic colitis but negative evaluation. became hypotensive bradycardic placed on ventilator. Subsequently was poorly responsive and eventually coded once more and succumbed		No prior vaccinations for this event.
MECHANICAL VENTILATION		**COVID19 (COVID19 (MODERNA)) (1201)**
The patient, who was a pharmacist, developed fatigue and shortness of breath hours after receiving vaccine. Two days later, on 01/28/2021, the patient went to local urgent care for worsening shortness of breath and was referred to Hospital for worsening dyspnea and hypoxia. The patient was admitted to the hospital We was found to have bilateral pulmonary infiltrates and treated for pneumonia with Rocephin and azithromycin. He was tested for COVID-19 multiple times, but each of the results were negative. Despite the negative results, there was high clinical suspicion for COVID-19 and the patient was started on Remdesivir and Decadron. The patient's oxygen requirements continued to worsen and the patient was transferred to another facility for higher level of care. There his hypoxia worsened and he required mechanical ventilation. Patient then developed hypotension and required vasopressors for blood pressure support. Furthermore, patient developed acute renal failure requiring hemodialysis. Despite mechanical ventilation with FiO2 100%, and for vasopressors, patient clinically deteriorated and family decided to palliatively extubate on 02/05/2021.		No prior vaccinations for this event.

MECHANICAL VENTILATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the Moderna COVID vaccine 1/28/21. He was tested for COVID 19 on 1/29/31. Results were received 1/30/21, at which time he was evaluated and found to be hypoxic with tachycardia. He was sent to the local ER and returned this same day. On 2/2/21, he was evaluated by the provider, who sent him to the emergency room with acute respiratory distress and poor O2 sats		No prior vaccinations for this event.
MECHANICAL VENTILATION		**COVID19 (COVID19 (MODERNA)) (1201)**
On January 1, 2021, patient was admitted to Medical Center with COVID. Tested positive on January 2, 2021. Spent 10 days in hospital. Once recovered from pneumonia and fever gone, on January 10, 2021, she was transferred to Rehabilitation Center for continued treatment. She spent 16 days there. She developed UTI and CDIF infections and was on/off oxygen. She started physical therapy. She was scheduled to be released to go home on January 27, 2021. On January 26, 2021, the day before going home, Rehabilitation Center gave her the Moderna vaccine. On January 27, the day she went home, she started feeling very weak and couldn't walk. My dad tried lifting her and they both fell to the ground. My dad called 911 and she was taken to Medical Center, with high fever and possible stroke symptoms (which later was negative). Two days later, she had difficulty breathing and was put on a ventilator. She was on a ventilator for about three days. They took it off and she slowly started recovering. The doctors did all kinds of tests (blood clot in lung, heart, etc.) and all was negative. The only thing they could trace it to was an adverse reaction to the vaccine. After spending 11 days at hospital and treating her for various infections, her heart stopped and she passed away suddenly.		No prior vaccinations for this event.
MECHANICAL VENTILATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Death Narrative: Family was able to be present at bedside shortly after patient was extubated. Fentanyl bolus given 10-15 minutes prior. Patient passed away soon after endotracheal tube removed. Time of		No prior vaccinations for this

death 10:14am.		event.
	MECHANICAL VENTILATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."		No prior vaccinations for this event.
	MECHANICAL VENTILATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.		No prior vaccinations for this event.
	MECHANICAL VENTILATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP,		No prior vaccinations for

hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (	this event.
MECHANICAL VENTILATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/28/2021- Seen by FNP for indigestion, chest pressure and palpitations. EKG reviewed and referral made to Cardiology. 1/29/2021-1800 Presented to ED in cardiac arrest-onset PTA. Patient was found unresponsive by his wife at their home. The last known well was at 1530 when she called him on the phone. The patient was pronounced at ~1850.	No prior vaccinations for this event.
MECHANICAL VENTILATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious,	No prior vaccinations for this event.

but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

MECHANICAL VENTILATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
73-year-old man s/p first dose of Pfizer at 10:20 AM Ambulated comfortably to exit after 20 minutes in observation but 10:45 collapsed while exiting the building 10:47 CPR initiated 10:49 medical team/EMS found no pulse, agonal respirations, ventricular fibrillation Paramedics and team performed ACLS; of note patient was intubated 7.5 ETT with bilateral breath sounds on ventilation; paramedic reported easy intubation with no apparent throat swelling; 11:02 transported to Emergency Department 11:30 Pronounced dead at Emergency Department	No prior vaccinations for this event.

MECHANICAL VENTILATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Client was administered the vaccine while symptomatic (01/25/21) although client did not know he was symptomatic for COVID-19. He had been exposed to a family member who had tested positive and should have been in quarantine but wasn't either because it was not felt he was considered a close contact by his family opinion or his family member never notified public health of this close contact...?. Clinet had presented to the ED following day after vaccination for shortness of breath and fatigue and an antigen test showed he was positive for COVID-19. He was sent home that same day 01/26/21. He was back in ED on 01/28/21 for worsening symptoms and admitted to hospital and later placed on ventilator. He passed away on 02/09/2021 (date of death was per his wife).	No prior vaccinations for this event.
MECHANICAL VENTILATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145.	No prior vaccinations for this event.

At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

MECHANICAL VENTILATION

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.	No prior vaccinations for this event.
MECHANICAL VENTILATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after	No prior vaccinations for this event.

EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

MECHANICAL VENTILATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My dad received the Pfizer vaccination on 2/5/21. He was admitted into the hospital the next day for C-Diff bacterial infection. He had been on dialysis treatments for kidney failure treatment since 2017 and had recently been diagnosed with stage 3 colon cancer in June 2020. He had completed his final treatment of chemotherapy on 2/4/21 and several weeks prior had been determined cancer free. On Tuesday 2/9/21 he was released from the hospital and went home. Early Thursday morning 2/11/21 @ approximately 1:30 am CST his eyes rolled back in head and he stopped breathing and was non responsive. My mother called 911 and attempted CPR. Paramedics arrived and were able to successfully get a pulse then transferred him to the hospital. He was put on a ventilator @ the hospital and then transferred to a different hospital a few hours later. He lost pulse/heartbeat several times @ the 2nd hospital he was transferred to. We were not allowed to travel with him or see him b/c of all of the COVID restrictions. We were communicating with the ICU doctor by phone who ultimately communicated to us that there was nothing further that could be done to save his life. He subsequently passed away @ approximately 8:55 am CST on 2/11/21.	No prior vaccinations for this event.
MEDICAL INDUCTION OF COMA	**COVID19 (COVID19**

(MODERNA)) (1201)

Patient called son around 6:30am on 2/18/21. When son tried to contact patient around 8:30am, he was not able to get a hold of patient. Son sent someone over to check on patient. They found patient on the floor. He was coherent at first but then lost consciousness. It believed he experienced a stroke sometime around 8:30-9:00am of 2/18/21. Patient was taken to hospital and then transferred to another hospital. He was put in a medically induced coma. He passed between 4:00 and 4:30 pm on 02/19/21.

No prior vaccinations for this event.

MEGACOLON

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Received Pfizer Covid Vaccine in the AM on 2/9/21. Arrived to emergency department later the same day complaining of nausea, weakness, fatigue, Vomiting, Diarrhea. Post operative diagnosis, Ischemic colon/toxic megacolon.

No prior vaccinations for this event.

MEMORY IMPAIRMENT

COVID19 (COVID19 (MODERNA)) (1201)

1/13/21 pt came into clinic for vaccine. Had difficulty remembering age. Called me Mon. 1/18/21 stating she was sick. When asked what her sx were, she stated fatigue. She was well the night of the shot, Thur. and Fri. but became tired on Sat. and Sun. I went through other sx with her such as h/a, fever, n/v, muscle aches, weakness and she said she experienced none of those. I questioned her about eating and drinking and she said she ate and drank water. She seemed fine so I told her to call her doctor if she was worse or the fatigue persisted or call 911. She agreed. Two staff from clinic called her Mon. and Tues, (1/18 and 1/19). On Tues. she may have had sl slurred speech. She was found deceased on

No prior vaccinations for this event.

MEMORY IMPAIRMENT

COVID19 (COVID19

	(MODERNA)) (1201)
Patient recieved vaccine 1 of covid 19 i 1/19/2021. She felt poorly on 1/20/2021. She felt dizzy and fell at 3 AM on 1/23/2021. She felt poorly and did not know her son's name which was not normal. She went to ER on 1/24. She was assessed as not having fractures. She was going to be transferred to a skilled nursing facility. She was not having respiratory complaints. She was awaiting transfer when her O2 levels started dropping substantially. She declined aggressive intervention and she died within a few hours.	No prior vaccinations for this event.
MEMORY IMPAIRMENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Per granddaughter's report, pt became very weak within hours of receiving the first dose of the Moderna COVID-19 vaccine and could not get out of bed the next morning without assistance, reported difficulty seeing, and did not recognize some family members. By Sunday, 1/31, pt was unable to be awakened, would not eat, and had low urinary output. Granddaughter reports that the morning of 2/1 he was awake and ate a small amount and seemed to be improving although still weak and unable to get out of bed. Granddaughter reported he died 2/1 around 10am in the morning.	No prior vaccinations for this event.
MENINGIOMA	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete	No prior vaccinations for this event.

effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021

MENTAL IMPAIRMENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient developed fever to 102 within 24 hours with decreased mentation. Stopped eating/drinking despite aggressively treating fever. Was DNR B status. Family agreed to a trial of IV fluids on 1/21 but was not successfully started until 1/22 after several attempts. Family wanted only comfort measures with no transfer to hospital. Patient continued to have fevers to 102-103 range. Patient passed on 1/23 . Patient did test positive for COVID in early September without significant illness. She was in usual state of health prior to vaccination.	No prior vaccinations for this event.

MENTAL IMPAIRMENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/23 - Mild injection site discomfort. Appetite loss compared to previous day. Beginning loss of mental acuity compared to previous day. 1/24 - Continued loss of appetite. Near complete loss of ability to move. Continued decline of mental acuity. Very little speaking. 1/25 - Stopped speaking completely. Loss of bowel control in the evening and continued until death. Complete loss of appetite. 1/26 - Near complete loss of ability to swallow. Moved to hospice 4:00pm. 1/27 - Died 4:00am	No prior vaccinations for this event.

MENTAL STATUS CHANGES	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient obtained initial dose of Moderna vaccine on Thurday, Jan 14. No adverse effects reported during initial 15 minute post vaccine waiting period. Saturday morning (Jan 16), patient developed severe cough, labored breathing, and fever. Additionally patient mental status changed suddenly, became non-	No prior vaccinations for this event.

communicative (unable to speak, but would scream if she was touched). O2 status was irregular, dropping to 78. Sunday morning, EMT and then hospice was hospice called. Monday morning, after hospice emergency kit was initiated, patient passed away.

MENTAL STATUS CHANGES

COVID19 (COVID19 (MODERNA)) (1201)

36 hours after vaccination, the patient had increased respiratory distress. He was placed on high flow nasal cannula oxygen with mild improvement. He then continued to be hypotensive requiring IV fluids and subsequently IV vasopressors. Patient's BP was stabilized with vasopresor, however he continued to deteriorate clinically with altered mental status and lethargy, concerned for bowel peroration based on physical exam by MD. He was then emergency intubated and placed on mechanical ventilation. He was then transferred to acute care hospital near by.

No prior vaccinations for this event.

MENTAL STATUS CHANGES

COVID19 (COVID19 (MODERNA)) (1201)

Extreme bouts of nausea first few days after vaccine. Estimated that patient died at home within 3-4 days after receiving the vaccine. Last phone call to daughter expressed extreme nausea and seemed to have altered mental status. Found dead by daughter on 01/04/2021.

No prior vaccinations for this event.

MENTAL STATUS CHANGES

COVID19 (COVID19 (MODERNA)) (1201)

"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable

No prior vaccinations for this event.

troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

MENTAL STATUS CHANGES	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
MENTAL STATUS CHANGES	**COVID19 (COVID19 (MODERNA)) (1201)**
Hypoxia, Decreased responsiveness, Narrative: 86yo male with PMHx HTN, Afib not on AC after head trauma, CVA, and colon cancer who was brought to the ED by his family on 2/17. Per documentation the pt was in his usual state of health until 2/16. Received Moderna covid vaccine #2 on 2/16/21 at 0900, and was monitored for 15 minutes following immunization no noted issues. Later that night, had myalgias and took Tylenol. Per the family he slipped on the ice and fell on his butt. Overnight, had several dark stools and vomitus. was brought to the ED by his family because he was being less responsive. Pt arrived to the	No prior vaccinations for this event.

emergency department in extremis. No pulse identified. CPR immediately initiated for several rounds lasting about 25-30 minutes. ROSC unable to be achieved. Patient expired on 2/17 at 1941. Of note, per previous documentation had waxing and waning mental status at baseline. No symptoms noted with 1st dose of Moderna vaccine, which was administered on 1/16/21.

MENTAL STATUS CHANGES	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse	No prior vaccinations for this event.

MENTAL STATUS CHANGES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Symptoms of fever (Tmax 102.9), diarrhea, and altered mental status started ~ 24 hours after vaccination. No evidence of septicemia with negative blood cultures Minimal improvement over 3 days, transferred to	No prior vaccinations for this event.

tertiary care center for MRI brain after which LP was recommended. However family declined as intubation would have been required and was not consistent with patient's goals of care.

	MENTAL STATUS CHANGES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient noted to have a change in status at 11:23PM that night. Her oxygen saturation had dropped from normal on room air to 82% and required oxygen. She was also noted to be lethargic with altered mental status and not responding verbally. She then began to mottle. Her oxygen saturation worsened to 51% on 4Liters of oxygen by the next day and she expired on 1/14/21.		No prior vaccinations for this event.

	MENTAL STATUS CHANGES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
All residents had been in isolation due to multiple cases of COVID in the facility. Resident voiced no health related complaints. He continued to visit with staff and required moderate assist with toileting. Resident had fall 0130 on 1-15-2021, which resulted in laceration with surgical repair. Resident was noted to change in mental status and respirations on morning of 1-16-2021 during morning blood sugar check. Resident had O2 @1.5l/m via n/c and respirations of 10 with periods of apnea and unresponsive to verbal stimuli. Blood sugar was 583. Resident deceased upon re-check after calling PCP to report status change.		No prior vaccinations for this event.

	MENTAL STATUS CHANGES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient received vaccine on Jan 23, 2021. developed weakness on Jan 25, 2021. Sent to ED on Jan 27, 2021 with hypoxia requiring 6 L O2, low Bp, declining mental status. Per family request transitioned to		No prior vaccinations for

hospice and passed away on Jan 30, 2021	this event.
MENTAL STATUS CHANGES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO WITHDRAWL EXTRME MEASURES	No prior vaccinations for this event.
MENTAL STATUS CHANGES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
MENTAL STATUS CHANGES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/23 - Mild injection site discomfort. Appetite loss compared to previous day. Beginning loss of mental acuity compared to previous day. 1/24 - Continued loss of appetite. Near complete loss of ability to move. Continued decline of mental acuity. Very little speaking. 1/25 - Stopped speaking completely. Loss of bowel control in the evening and continued until death. Complete loss of appetite. 1/26 - Near complete loss of ability to swallow. Moved to hospice 4:00pm. 1/27 - Died 4:00am	No prior vaccinations for this event.

MENTAL STATUS CHANGES		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.	Influenza Vaccine	

MENTAL STATUS CHANGES		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccinated 2/20. At that time, had symptoms of incarcerated hernia, went to ED for evaluation. Not felt to warrant hospital admission. Returned two days later with agitation, altered mental status, and incarceration. Went to OR, uncomplicated hernia repair. Postoperatively, did not recover mental status. Went into arrythmias POD 4, hypotension ensued, had multiple interventions and evaluations without satisfying answers for clinical course.	No prior vaccinations for this event.	

METABOLIC ACIDOSIS		**COVID19 (COVID19 (MODERNA)) (1201)**
Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain	No prior vaccinations for	

oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127	this event.
METABOLIC ACIDOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.	No prior vaccinations for this event.
METABOLIC ACIDOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA	No prior vaccinations for this event.

Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia

METABOLIC DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver failure, pneumonia, and DIC>"	No prior vaccinations for this event.
METABOLIC FUNCTION TEST	**COVID19 (COVID19 (MODERNA)) (1201)**
12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family	No prior vaccinations for this event.

on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics

METABOLIC FUNCTION TEST	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, Headaches, chest pain, loss of appetite, confusion, elevated liver enzymes 1/8-1/15/21	No prior vaccinations for this event.

METABOLIC FUNCTION TEST	**COVID19 (COVID19 (MODERNA)) (1201)**
Presented to Urgent Care for weakness and confusion, transferred to ED, patient had a cardiac arrest and was unable to be resuscitated	No prior vaccinations for this event.

METABOLIC FUNCTION TEST	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.	No prior vaccinations for this event.

METABOLIC FUNCTION TEST	**COVID19 (COVID19**

	(MODERNA)) (1201)
Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.	No prior vaccinations for this event.
METABOLIC FUNCTION TEST	**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29	No prior vaccinations for this event.
METABOLIC FUNCTION TEST	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
METABOLIC FUNCTION TEST	**COVID19 (COVID19 (MODERNA)) (1201)**
Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127	No prior vaccinations for this event.

METABOLIC FUNCTION TEST

COVID19 (COVID19 (MODERNA)) (1201)

"Was given vaccine around 1:30Pm on 2-11-2021. He and his wife waited in the building for 15 minutes and then left. he denied complaint. (He was waiting to have both Covid shots before he went to cardiologist Re: CAD.) He had an alarm going off in his house, was going to basement to check it out. Police officer heard alarm, came into house, & heard a thud when Doc fell. He was in PEA (Pulseless Electrical Activity) when brought into ER. Given 5 ""rounds of Epinephrine with no response."

No prior vaccinations for this event.

METABOLIC FUNCTION TEST

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

No prior vaccinations for this event.

	METABOLIC FUNCTION TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Had no immediate issues with the vaccine. He had returned from the hospital on 12/21 and had some concerns about his weight which were shared with his physician on 1/4/21. On 1/5/21 had a visit with his cardiologist for a pacemaker check. On 1/8/21 staff were called to his room, he was on the floor, bluish skin color. No vital signs found, no heart rhythm heard at 2200.		No prior vaccinations for this event.

	METABOLIC FUNCTION TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who		No prior vaccinations for this event.

was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

METABOLIC FUNCTION TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Fatigue, muscle aches, vomiting, hematoma No prior vaccinations for this event.

METABOLIC FUNCTION TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

The patient was observed to be lethargic on 1/29/21 at 1515. BP-80/50, P-75, RR-27, T-100.1. He was given a bolus of NS 150 mlx2. and Rocephin 1 gram IM.	No prior vaccinations for this event.

METABOLIC FUNCTION TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident was noted on 1/25 with an increased functional decline as she would not feed herself with utensils, but would eat finger foods if placed in her hand. She was started on Rocephin IM for possible infections. Labs had been obtained on 1/21/21, unremarkable for CBC and CMP. 75,000 colony count on urine. On 1/26/21 she was noted with right sided weakness and further decline. She was sent to Hospital for further evaluation. We were notified that she expired on 1/28/2021. Resident had been noted with a decline in function about 2 weeks earlier when she would not stand or transfer any longer. She was still responsive, taking meds, and feeding herself until 1/26/21. Further information on admitting diagnoses and progress notes from hospital have not been available to date.	No prior vaccinations for this event.

METABOLIC FUNCTION TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Began with vomiting and diarrhea. C/O chest pain. Bradycardia. Hypotension. 2 seizures in 45 minutes after not having one in years. We gave fluids. Gave Zofran. Comfort measures. Pt passed at midnight. Was completely fine one day before. Had minimal issues with COVID though did have a pneumonia that was treated w ATB early on and resolved.	No prior vaccinations for this event.

METABOLIC FUNCTION TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Patient began feeling nauseated on 1/18/21 around 6pm, and had uncontrolled diarrhea, reported that she did not feel right. Staff reported to this writer, that her skin tone was gray in tone and she just didn't look good. She was transferred to the HOSPITAL ER VIA AMBULANCE.	No prior vaccinations for this event.

METABOLIC FUNCTION TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.	No prior vaccinations for this event.

METABOLIC FUNCTION TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
On 2/5/2021 resident noted to be azotemic. Creatinine up to 3.8 and BUN in 80's. He was started on NS hydration. On 2/7/2021 he was noted without VS, per MD notes, possible VF arrest, renal failure; death	No prior vaccinations for this

unclear exact cause.	event.
METABOLIC FUNCTION TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
METABOLIC FUNCTION TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer,	No prior vaccinations for this event.

however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

METABOLIC FUNCTION TEST

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of

No prior vaccinations for

consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.	this event.
METABOLIC FUNCTION TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home	No prior vaccinations for this event.

notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

METABOLIC FUNCTION TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support	No prior vaccinations for this event.

vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

METABOLIC FUNCTION TEST ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

No prior vaccinations for this event.

METABOLIC FUNCTION TEST ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

See initial report

No prior vaccinations for this event.

METABOLIC FUNCTION TEST ABNORMAL COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO

No prior vaccinations for this event.

WITHDRAWL EXTRME MEASURES

METABOLIC FUNCTION TEST ABNORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.	No prior vaccinations for this event.	
METABOLIC FUNCTION TEST NORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received Moderna COVID vaccine on 12/30/2020 at a Pharmacy clinic where he was a resident. Nurses at the facility reported that he was responsive and showed no signs of any adverse effects until 1/2/2021 when he was observed slightly unresponsive and staring at the ceiling and trembling. He had a fever of 101F at this time. The facility ordered labs and a rapid COVID test (all of which came back normal) and started IV antibiotics. A few hours later, patient began bleeding from his eyes, nose, and mouth and was sent to the local ER. The patient refused being admitted to the ICU for possible sepsis/hemorrhage and died the following day on 1/3/2021. All healthcare professionals involved agreed that this was not likely due to the vaccine, but needed to be reported nonetheless.	No prior vaccinations for this event.	
METABOLIC FUNCTION TEST NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1 fall after first dose on 1/8/2021 at 1930; no injuries; 4 falls after second dose on 1/14/21 at 1545, 1/15/21 at 1700, 1/21/21/at 1220 and 1/21/21 at 1330 all falls with no injuries. Started Ceftriaxone 1 GM	No prior vaccinations for	

IM daily for 5 dyas on 1/21/21 for UTI: E. Coli	this event.
METABOLIC FUNCTION TEST NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was noted on 1/25 with an increased functional decline as she would not feed herself with utensils, but would eat finger foods if placed in her hand. She was started on Rocephin IM for possible infections. Labs had been obtained on 1/21/21, unremarkable for CBC and CMP. 75,000 colony count on urine. On 1/26/21 she was noted with right sided weakness and further decline. She was sent to Hospital for further evaluation. We were notified that she expired on 1/28/2021. Resident had been noted with a decline in function about 2 weeks earlier when she would not stand or transfer any longer. She was still responsive, taking meds, and feeding herself until 1/26/21. Further information on admitting diagnoses and progress notes from hospital have not been available to date.	No prior vaccinations for this event.
METABOLIC FUNCTION TEST NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia	No prior vaccinations for this event.
METABOLIC FUNCTION TEST NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

right arm swelling immediately after injection. followed by bilateral lower leg edema, chills and body aches that continued daily at 2 weeks post immunization admin 2/4/21 treated with dexamethasone 6mg PO x 7 days- this resolved his s/s 2/13/21 patient passed away at facility	No prior vaccinations for this event.
METAMYELOCYTE PERCENTAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further	No prior vaccinations for this event.

testing.

METAMYELOCYTE PERCENTAGE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild	No prior vaccinations for this event.

patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

	METASTASES TO BONE	**COVID19 (COVID19 (MODERNA)) (1201)**
chills 1 day after vaccine administration; found dead by family 1/18/2021 Narrative: Per patient family report, patient said the next day after vaccination that he didn't feel well because of chills. Patient was found dead at home by his family on January 18th. He was a 74yo man with castrate resistant prostate cancer and liver and bone metastases with rising PSA, status post intravenous chemotherapy 1/7/21		No prior vaccinations for this event.
	METASTASES TO LIVER	**COVID19 (COVID19 (MODERNA)) (1201)**
chills 1 day after vaccine administration; found dead by family 1/18/2021 Narrative: Per patient family		No prior vaccinations for

report, patient said the next day after vaccination that he didn't feel well because of chills. Patient was found dead at home by his family on January 18th. He was a 74yo man with castrate resistant prostate cancer and liver and bone metastases with rising PSA, status post intravenous chemotherapy 1/7/21		this event.
METASTASES TO LIVER		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.		No prior vaccinations for this event.
METHAEMOGLOBIN URINE ABSENT		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.
MIGRAINE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient stated he had a migraine after the vaccine. We were advised of a change in appetite on Thursday February 4th. Patient died on February 6th.		No prior vaccinations for this event.

MITRAL VALVE INCOMPETENCE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	No prior vaccinations for this event.
MITRAL VALVE INCOMPETENCE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.	No prior vaccinations for this event.
MOANING	**COVID19 (COVID19 (MODERNA)) (1201)**
I video chatted with her Thursday after receiving the vaccine. My mom was in poor health but she was talking in complete sentences and responded appropriately. She was upright in bed and made eye contact. She smiled and denied pain. By Sunday, she was extremely weak and unable to sip water with a straw. Her health had changed dramatically and rapidly. She moaned in pain and was very fatigued. Her condition continued to deteriorate over the week and she stopped talking and was constantly sleeping. They started antibiotics for the oozing cancer lesion and then morphine for pain and end of life care. She passed away on January 22nd which was 15 days post vaccination.	No prior vaccinations for this event.
MOANING	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

My mom received the Covid 19 vaccine on Jan 5, 2021 and became very about a week later. I was informed that she tested positive for Covid 19 on January 14th. One January 17th she became very tired and weak and would not eat. Hospice called me and told me that she was in a decline state. I saw her on January 25 and 26 and she was just sleeping and could not open her eyes. Her vitals were good and she seemed to understand when I talked to her - she would squeeze my hand and moan but she could not talk or open her eyes. My mom passed away on January 27, 2021 just 22 days after receiving the Covid 19 vaccine. She was very think to begin with and being to weak and tired to eat resulted in her losing even more weight. Some of the other residents were given fluids to help and they recovered. My mom was not given fluids. I believe there were 20 deaths in her care home for the month of January when they vaccinated. This was an alarming number of deaths for the home. The facility had very few Covid deaths in 2019 and 2020. I asked every week if they had any Covid and or Covid deaths and this amount was shocking to me and the workers there.

No prior vaccinations for this event.

MOBILITY DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient received vaccine on 1/4/2021. He was in Hospice for CHF and renal failure, but was able to get up in his wheelchair and eat and take medications and talk. On 1/5/2021 am, he was noted to be very lethargic an could only mumble, could not swallow. No localizing neurologic findings. He was too lethargic to get up in chair.

No prior vaccinations for this event.

MOBILITY DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Per granddaughter's report, pt became very weak within hours of receiving the first dose of the Moderna COVID-19 vaccine and could not get out of bed the next morning without assistance, reported difficulty seeing, and did not recognize some family members. By Sunday, 1/31, pt was unable to be awakened, would not eat, and had low urinary output. Granddaughter reports that the morning of 2/1 he was awake and ate a

No prior vaccinations for this event.

small amount and seemed to be improving although still weak and unable to get out of bed. Granddaughter reported he died 2/1 around 10am in the morning.

MOBILITY DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Blood pressure went down until he died; Couldn't hear his heartbeat; neck was sweating; He was cold; Couldn't get up; Death; Sick; immediately very tired; he was tired; Hands were shaking; Slept for too long; A spontaneous report was received on 18 Feb 2021 from a consumer concerning a 81-years-old, male patient who received Moderna's COVID-19 vaccine and developed immediately very tired, hands were shaking, neck was sweating, was cold, sick, couldn't get up, couldn't hear his heartbeat and blood pressure went down until he died. Patients' medical history, as provided by patient's spouse, was emergency room(ER) admission in November 2020 because he had a congested chest (he had fluid around his heart). At that time, they gave him pills for kidney function. Other concomitant medication reported was Coumadin, blood thinner. Two weeks before receiving the vaccine, patient's EKG was normal. On 11 Feb 2021, in the morning, patient received their first of two planned doses of mRNA-1273(BATCH/LOT # 007M20A) probably in the right arm for the prophylaxis of COVID-19 infection. On 11 Feb 2021, approximately after 15 minutes of receiving vaccine, they left and patient was immediately very tired, his hands were shaking. So, patient's spouse made them down sleep for too long. On Friday, 12 Feb 2021 she tried to pick him up, but he was tired, exhausted, and sick. On Saturday, 13 Feb 2021, she brought him a coffee and he couldn't hold it because his hands were shaking, so she gave him the coffee and then made him pee on the bed because he couldn't get up. At lunch time she made him eat something and he fell sleep again. His wife was hanging around him all day and around 7:30pm she realized that he was cold, and his neck was sweating, she couldn't hear his heartbeat. So, she called emergency services and when they arrived, her husband's blood pressure went down until he died. Treatment for the events were not provided. Action taken with mRNA-1273 was not applicable. Patient was pronounced dead on 13 Feb 2021 20:00. The cause of death was not provided. The plans for an autopsy were not provided. The events of blood pressure went down until he died and couldn't hear his heartbeat were fatal. The outcome for the remaining events	No prior vaccinations for this event.

were unknown.; Reporter's Comments: This case concerns an 81 year old, male patient, who experienced a serious event of death among others, 2 days after receiving mRNA- 1273 (Lot# 007M20A). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

MOBILITY DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

After being observed for approximately 20 minutes and patient walked to her car without assistance I was called to assess the patient in the parking lot for troubles breathing. EMS was called as I made my way outside. Upon my arrival patient was leaning out of the car and stating that she could not breath. She was able to tell me that she was allergic to penicillin. Oxygen was immediately placed on the patient with minimal relief. Lung sounds were coarse throughout. She then began to vomit about every 20-30 seconds. Epipen was administered in the right leg with no relief. Patient continued to complain of troubles breathing and vomiting. A second epipen was administered in the patients right arm again with no relief. A few minutes later patient was given racemic epinephrine through the oxygen mask. There appeared to be mild improvement in her breathing as she appeared more comfortable, but still complaining of shortness of breath and vomiting. When EMS arrived patient was unable to transport herself to the stretcher. When EMS and clinical staff transferred patient to the stretcher she became unresponsive. She appeared to still be breathing. She did not respond to verbal stimuli. Per ED report large amount of fluid was suctioned from the patients lungs following intubation in the ambulance. When patient arrived to the ED she was extubated and re-intubated without difficulty and further fluid was suctioned. At that time patient was found to be in PEA, shock was delivered. Shortly thereafter no cardiac activity was found and patient pronounced dead.

No prior vaccinations for this event.

MOBILITY DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident was noted on 1/25 with an increased functional decline as she would not feed herself with utensils, but would eat finger foods if placed in her hand. She was started on Rocephin IM for possible infections. Labs had been obtained on 1/21/21, unremarkable for CBC and CMP. 75,000 colony count on urine. On 1/26/21 she was noted with right sided weakness and further decline. She was sent to Hospital for further evaluation. We were notified that she expired on 1/28/2021. Resident had been noted with a decline in function about 2 weeks earlier when she would not stand or transfer any longer. She was still responsive, taking meds, and feeding herself until 1/26/21. Further information on admitting diagnoses and progress notes from hospital have not been available to date.		No prior vaccinations for this event.
	MOBILITY DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The vaccine was given on Monday. Tuesday afternoon he developed weakness in both legs and could not stand up. This was a new development; he had neuropathy in one leg but he had been able to stand up and walk three hours before. He was helped to the bathroom. He said he felt better and might want to stand up again. He was helped to bed. He was found dead around 5:30 Wednesday morning. He was 94 years old and had a lot of medical conditions. No one has indicated his death had anything to do with the vaccine. I'm sure it's just a coincidence that he died so soon after receiving the vaccine		No prior vaccinations for this event.
	MOBILITY DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My father was in weak condition to begin with. He didn't get out of bed for the next few days after receiving the vaccine. The little amount that he ate was consumed in bed. He began aspirating his food which lead to pneumonia. He wasn't strong enough to fight off the pneumonia even with antibiotics. He died on 1/23/21. While he might have passed soon in any case, I believe that the vaccine may possibly have increased his		No prior vaccinations for this event.

weakness/exhaustion thereby hastening his demise.

	MOBILITY DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident had slight/slow decline in health prior to vaccine but continued to be able to walk around with walker at community. The day of the vaccine she had a fever. 2 days after vaccine resident did not get out of bed all day and refused to eat. She had small amounts of orange juice as her blood sugar level was low due to not eating. Resident was diagnosed with a UTI and began an oral antibiotic. 3 days after and on day 5 after vaccine resident began feeling weak and had a fall on each day. The following day again resident spent the day in bed. The next day she was quite restless, was on the edge of her bed attempting to self transfer often throughout the day. Resident continued to be restless on the 10th of Feb, had further decline on the 11th of Feb. Resident passed away early the AM of Feb. 12th.		No prior vaccinations for this event.

	MOBILITY DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.		No prior vaccinations for this event.

MOBILITY DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/23 - Mild injection site discomfort. Appetite loss compared to previous day. Beginning loss of mental acuity compared to previous day. 1/24 - Continued loss of appetite. Near complete loss of ability to move. Continued decline of mental acuity. Very little speaking. 1/25 - Stopped speaking completely. Loss of bowel control in the evening and continued until death. Complete loss of appetite. 1/26 - Near complete loss of ability to swallow. Moved to hospice 4:00pm. 1/27 - Died 4:00am	No prior vaccinations for this event.
MOBILITY DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had declining health for the past 6 months, dementia and unable to walk. Patient had decreased appetite starting 1/1/21. After 1st vaccine shot patient appetite decreased further. After 2nd vaccine shot patient fatigue increased to the point where she could not get out of bed and had minimal appetite. Patient passed away 10 days after receiving 2nd shot on 2/22/21. Patient did not go to ED and was not hospitalized.	No prior vaccinations for this event.
MOBILITY DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine	Influenza Vaccine

without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.

	MONOCYTE COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
	MONOCYTE COUNT DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.
	MONOCYTE COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs		No prior vaccinations

(see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day for this event. labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a

transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

MONOCYTE COUNT INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021

No prior vaccinations for this event.

MONOCYTE COUNT NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile

No prior vaccinations for this event.

stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

MONOCYTE COUNT NORMAL	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild	No prior vaccinations for this event.

patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

MONOCYTE PERCENTAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
MONOCYTE PERCENTAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by	No prior vaccinations for

EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.		this event.
MONOCYTE PERCENTAGE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
MONOCYTE PERCENTAGE ABNORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021		No prior vaccinations for this event.

	MONOCYTE PERCENTAGE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."		No prior vaccinations for this event.
	MOUTH BREATHING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
view 2/5/2021 09:23 e Progress Note Note Text: Patient passed away in the facility this morning. view 2/5/2021 08:39 Orders - Administration Note Note Text: Resident passed. view 2/5/2021 08:33 Nurses Note		No prior vaccinations for this event.

Note Text: Body released to funeral home at this time. Personal effects sent with resident include: 1 pair of glasses, 1 yellow wedding band, 1silver spoon ring, 1 ring with black and clear stones. Resident has own teeth view 2/5/2021 08:32 Nurses Note Note Text: cause of death per CRNP failure to thrive. view 2/5/2021 07:44 Orders - Administration Note Note Text: Take and document temp & PO2 every 4 hours for MONITORING Resident passed. view 2/5/2021 06:49 Nurses Note Note Text: Son returned call and was updated of resident's passing this am view 2/5/2021 06:33 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Unknown Resident expired @ 0604 [linked] view 2/5/2021 06:06 Nurses Note Note Text: Res found without pulse or respirations. Pronounced at 0604. Updated. N/o's for RN to pronounce, release body to funeral home, dispose of medications per facility policy. Daughter updated. Funeral Home called to release body. view 2/5/2021 05:26 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Pulse ox 60% on O2 @ 5L/min via mask. Resps 44 per minute. view 2/5/2021 01:57 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/5/2021 00:52 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Residents resps are 40 per minute, pulse ox 76% on O2 @ 5L/min via mask. Resps are labored, shallow and rapid. view 2/5/2021 00:48 Nurses Note Note Text: Nonresponsive to verbal and tactile stimulation. Appears comfortable. view 2/4/2021 22:01 Nurses Note Note Text: Resident resting comfortably, breathing becoming increasingly shallow, wearing O2 via mask at 5L via mask, no dyspnea noted, feet are mottled, oral and peri care provided Q2H. No s/s of pain or discomfort. view 2/4/2021 21:40 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective [linked] view 2/4/2021 19:32 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger medicated for air hunger, RR 28 to 32/ min view 2/4/2021 19:22 Nurses Note Note Text: Daughter updated on N/O to increase Morphine Sulfate 20mg/mL 0.25mL to Q2H prn from Q6H prn. view 2/4/2021 18:06 Nurses Note Note Text: POA Daughter and daughter aware of residents current condition. view 2/4/2021 11:58

Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/4/2021 11:13 Nurses Note Note Text: Pt. noted to be lethargic at this time. Does respond to verbal and tactile stimuli by opening her eyes but non verbal currently. Skin warm and dry. No mottling or apnea observed at this time. O2 sat 88% with O2 at 2 LPM via n/c. On increased to 3 LPM via mask as pt. noted to be mouth breathing. Respirations 28. F/U O2 sat 93%. HOB elevated. Pt. medicated with morphine by LPN. Daughter updated on pt.'s condition. Does not want pt. sent out to hospital and would like comfort measures to continue. Daughter also in agreement with delay in d/c d/t pt.'s condition.CRNP updated on pt.'s condition, delay in d/c and daughter's wishes. No n/o's at this time. view 2/4/2021 10:56 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB Resident showing s/s of discomfort. SOB at this time and high respirations. Repositioned, changed for incontinence care and mouth care provided. view 2/4/2021 10:34 Progress Note Note Text: Spoke with RN regarding change in condition. Updated Sr Living regarding change. Recommendation to cancel d/c/transfer for today, see how resident does through the weekend and re-evaluate on Monday. Daughter updated on cancellation of d/c today. view 2/4/2021 10:04 Nurses Note Note Text: Daughter aware that resident's O2 sat was 88% on room air on 3-11 shift and that oxygen was applied via nasal cannula. view 2/4/2021 10:03 Nurses Note Note Text: N/O: Discharge 2/4/21 with scripts to Sr. Living. Daughter aware. view 2/4/2021 09:53 Nurses Note Note Text: Pt. to be d/c'd to another facility this am as per MD order. Pt. alert and responsive. Skin assessment done as per facility policy. No pressure areas noted at this time. No s/sx of pain or discomfort observed at this time. V.S. 97.0 67 20 O2 sat 95% with O2 at 2 LPM via n/c. view 2/4/2021 07:45 Nurses Note Note Text: Resident seen by Dr. for discharge. Orders pending at this time. view 2/4/2021 07:36 Nurses Note Note Text: CRNP and Dr. updated on O2 sat 88% on RA with f/u of 93% with O2 on at 2 LPM as well as rest of VS, 3-11 shift 2/3/21. No n/o's at this time. view 2/3/2021 21:17 Nurses Note Note Text: Resident Sp02 88% on RA. Pulse 124. Respirations 40. PRN morphine given and O2 applied via NC at 2L/min. After recheck pulse ox up to 93%, pulse 100, and respirations 22. Resident appears comfortable at this time. view 2/3/2021 20:05 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective [linked] view 2/3/2021 19:48 Orders - Administration

Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN given for SOB after elevation of HOB not effective. view 2/3/2021 11:51 Nurses Note Note Text: CRNP updated rapid COVID test done for d/c tomorrow was negative. No n/o's at this time. view 2/3/2021 11:44 Nurses Note Note Text: Daughter notified of rapid covid swab being negative. view 2/3/2021 09:50 Orders - Administration Note Note Text: Obtain Rapid Covid test on 2/3/2021 for discharge. Please give copy of results to Social Worker every day shift for covid testing for 1 Day Completed and negative. view 2/3/2021 08:45 Skilled Nursing Note Reason for skilled service: Therapy describe skilled service: Nursing, therapy assessment: V.S. 97.8 79 18 138/84 Orientation: Oriented to self only. Oxygen: O2 sat 94% on RA Edema: Trace edema noted BLE. Pedal pulses present. Pain: Denies pain or discomfort at this time. Nursing note: Pt. alert and responsive. Skin warm and dry. Lung sounds diminished. No respiratory distress observed at this time. Abdomen soft. BS+ in all 4 quads. Continent/Incontinent of B&B. 1 assist with ambulation, transfers. 1 assist with ADL's. Working with therapy on gait training, therapeutic exercise, therapeutic activities & neuromuscular reeducation. view 2/2/2021 14:37 Progress Note Note Text: Per health professional at Sr Living, prepared to accept patient to their Memory Care Unit 2/4. Transportation arranged for 11 AM per family request. Daughter (POA) updated on d/c time on 2/4/21. Facility requesting rapid COVID test completed prior to d/c and results sent to them. All other information sent for continuity of care.

MOUTH HAEMORRHAGE

COVID19 (COVID19 (MODERNA)) (1201)

Resident became lethargic and reports of blood coming from resident's nose and mouth on the morning of 1/13/21. Resident went out to ER for eval, and came back to facility with dx of pneumonia and recommendations for resident to be placed on hospice. Resident deceased on 1/14/21. Unknown if vaccine related, but with timeline of events I was advised to report this per medical director of facility, as well as Pharmacy who administered the vaccine.

No prior vaccinations for this event.

MOUTH HAEMORRHAGE

COVID19 (COVID19 (MODERNA)) (1201)

Patient received Moderna COVID vaccine on 12/30/2020 at a Pharmacy clinic where he was a resident. Nurses at the facility reported that he was responsive and showed no signs of any adverse effects until 1/2/2021 when he was observed slightly unresponsive and staring at the ceiling and trembling. He had a fever of 101F at this time. The facility ordered labs and a rapid COVID test (all of which came back normal) and started IV antibiotics. A few hours later, patient began bleeding from his eyes, nose, and mouth and was sent to the local ER. The patient refused being admitted to the ICU for possible sepsis/hemorrhage and died the following day on 1/3/2021. All healthcare professionals involved agreed that this was not likely due to the vaccine, but needed to be reported nonetheless.	No prior vaccinations for this event.
MOUTH ULCERATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
MOVEMENT DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of the MCA territory (TPA not recommended). CTA did show distal L M1/M2 occulsion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.	No prior vaccinations for this event.
MOVEMENT DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.

No prior vaccinations for this event.

MOVEMENT DISORDER

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.

Influenza Vaccine

MULTIMORBIDITY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

No documented vaccine reaction Hospitalized due to co-morbities No prior vaccinations for this event.

MULTIPLE ORGAN DYSFUNCTION SYNDROME **COVID19 (COVID19 (MODERNA)) (1201)**

Patient had Covid-19 in October of 2020. He recovered. He received the vaccination on 12/30/2020 with no complaints. On 01-05-2021 it was noted to he was incontinent of urine and bilateral lower extremity edema. Lab work was completed showed acute kidney injury. He had decreased blood pressure and oxygen saturations on 01-06-2021 He was admitted to the hospital with rapid progression of symptoms and suggested multi-system failure. He had a long cardiac history. On 01-14-2021 he passed away with a diagnosis of Cardiomyopathic CHF, A.Fib contributory.

No prior vaccinations for this event.

MULTIPLE ORGAN DYSFUNCTION SYNDROME **COVID19 (COVID19 (MODERNA)) (1201)**

jaundice->hemolytic anemia-> hemorrhagic shock->multi organ failure->death pt admitted to ICU 2/16 with Hgb=3.4, treated with steroids, supportive care , pressors, pt died 2/20/21

No prior vaccinations for this event.

MULTIPLE ORGAN DYSFUNCTION SYNDROME **COVID19 (COVID19 (MODERNA)) (1201)**

High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of

No prior vaccinations for this event.

breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death		
MULTIPLE ORGAN DYSFUNCTION SYNDROME		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient stated he wasn't feeling well on January 25, 2021, wasn't eating and complained of abdominal pain. Patient noted to have indigestion and was constipated. Meds provided and labs ordered. On morning of January 26, 2021, patient became weak, lethargic and hypoxic and was sent to emergency department around 0700 hours on January 26, 2021. At approximately 1100 hours, emergency physician notified this writer that patient was not going to overcome his illness and would be placed on comfort care. At approximately 1130 hours, this writer was notified that patient had passed away from multi-organ failure.	No prior vaccinations for this event.	
MULTIPLE ORGAN DYSFUNCTION SYNDROME		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Legs started swelling and shortness of breath Thursday January 21 2021 Was rushed to hospital with kidney failure and fluid build up around lungs and entire body Blood pressure dropped and had multiple organ failure	No prior vaccinations for this event.	

MULTIPLE ORGAN DYSFUNCTION SYNDROME

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

She started having breathing problems/heart attack appearance. on 1/22/21 and went to the ER. Upon admittance was told it was an anaphylactic shock from the Covid shot. They kept her in ICU and released her 1/23/21. At 12:45 am on 1/24/21 she passed out and we called the ambulance. Hospital admitted her and worked through multiple organ failure issues and thought her numbers were under control. She was released on 1/27/21 and was driving on 1/28/21 around 4:15 pm and appears to have had heart failure and had a wreck. She passed away that day.

No prior vaccinations for this event.

MUSCLE RIGIDITY

COVID19 (COVID19 (MODERNA)) (1201)

ON 1/14/2021 TYPICAL UTI SYMPTOMS FOR RESIDENT DEVELOPED INCLUDING FEVER AND RIGIDITY. RESIDENT IS NON-VERBAL. IV ANTIBIOTICS WERE STARTED. FREQUENT UTI'S ARE COMMON FOR THIS RESIDENT.

No prior vaccinations for this event.

MUSCLE RIGIDITY

COVID19 (COVID19 (MODERNA)) (1201)

Death Narrative: Patient received Covid vaccine on 2/2/21, person reports his legs were more rigid with some sweating the day of the vaccination with leg rigidity that was slowly improving. No other adverse effects reported for following 7 days. Person states he had vomiting episode earlier this week, person states he had no other symptoms before or after the vomiting episodes. On morning of 2/12/21, person reports patient got up ready for breakfast with no issues. She says he asked for chorizo and oatmeal but she laughed and said don't you mean chorizo and eggs. He said yes. They got him into W/C and he was rolling himself into dining room got stuck in hallway. She says he took several breaths then 3 very deep breaths and passed away. She called 911 they took his VS but he has passed. She told them to leave him

No prior vaccinations for this event.

along no resuscitation.

	MUSCLE RIGIDITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt	No prior vaccinations for this event.

well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

MUSCLE SPASMS

COVID19 (COVID19 (MODERNA)) (1201)

Do not know if patient informed her physician that she received vaccine on 1/29/2021. She had appt at 3:15 pm on 1/29 and afterwards stated she received the Moderna vaccine. Reporter is uncertain if this was at a health office or clinic. She drove herself to the ER at about 3am on 1/30/2021 with increased cramping and pain.

No prior vaccinations for this event.

MUSCLE SPASMS

COVID19 (COVID19 (PFIZER-BIONTECH))

		(1200)
"Pt had 2nd vaccine, went home and started having ""cramping"" in all of her muscles. It became bad enough that she was taken to local ED where she then started coughing up blood, required intubation and about 6 hrs later, died."	No prior vaccinations for this event.	
MUSCLE TWITCHING		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 10 minutes after receiving the COVID- 19 vaccine resident displayed seizure activity, staring straight ahead and strong allover muscle jerking of both the up and lower extremities, color became gray, activity lasted approximately 3 minutes, resident then became relaxed, color returned to normal, BP-140/80, 97.8, 60, 16, sleeping the remainder of the shift,. Resident continued to decline until resident CTB on 1/19/21	No prior vaccinations for this event.	
MUSCULAR WEAKNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
"death. Per son pt was not feeling well after the vaccination ""like her legs were weak."" Son found the mom in her bed 1am on 2/12/2021 unresponsive."	No prior vaccinations for this event.	
MUSCULAR WEAKNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient described feeling nervous, anxious the next morning (Wednesday) after the vaccine. He later fell in the bathroom after using the restroom, his legs gave out (his words) and consequently was on the ground for 23 hours before being transported to the hospital. That was Thursday afternoon. He was diagnosed with COVID-19 on Saturday night and died the following Friday morning.	No prior vaccinations for this event.	

	MUSCULAR WEAKNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021		No prior vaccinations for this event.
	MUSCULAR WEAKNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The vaccine was given on Monday. Tuesday afternoon he developed weakness in both legs and could not stand up. This was a new development; he had neuropathy in one leg but he had been able to stand up and walk three hours before. He was helped to the bathroom. He said he felt better and might want to stand up again. He was helped to bed. He was found dead around 5:30 Wednesday morning. He was 94 years old and had a lot of medical conditions. No one has indicated his death had anything to do with the vaccine. I'm sure it's just a coincidence that he died so soon after receiving the vaccine		No prior vaccinations for this event.
	MUSCULAR WEAKNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's		No prior vaccinations for this event.

wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.

MUSCULOSKELETAL DISCOMFORT	COVID19 (COVID19 (MODERNA)) (1201)
Individual developed severe body aches, severe shoulder discomfort, high fevers (documented max temp. 103.7 F). Daughter reported that she became non-responsive with high fevers, and when the fevers decreased she was more lucid. Her condition rapidly progressed to nausea vomiting, diarrhea and patient died on 2/9/2021.	No prior vaccinations for this event.

MUSCULOSKELETAL STIFFNESS	COVID19 (COVID19 (MODERNA)) (1201)
loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen	No prior vaccinations for this event.

levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

MUSCULOSKELETAL STIFFNESS	**COVID19 (COVID19 (MODERNA)) (1201)**
My grandpa got his second covid vaccine on Thursday. Saturday he complained of stiff neck. Sunday he had low grade fever, nausea and vomiting, chills, and mild headache. He was feeling bad enough to call squad at 3 pm. The paramedics did evaluation and thought he was just experiencing normal side effects from vaccine and felt no need to transport to hospital so my grandpa decided to stay home and just rest. At 2 am that same night he went into cardiac arrest and was not able to be brought back	No prior vaccinations for this event.
MUSCULOSKELETAL STIFFNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
This is a 94-year-old male who is brought in by ambulance after being found on the floor with unknown downtime. He was in asystole upon EMS arrival. He remains in asystole. No advanced airway is in place. The patient is getting compressions from Lucas device upon arrival. It was reported that he was last talked	No prior vaccinations for this event.

to by family at 2 PM. The patient got his SARS-CoV-2 vaccination this morning. The patient is evaluated emergently. CPR was ongoing with 3 rounds of epinephrine given. The patient remains in asystole. He has rigor mortis. The patient's pupils are fixed and dilated. The patient has compressions paused and ultrasound is used to evaluate for cardiac activity. None is detected. The patient has no electrical activity on monitor. The patient's time of death is 2113.

MUSCULOSKELETAL STIFFNESS	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.

	MYALGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Cardiac arrest; Pain on her upper right chest; Lot of pain in lower abdomen; Pain underneath arm; Thought it was muscle aches; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed upper right chest pain and underneath the arm, severe abdominal pain, muscle aches and cardiac arrest. The patient's medical history was not provided Concomitant product use was not provided by the reporter. On 14 Jan 2021, approximately five days prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly in the arm for prophylaxis of COVID-19 infection. On 19 Jan 2021, the patient developed upper right chest pain and pain underneath the arm. They thought it was muscle aches. Sometime later, the patient developed a lot of pain in the lower abdomen. The called emergency services and an ambulance arrived but the patient then suffered cardiac arrest. Treatment for the event included tramadol. Action taken with mRNA-1273 in response to the events was not applicable due to the patient was died. The patient died on 19 Jan 2021. The cause of death was reported as cardiac arrest. Autopsy were not provided.; Reporter's Comments: Company Comment: This case concerns a 92-year-old female patient who experienced unexpected serious events of cardiac arrest, upper right chest pain and underneath the arm, severe abdominal pain, muscle aches. The event occurred 5 days after the administration of the first dose of the vaccine mRNA-1273 vaccine (Lot #: unknown, expiration date-unknown). Although a temporal association exist between the events and the administration of the vaccine, in the absence of critical details such as the patient's medical history, any diagnostic test or autopsy result, adequate evaluation and assessment cannot be established. Main field defaults to æpossibly related' for all events.; Reported Cause(s) of Death: Cardiac arrest		No prior vaccinations for this event.

	MYALGIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Two days later passed away; difficulty breathing, shortness of breath; difficulty breathing, gurgling; Not feeling		No prior vaccinations

well; Achiness; Severe fever; Chills; A spontaneous report was received from a physician concerning a 56-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed fever, chills, achiness, shortness of breath, gurgling and unresponsive. The patient's medical history was not provided. Concomitant product use was not provided. On 19 Jan 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Lot 042L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. After receiving the vaccine on 19 Jan 2021, the patient experienced fever, chills, shortness of breath, gurgling and achiness. On 21 Jan 2021, the patient was found unresponsive. Emergency medical services were called to perform life saving measures however, they were unsuccessful. No further treatment information was provided. The patient died on 21 Jan 2021. The cause of death was reported as unknown. An autopsy was planned.; Reporter's Comments: This case concerns a 56-year-old, female, who experienced a serious event of death, with many other events after receiving second dose of mRNA-1273 (Lot# 042L20A). Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

for this event.

MYALGIA

COVID19 (COVID19 (MODERNA)) (1201)

Pt died on 2/15/21. On 2/13/21, pt complained of muscle aches. No prior vaccinations for this event.

MYALGIA **COVID19 (COVID19 (MODERNA)) (1201)**

Started feeling unwell; Headaches; Body aches; Chest pain; Didn't had wishes to eat; Diarrhea; COVID-19 pneumonia; A spontaneous report was received from a consumer concerning a 69-year-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced COVID-19 pneumonia, feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea The patient's medical history high blood pressure which was controlled with medication. Concomitant product use included nifedipine and fenofibrate. On 20-JAN-2021, approximately a week and a half or two prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number 030L20A) intramuscularly in the right

No prior vaccinations for this event.

arm for prophylaxis of COVID-19 infection. A week and a half or two later the patient stated feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea for which patient was hospitalized on 06-FEB-2021. Since everything seemed to be fine the patient was discharged on an unknown date in FEB-2021 however, patient's family was not notified that it was a late reaction to the vaccine's first dose. Later, due to shortness of breath he was hospitalized again on 08-FEB-2021 and was diagnosed for pneumonia and was intubated on the same day. Due to COVID-19 situation patient's family could not be in the facilities and that there wasn't any follow up of the patient given to the family, so family did not have much information. During the first hospitalization(06-FEB-2021) the patient had a blood test which showed a normal result and was tested for COVID-19 and Influenza, both were negative. During second hospitalization (08-FEB-2021) the hospital said that the patient was stable. The patient's family did not know the results of the tests conducted at the time. The action taken with the vaccine in response to the events is not applicable. The outcome of COVID-19 pneumonia was fatal. The patient died on 14 Feb 2021 The cause of death was reported as COVID-19 related pneumonia. The autopsy was not done.; Reporter's Comments: Very limited information regarding this event has been provided at this time. The cause of death was reported as COVID-19 related pneumonia. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the events are assessed as unlikely related. Further information has been requested.; Reported Cause(s) of Death: COVID-19 pneumonia

MYALGIA **COVID19 (COVID19 (MODERNA)) (1201)**

Fever, chills, fatigue, muscle aches, nausea, death 48 hours after injection No prior vaccinations for this event.

MYALGIA **COVID19 (COVID19 (MODERNA)) (1201)**

Hypoxia, Decreased responsiveness, Narrative: 86yo male with PMHx HTN, Afib not on AC after head trauma, CVA, and colon cancer who was brought to the ED by his family on 2/17. Per documentation the pt was in his usual state of health until 2/16. Received Moderna covid vaccine #2 on 2/16/21 at 0900, and was

No prior vaccinations for this event.

monitored for 15 minutes following immunization no noted issues. Later that night, had myalgias and took Tylenol. Per the family he slipped on the ice and fell on his butt. Overnight, had several dark stools and vomitus. was brought to the ED by his family because he was being less responsive. Pt arrived to the emergency department in extremis. No pulse identified. CPR immediately initiated for several rounds lasting about 25-30 minutes. ROSC unable to be achieved. Patient expired on 2/17 at 1941. Of note, per previous documentation had waxing and waning mental status at baseline. No symptoms noted with 1st dose of Moderna vaccine, which was administered on 1/16/21.

MYALGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at	No prior vaccinations for this event.

time of this report."

	MYALGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Fatigue, muscle aches, vomiting, hematoma No prior vaccinations for this event.

MYALGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	

muscle aches-increased pain to lower back No prior vaccinations for this event.

MYALGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	

Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021.	No prior vaccinations for this event.

	MYALGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient complained of soreness in muscles morning after receiving the shot. She went about her day had a smoothie, spoke to people and also went for a walk came home and went into her jacuzzi tub and consequently passed away while in the tub. She was found by her husband at around 545pm, time of death	No prior vaccinations for this event.

is unknown and cause of death is currently pending.

	MYALGIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her	No prior vaccinations for this event.

husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool

Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

MYCOBACTERIUM TUBERCULOSIS COMPLEX TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

"On 1/15/2021 at 1800, resident noted to be lethargic and shaking, stating ""I don't care."" repeatedly. C/O head and neck pain. T100.6. Given Tylenol with no relief of pain. Order received for Aleve and administered.. Assisted to bed as usual in evening. Monitored during night shift and noted to be resting comfortably/sleeping.. Noted agonal breathing at 4:10 AM 1/16/2021 , T 99.4, Absence of vital signs at 4:15AM 1/16/21 and death pronounced at 4:40AM 1/16/21."

No prior vaccinations for this event.

MYCOPLASMA TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became

No prior vaccinations for this event.

acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.

MYDRIASIS

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

No prior vaccinations for this event.

MYELOCYTE PERCENTAGE

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

No prior vaccinations for this event.

MYELODYSPLASTIC SYNDROME

COVID19 (COVID19 (MODERNA)) (1201)

High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills,

No prior vaccinations for this event.

fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

MYOCARDIAL INFARCTION

COVID19 (COVID19 (MODERNA)) (1201)

Medical docter state patient has a acute cardiac attack No prior vaccinations for this event.

MYOCARDIAL INFARCTION **COVID19 (COVID19 (MODERNA)) (1201)**

"""Moderna COVID-19 Vaccine EUA"" It has been reported to me that pt. had gone into hospital for a heart catheterization on 1/12/2021. It was found during this procedure that pt. had suffered a MI. She was release to home the following day and passed away at her residence on 1/15/2021."

No prior vaccinations for this event.

MYOCARDIAL INFARCTION

COVID19 (COVID19 (MODERNA)) (1201)

patient received covid vaccine and had a heart attack the next day and died No prior vaccinations for this event.

MYOCARDIAL INFARCTION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had heart attack. Spoke with spouse on 2/3/2021 stated had multiple health issues including heart and lung issues.	No prior vaccinations for this event.

MYOCARDIAL INFARCTION	**COVID19 (COVID19 (MODERNA)) (1201)**

Patient died of a heart attack on 1/31/21, 2.5 weeks after vaccination No prior vaccinations for this event.

MYOCARDIAL INFARCTION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had no reaction at the clinic. Patient is a medical doctor whose partner called in this death. States patient had no complaint on 1/13 nor 1/14 while at work. States patient died at home on 1/15 a.m. Physician who stated she was called to the patient's home @ 0157 1/15/2021 and found cyanotic from head to toe. State girlfriend found him sitting in the chair a few minutes before they called her. The Coroner did not order autopsy. Did not sent patient to the hospital. Sent him directly Funeral Home. Death Certificate Number 123-2021-002593 list cause of death as pending. I spoke with the patient's primary doctor who gave me the history of HTN, Diabetes, & High Cholesterol. States he had not seen this patient since April 2020. They were also friends and he was not aware of any medical problems. The Coroner state she thinks patient has a heart attack. Neither the Coroner nor PMD think death was related to COVID Vaccine. Informed both that MSDH would have to complete VAERS. Both voiced understanding.	No prior vaccinations for this event.

MYOCARDIAL INFARCTION	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS	No prior vaccinations

found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive MI, PE or ruptured AAA"". Death certificate notes indicate ""signficant conditions contributing to death after cardiac arrest; ASCVD""."

for this event.

MYOCARDIAL INFARCTION	COVID19 (COVID19 (MODERNA)) (1201)
Myocardial Infarction	No prior vaccinations for this event.

MYOCARDIAL INFARCTION COVID19 (COVID19 (MODERNA)) (1201)

Found lying face down without respiration or pulse, believed to be within 5 minutes of event. ACLS procedures unsuccessful. Unable to get autopsy. Believed to be heart attack secondary to COVID infection, but unconfirmed. Relative contribution of recent vaccination unknown.

No prior vaccinations for this event.

MYOCARDIAL INFARCTION	COVID19 (COVID19 (MODERNA)) (1201)

The coroner said it was some type of heart attack; A spontaneous Report Received from a Health care professional concerning a 84 year old male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and who experienced a heart attack / myocardial infarction. The patient's had undergone triple bypass surgery years ago. Concomitant medications were vitamins. On 18-Jan-2021 prior to onset of events the patient received his first of first two planned doses of (mRNA-1273) COVID-19 vaccine of unknown batch no, unknown route and unknown site of administration for prophylaxis of COVID-19 infection. On 13-Feb-2021 the patient experienced death 27 days after the first dose of the vaccine. The coroner said it was some type of heart attack and think he expired sometime Saturday 13-Feb-2021. On 16-Feb-2021 the patient was

No prior vaccinations for this event.

supposed to have his second dose of (mRNA-1273) COVID-19 vaccine. The event, heart attack, was fatal.; Reporter's Comments: This is a case of death to heart attack in a 84-year-old female subject with a hx of triple bypass surgery, who died 27 days after receiving first dose of vaccine. Very limited information has been provided at this time. No death certificate provided. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of Death		
	MYOCARDIAL INFARCTION	**COVID19 (COVID19 (MODERNA)) (1201)**
"Possible heart attack on 2/5/21. Complaint: "" On Feb 5th I believe I experienced a mild hear attack"" (Comment: He said he felt ""clammy, sweaty, excruciating pain on my left side - including his left arm, and left leg, dizzy, exhausted."" This happened after work, and after taking a shower. He said that was the first time he's experienced it, and that it has not happened since then. He said he has constant headaches, ""It just went away yesterday.""""		No prior vaccinations for this event.
	MYOCARDIAL INFARCTION	**COVID19 (COVID19 (MODERNA)) (1201)**
I am the patient's daughter as well as an RN-BSN. My mother was given the Moderna vaccine on Feb 11, 2021 and on Feb 15, 2021 she had a CVA and MI. She was found on her apt. floor unconscious. She was transferred to the Hospital by ambulance where a CT scan and other tests were done. It was determined she had a stroke and heart attack. My mother was in great health, took no medications, and lived alone in her apt. before this incident. The medical professionals determined she would not recover so she was admitted to hospice and died on Feb. 21, 2021. I believe there is a relationship between the vaccine and the CVA and MI.		No prior vaccinations for this event.
	MYOCARDIAL INFARCTION	**COVID19 (COVID19 (MODERNA)) (1201)**
On 3/2/2021, clinic was notified by patient's family that patient had deceased on 2/28/2021 from a		No prior vaccinations for this

heart attack. Unsure of any relation to the Moderna vaccine but reporting for due diligence. event.

MYOCARDIAL INFARCTION **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death by massive heart attack. Pfizer-BioNTech COVID-19 Vaccine EUA No prior vaccinations for this event.

MYOCARDIAL INFARCTION **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Fever, shortness of breath and chest pain that resulted in a heart attack a few hours after vaccination No prior vaccinations for this event.

MYOCARDIAL INFARCTION **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident was found deceased at approximately 6pm in her apartment No prior vaccinations for this event.

MYOCARDIAL INFARCTION **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

The day following the vaccine, the patient complained of throat issues and anxiety. This was not new... however . That evening he reported difficulty breathing and was placed on oxygen; a COVID test was performed and was negative. On 12/30/2020, patient complained of sternal pressure and was transferred to the hospital. The patient died 12/31/2020 and records obtained from the hospital indicated the patient died from a massive myocardial infarction. No prior vaccinations for this event.

MYOCARDIAL INFARCTION **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

The patient had a heart attack and died at a local hospital morning of 1/19/2021. No prior vaccinations for this event.

MYOCARDIAL INFARCTION **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

passed away-heart attack; This is a spontaneous report from a contactable consumer, the daughter of the patient from a Pfizer Sponsored program Pfizer First Connect. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration on 19Jan2021 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 24Jan2021, the patient passed away due to a heart attack. It was not reported if an autopsy was performed. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Reported Cause(s) of Death: passed away-heart attack

No prior vaccinations for this event.

MYOCARDIAL INFARCTION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Myocardial Infarction No prior vaccinations for this event.

MYOCARDIAL INFARCTION COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

she was hurting at her chest/ Chest pain; on her left arm hurt real bad that's what the clot on her left arm; on her left arm hurt real bad that's what the clot on her left arm; She passed away; heart attack; This is a spontaneous report from a contactable consumer. An 87-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Jan2021 at single dose for COVID-19 immunisation. Medical history included diabetes mellitus, for which she was taking a pill like an hour before she would take her meal. On Monday (Jan2021) the patient experienced was hurting at her chest/ chest pain, her left arm hurt real bad as she had a blockage in her left arm/clot on her left arm, and they wanted to put in a stent and after the surgery it went well and she all go home in two

No prior vaccinations for this event.

days. The patient was hospitalized in Jan2021 due to the events. She had a heart attack and that the chamber between the dividers had a hole in it and her heart tissue was too thin so much thin she couldn't repair it. The patient passed away on 26Jan2021. The patient was tested negative for COVID-19 on unknown date. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: She passed away		
	MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Myocardial infarction Narrative: PMH significant for aortic valve stenosis, mitral valve stenosis, CKD, CHF, DM, HTN, obesity, hypothyroidism and dyslipidemia. Per report from primary care - the patients wife reports that the patient went on Saturday (1/30/21 - about 1050) morning to receive his COVID vaccine. He returned home and told her about the experience and denied any side effects. He then proceeded to sit in his easy chair for a while and around 1:30, she asked him if he wanted any lunch. The patient's wife reports he ""grumbled"" at her, and then got up to go to the bathroom. She then heard a loud crash and found him lying on the floor of the bathroom, with his head knocking hole in the wall as he fell. She could not detect a pulse. She called 911 and began compressions. First responders to the scene likewise tried to revive him but were not successful in her efforts. Per primary care documentation - Uncertain if related to Pfizer vaccine; vaccine administered on 1/30/21 and approximately 3 hours later suffered fatal MI at home."		No prior vaccinations for this event.
	MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
One week to the day after patient's first vaccine he died of a heart attack; This is a spontaneous report from a contactable consumer and from a contactable physician. A 71-year-old male patient (husband) received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration		No prior vaccinations for this event.

on 12Jan2021 at single dose on the right arm for COVID-19 immunization. The patient medical history included past heart conditions. No known allergies. Patient took other medications in two weeks. Facility type vaccine was doctor's office/urgent care. No other vaccine received in four weeks. One week to the day after patient's first vaccine he died of a heart attack on 19Jan2021 18:30. Cause of death was heart attack. No COVID prior vaccination. No COVID tested post vaccination. It was unknown if an autopsy was performed. The physician reported that the patient arrived DOA. Physician signed the death certificate based on the patient's prior diagnosis. Physician would not provide additional cause of death medical background without consent. He was not aware of any adverse events experienced from the time of vaccination to the date of death. Follow-up (05Feb2021): This is a follow up spontaneous report from a contactable physician. This physician reported in response to HCP telephonic follow up activity which the following: patient death and cause of death were confirmed. Follow-up attempts are completed. No further information is expected. Information about Lot number is not available.; Sender's Comments: Based on the temporal relationship, the association between the event fatal heart attack with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: One week to the day after patient's first vaccine he died of a heart attack

MYOCARDIAL INFARCTION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

She started having breathing problems/heart attack appearance. on 1/22/21 and went to the ER. Upon admittance was told it was an anaphylactic shock from the Covid shot. They kept her in ICU and released her 1/23/21. At 12:45 am on 1/24/21 she passed out and we called the ambulance. Hospital admitted her and worked through multiple organ failure issues and thought her numbers were under control. She was released on 1/27/21 and was driving on 1/28/21 around 4:15 pm and appears to have had heart failure and

No prior vaccinations for this event.

had a wreck. She passed away that day.

	MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/4/21, at around 3:00pm he began feeling very tired and he began burping in the evening. The following morning, he woke up early and was still burping and not feeling well. At around 5:00am, he collapsed. My mother called 9-1-1 and began giving CPR. The parademics arrived and tried to revive him, and transported him to the hospital but at 6:11am, he was pronounced dead of a heart attack. He was healthy.		No prior vaccinations for this event.
	MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received her vaccine on 2/2/2021 in the morning. She was observed for over 15 minutes and had no history of any anaphylactic reaction of any sort. She felt fine and went home. 2/15/2021 we were notified by her family that she had passed away on 2/7/2021 at home. The cause of death was stated as myocardial infarct secondary to coronary artery disease. We do not think it had to do with the vaccine administration. The patient had many comorbidities.		No prior vaccinations for this event.
	MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient had swelling around her jaw after her second shot of the covid , Pfizer vaccine (.5 ml IM) on the Friday morning, January 29th, I took her to a follow up appointment with the cardiologist at 3:00 pm, as a follow up to a small heart attack event with hospitalization two weeks previously, at the cardiologist she was		No prior vaccinations for this event.

given the ok/all is well. That next morning early, she had a 911 event at her assisted living apartment and was sent back to the hospital, having had another heart attack. Patient died on the following Thursday, February 4, 2021. I do not know if the vaccination had any cause for my mothers death; but I feel it is necessary to report this series of heart attacks after she received the pfizer vaccine. Her Certificate of Death records the cause of death as ""Coronary Artery Disease""."

MYOCARDIAL INFARCTION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Patient died 3 days after receiving his first dose of the Covid vaccine. He saw his doctor 2 weeks prior to his death with absolutely no complaints, very healthy. He had no prior heart conditions and was pronounced dead of a heart attack.	No prior vaccinations for this event.

MYOCARDIAL INFARCTION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Cardiac Event MI or Stroke; Cardiac Event MI or Stroke; This is a spontaneous report from a contactable consumer (Son in law). A 73-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration at left arm on 17Feb2021 14:00 at single dose for covid-19 immunisation. Medical history included atrial fibrillation (AFib), prostate cancer Survivor. Concomitant medication included alirocumab (PRALUENT), escitalopram oxalate (LEXAPRO), apixaban (ELIQUIS), nitroglycerin and Ca channel blocker. The patient received the first dose of BNT162B2 on an unknown date for covid-19 immunisation. The patient experienced cardiac event myocardial infarction (MI) or stroke on 17Feb2021. Adverse event result in Doctor or other healthcare professional office/clinic visit. It was unknown if treatment received for the events. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient was not been tested for	No prior vaccinations for this event.

COVID-19. The patient died on 19Feb2021. It was unknown if an autopsy was performed. The outcome of the events was fatal. The reporter didn't know if this was associated or not. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Cardiac Event MI or Stroke; Cardiac Event MI or Stroke

MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Minor arm pain on 2nd day of each vaccine Diarrhea 3 days after 2nd vaccine Massive heart attack (left ventricle) 8 days (2/24/21) after vaccine Home hospice 3:30pm 2/24/21 Stopped breathing 5:45 am, pronounced dead at 8:22 am on 2/25/21	No prior vaccinations for this event.
MYOCARDIAL INFARCTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with	No prior vaccinations for this event.

outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away

MYOCARDIAL ISCHAEMIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia

No prior vaccinations for this event.

MYOCARDIAL ISCHAEMIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in

No prior vaccinations for this event.

the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

MYOCARDIAL NECROSIS MARKER

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had

No prior vaccinations for this event.

received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

MYOCARDIAL NECROSIS MARKER NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.

No prior vaccinations for this event.

MYOCARDIAL NECROSIS MARKER NORMAL

COVID19 (COVID19

(PFIZER-BIONTECH))
(1200)

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition:

No prior vaccinations for this event.

Deceased

	MYOCLONUS	**COVID19 (COVID19 (MODERNA)) (1201)**
Per EMS/Hospital report patient had difficulty breathing and cardiac arrest with prolonged CPR (greater than 45 mins in the ER) who was resuscitated. Family subsequently arrived including son and daughter and all family members were in the ER room are in agreement that patient would not want further aggressive cares given her extremely poor prognosis in light of chronic debilitation with numerous medical issues and now a very long period of CPR. Hospital Course After updating family they stated patient would not want further aggressive cares given her grim prognosis and chronic severe and debilitating medical issues. She continued to have myoclonic jerking. She was extubated to comfort cares in the ER and did not pass immediately therefore brought to a room. She received comfort cares and passed away at 0450 with family present.		No prior vaccinations for this event.
	MYOGLOBIN BLOOD INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied.		No prior vaccinations for this event.

CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Pt started complaining of chest heaviness and shortness of breath on the afternoon of 1/21/21. EMS was called to the patients home and she was found to have an O2 sat in the 70's. She was admitted to hospital and found to have a proBNP of 5000. She tested negative for Covid-19. She was determined to be in acute-on-chronic heart failure and was referred for hospice care. She passed away on the evening of 1/24/21.

No prior vaccinations for this event.

N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

NASOPHARYNGITIS

COVID19 (COVID19

	(MODERNA)) (1201)
Feb 8 states she had a cold. Feb 9 added stomach ache and nausea. Feb 9 visited urgent care facility for exam and Covid-19 test. Rapid test results were negative. Appeared tired but fine. Told to go home and rest. Feb 10 at 9:00 am found dead on the floor in pool of blood and aspirated. Excessive blood in toilet, pooled on floor and hallway rug.	No prior vaccinations for this event.
NASOPHARYNGITIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt son, reports patient passed away on 2/1/21 in the early hours. Pt wife, told Pt's son that patient started feeling ""bad"" with common cold like symptoms on 1/31/21, had a temp of 99.0. Pt's wife went to take a shower, when she got out patient was unresponsive. She called EMS, they pronounced patient deceased upon arrival. á Pt's son also reports patient and Pt's wife both had their 1st COVID-19 vaccine 13 days prior. He was told by EMT on sight to notify the facility where they received their vaccines. He did contact them and was told to notify PCP."	No prior vaccinations for this event.
NASOPHARYNGITIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19	No prior vaccinations for this event.

immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The

patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second

COVID-19 Vaccine.; Reported Cause(s) of Death: Death

NASOPHARYNGITIS	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting	No prior vaccinations for this event.

to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away

	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient woke apx 0200 complaining of nausea to group home staff. Vitals were checked at that time and WNL. Patient went back to bed. When staff went to wake patient apx 0530, he was unresponsive and had no pulse. Chest compressions were started and EMS called.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Extreme bouts of nausea first few days after vaccine. Estimated that patient died at home within 3-4 days after receiving the vaccine. Last phone call to daughter expressed extreme nausea and seemed to have altered mental status. Found dead by daughter on 01/04/2021.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19**

		(MODERNA)) (1201)
Resident c/o nausea evening of 1/29 (nausea common for her post dialysis), had a large emesis at approx 2220, 0030 (unusual for resident to vomit)- received Zofran per order. Skin cool and damp, Blood sugar 147 (checked due to h/o diabetes and poor intake). At approx 230am Blood pressured checked and noted to be 52/29. Resident transferred to ER, intubated and transferred to higher level of care where she passed away on 1/30 at 736pm. Resident's medical notes indicated likely shock, cardiogenic in nature, sepsis (source unknown) along with a multitude of other co-morbidities that resident has.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient went home around 11 am on 1-31-21 after her vaccine and 15 minute observation period. She was eating breakfast after at home and complained to a neighbor that her teeth hurt and she was nauseated after eating. In the afternoon, she felt dizzy and had diarrhea accompanied with blood. Close to 9 PM, her son went to check on her. The patient was found on the floor--she was unresponsive and had purple lips. Her son called an ambulance and started chest compressions. The patient passed away at the hospital. The doctor has ordered an autopsy, and the results are pending.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
patient passed away 2 days after vaccine. patient had temperature, nausea, and vomiting after vaccine.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
1-2 days after vaccine, pt developed weakness, fatigue, body aches, nausea, headache and poor		No prior vaccinations for this

appetite. Pt was admitted to the hospital on 2/5/21 and death occured on 2/6/21		event.
	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had the first Moderna Covid vaccine on Thursday 1/21/2021. She had a bit of sore arm on that day and the day after. On Saturday 1/23/2021, she had a fever of 100.5 F (11AM), nausea, light headache and chills. The temperature went down after she took ibuprofen. Patient's husband enrolled her to V-Safe to report all the adverse effects she experienced. On Sunday 1/24/2021, her temperature was 98.3F. She still had nausea and no appetite. She and her husband watched a football game in their bedroom upstairs. Husband noticed that his wife was pacing around the room many times. At 7Pm, Husband went downstairs for dinner but she refused to come down to eat. He went upstairs around 8pm, TV was still on. He turned off TV and went down stairs again thinking his wife felt as sleep while watching TV. He went back upstairs for bed around 10:30 PM. Husband said his wife had a deviated septum so she would snore very loudly when asleep. He didn?t hear her snoring so he went to check on her and found her not responsive. Husband called emergency services. Paramedic came at 10:45 and said patient was passed. Husband sent many texts to V-safe after that to report the incident. No response was received from V-safe. Patient?s doctor told her husband that she died due to cardiac arrest.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
patient tested positive for covid on 1/29/21. was hospitalized on 2/8/21 for shortness of breath, generalized weakness, nausea.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Feb 8 states she had a cold. Feb 9 added stomach ache and nausea. Feb 9 visited urgent care facility for		No prior vaccinations

exam and Covid-19 test. Rapid test results were negative. Appeared tired but fine. Told to go home and rest. Feb 10 at 9:00 am found dead on the floor in pool of blood and aspirated. Excessive blood in toilet, pooled on floor and hallway rug. for this event.

NAUSEA **COVID19 (COVID19 (MODERNA)) (1201)**

Nausea, vomiting and generalized weakness. No prior vaccinations for this event.

NAUSEA **COVID19 (COVID19 (MODERNA)) (1201)**

Patient became nauseated about 10 minutes after vaccine administered, this subsided but returned several hours after the vaccine was given. She continued with intractable nausea and vomiting for about 24 hours. This patient was enrolled in hospice and she continued to decline and refused to eat or drink. She was taking Ibuprofen due to intractable back pain. Her emesis was coffee ground color. After this her condition continued to decline until her death

No prior vaccinations for this event.

NAUSEA **COVID19 (COVID19 (MODERNA)) (1201)**

She had pain in the injection site Tuesday night and then during Tuesday she got worse with nausea and some fever. By Wednesday she was complaining that she could not pee even though she was drinking a lot of fluids. She continued to complain it was the worst she ever felt and then at 0600 Thursday morning she woke us up and said she needed to go to the hospital. We arrived at the hospital just before 0700 and she immediately threw up in the trash can. We went into a treatment room and they took blood and started fluids as she became incoherent. She said she had taken Tylenol so they started a drug to counter that but her liver function was all wrong and they started to look for a hospital that could transplant a liver. She was air evade about 0930 to Medical center and just over 30 hours latter she was dead. There is a pending autopsy. She was a healthy 39 year old mother who got the shots because she worked as a surgical tech and she was the

No prior vaccinations for this event.

single mother of a 9 year old little girl.

	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Individual developed severe body aches, severe shoulder discomfort, high fevers (documented max temp. 103.7 F). Daughter reported that she became non-responsive with high fevers, and when the fevers decreased she was more lucid. Her condition rapidly progressed to nausea vomiting, diarrhea and patient died on 2/9/2021.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
2/12/2021 woke up with sore arm and back. 2/13/2021 woke up with headache around 1am. Headache and nausea all morning. Mid-late afternoon started having seizures. Admitted to Hospital 2/15/2021 expired. Reported per wife on 2/25/2021.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Fever, chills, fatigue, muscle aches, nausea, death 48 hours after injection		No prior vaccinations for this event.

NAUSEA	**COVID19 (COVID19 (MODERNA)) (1201)**	
My grandpa got his second covid vaccine on Thursday. Saturday he complained of stiff neck. Sunday he had low grade fever, nausea and vomiting, chills, and mild headache. He was feeling bad enough to call squad at 3 pm. The paramedics did evaluation and thought he was just experiencing normal side effects from vaccine and felt no need to transport to hospital so my grandpa decided to stay home and just rest. At 2 am that same night he went into cardiac arrest and was not able to be brought back		No prior vaccinations for this event.
NAUSEA		**COVID19 (COVID19 (MODERNA)) (1201)**
Within 10 minutes following the second vaccination, patient reported dizziness and nausea, had an episode of vomiting but recovered within 30 minutes. It was reported to our clinic that the patient was found deceased on March 1, 2021 at approximately 10 pm. Cause of death is not determined at this time.		No prior vaccinations for this event.
NAUSEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.		No prior vaccinations for this event.
NAUSEA		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.

Influenza Virus Vaccines - Unknown date/type or brand

NAUSEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 1/11/21 noted with headache, nausea/vomiting, severe melaise. On 1/12/21 resident expired.

No prior vaccinations for this event.

NAUSEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"83yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, the patient reportedly got up in the middle of the night with c/o feeling ""blah"", restlessness, and nausea. VS normal, no other s/sx. At 4:15am, the patient was asked to go back to bed, assisted by a nurse and GNA. At 6am, GNA was going to do morning VS and found the patient unresponsive, no pulse, no respirations. GNA notified the nurse. At 6:03am, CPR started and EMS called. At 6:15am, EMS arrived and took over. At or around 6:30am, EMT called time of death"

No prior vaccinations for this event.

NAUSEA

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.	No prior vaccinations for this event.
NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
She had the first dose of Pfizer vaccine at the Campus on Friday 1/15 at 4:30 pm. After the vaccine, she had no new symptoms or signs of vaccine reaction and MD friend reports that he checked her pulse which was not elevated from baseline. On 1/16, she awakened and continued to feel at her recent baseline. However, in the early afternoon, she complained of headache, nausea/epigastric pain, and chest heaviness. These apparently were not unusual symptoms for her to feel intermittently. Per her niece, who has a home O2 sat device, her 02 sat that morning was 97 with a HR of 87 irregularly irregular. She was afebrile. (continue on page 2)	No prior vaccinations for this event.
NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of	No prior vaccinations for

breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away		this event.
	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.		No prior vaccinations for this event.

	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient's wife called this morning stating that her husband has passed away last night. After receiving first dose of Pfizer COVID-19 vaccine at around 0830, patient remained in the Immunizations Department for the 15-minute monitoring period. Per wife, patient's only complaint was pain at the injection site. At 1300, wife states that patient complaint of dizziness which ""dissipated after a few minutes"" followed by a headache which ""dissipated after a few minutes"" as well. Then patient complained of nausea, no vomiting and ""couldn't relax."" Per wife, from around 1400/1500, patient stayed on his recliner while still having a conversation with her--""he didn't get up to eat."" Last conversation they had was around 2000/2100. Per wife, at around 2100/2200, patient was quiet and when she checked on him, ""he wasn't responding anymore."" Wife then called 911, ""but they couldn't revive him.""""		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On Saturday, 1/16/2021, Patient went to the grocery store. Upon her return, she indicated she was experiencing N/V and some throat swelling. Patient subsequently collapsed and expired before she could be brought to an emergency room. During investigation by Coroners Office, it has been reported that Patient may have gotten some takeout food while she was out. Labs are pending and the Coroners investigation is ongoing. Spouse believes that her death was caused by the vaccine.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness; respiratory distress Narrative: Patient tolerated his 1st dose of the COVID-19		No prior vaccinations for

vaccine well, on 12/16/2020, and received his 2nd dose on 1/6/2021. Patient had some mild clinical decline the past few days prior to 2nd vaccination, with a decreased appetite and some increased fatigue per nursing report, but no significant changes. He experienced nausea on the evening of 1/6/21, which was effectively managed, but by early morning he spiked a fever of 102.9 with a sat of 86.1%. He continued to deteriorate from that point on and died 1/7/21 @13:20. Clinically, the presentation was most consistent with an aspiration pneumonia.	this event.
NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
family states seemed short of breath since after the covid vaccine. Staff said beginning on 1/22/21 the patient seemed sluggish, more tired, and nausea noted. She stayed in her room more after the vaccine because worried about giving/getting COVID to others. was talking on the phone at 11:30 PM on 1/26/21 to staff person about temperature of room. at 12:15 AM on 1/27/21 staff noted not breathing, started CPR and called EMS. When EMS arrived they stopped the code because she was too long deceased.	No prior vaccinations for this event.
NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
According to medical report, Pt presented to the ED on 1/14/21 w/ cc of SOB for 1 day. She received her COVID-19 vaccine on 1/9/21. Pt stated that she developed a dry hacking cough 2 days prior to the vaccine on 1/7/21. Over the last few days prior to admission, she developed generalized weakness, SOB, loss of sense of taste and smell w/ associated decreased appetite and nausea ultimately SOB in the24 hours prior to admission. Final Diagnosis- acute hypoxic respiratory failure secondary to COVID-19 pneumonia. Pt died on 2/3/21. See Medical report for more information.	No prior vaccinations for this event.

NAUSEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began feeling nauseated on 1/18/21 around 6pm, and had uncontrolled diarrhea, reported that she did not feel right. Staff reported to this writer, that her skin tone was gray in tone and she just didn't look good. She was transferred to the HOSPITAL ER VIA AMBULANCE.		No prior vaccinations for this event.
NAUSEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver failure, pneumonia, and DIC>"		No prior vaccinations for this event.
NAUSEA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer Covid Vaccine in the AM on 2/9/21. Arrived to emergency department later the same day complaining of nausea, weakness, fatigue, Vomiting, Diarrhea. Post operative diagnosis, Ischemic colon/toxic megacolon.		No prior vaccinations for this event.
NAUSEA		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

On 2/7/21 resident complainted of not feeling well, nausea, vomiting and weakness sent to ER passed away.

No prior vaccinations for this event.

NAUSEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient reported to Emergency room on 01/23/2021 with complaint of nausea. According to ER record patient reported he received a COVID 19 vaccine Pfizer the day before. Work up in the ER (CT ABD PELVIS) reveal a clotted of SMA. CT CHEST REVEALED BILATERAL PULMONARY EMBOLUS. THE PATIENT WAS TRANSFERRED TO THE STATE HOSPITAL. HE WAS SCHEDULED FOR EMERGENT VASCULAR SURGERY WHICH WAS CANCELLED AS THE PATIENT DIED SHORTLY AFTER HIS ARRIVAL.

No prior vaccinations for this event.

NAUSEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident was given the Pfizer vaccine on January 22, 2021, nausea and shortness of breath was taken to the Hospital on the 23rd of January and passed on the 24, 2021

No prior vaccinations for this event.

NAUSEA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting

No prior vaccinations for this event.

diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

SOB, DOE, oxygen desaturation, nausea. Ems transport to ER for eval No prior vaccinations for this event.

	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Light headedness, fatigue, nausea No prior vaccinations for this event.

	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches;	No prior vaccinations for

Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021.

this event.

Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was

unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was found with no pulse no heart rate by a staff member around 11 pm. Earlier that day seen by myself for fatigue, sorethroat, nausea.		No prior vaccinations for this event.

	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient was not vaccinated at hospital. Caregiver reports that patient was vaccinated with second dose on Monday 2/15/21. Tuesday patient experienced n/v/d. Went to an ED on Wednesday and was cleared and sent home. Thursday reported shortness of breath to her caregiver and then collapsed. Patient was brought to as PEA arrest and ultimately died.		No prior vaccinations for this event.

	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose		No prior vaccinations for this event.

of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice, memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200 mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation: tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed, metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol

sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral patchy opacities

	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/22/2021 10:09 pm resident reported 1 episode of being nauseous and having dry heaves, no temperature, MD notified and nurse was told to continue to monitor, no new orders, daughter made aware. Vital signs being done every 4 hours. 2/23/2021 3:04am resident complains of nausea, scant BM amount x 2, MD notified and no new orders, continue to monitor and encourage fluids, vital signs continue every 4 hours.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.		No prior vaccinations for this event.
	NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per Patients Wife - Same day - Flu like symptoms, Nausea, Headache. Restless that night. Next day - Weak, shortness of breath. Wife called squad to get him out of his wheelchair but patient refused hospital		No prior vaccinations for this event.

as it gets him agitated. Patient passed away around 11 AM the day after vaccination.

NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Severe headache, nausea and vomiting No prior vaccinations for this event.

NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.

NAUSEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
blood clot; death cause: Heart Problems; tired; nauseous; This is a spontaneous report from a contactable consumer. An 81-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number EL3248), via an unspecified route of administration at single dose in the left arm on 19Jan2021 14:00 for covid-19 immunisation. Medical history included heart problems, pacemaker. Concomitant medication included heparin. The patient experienced death cause: heart problems on 20Jan2021, blood clot on an unspecified date with outcome of unknown that required hospitalization, tired on 19Jan2021 with outcome of unknown, nauseous on 19Jan2021 with outcome of unknown. The patient was hospitalized for blood clot from 16Jan2021 to 18Jan2021. The patient died on 20Jan2021. An autopsy was not performed. The events were described as follows: The patient was tired and nauseous about 3 hours after her vaccine. She had been in the hospital 16Jan2021 to 18Jan2021 for a blood clot. The patient died at her home on 20Jan2021 between 4 and 7 pm. No treatment required. The vaccine was administered at Hospital Facility. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19.; Reported Cause(s) of Death: death cause: Heart	No prior vaccinations for this event.

Problems

NAUSEA	**COVID19 (COVID19 (UNKNOWN)) (1202)**
Received first SARS-CoV2 vaccination yesterday at local store Experienced new symptoms of chills, nausea as well as worsening from baseline dyspnea at night. Wife states he had rough morning breathing and had sudden loss of consciousness and unresponsiveness and failed to respond to bystander CPR. He expired at his home.	No prior vaccinations for this event.
NECK PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
"On 1/15/2021 at 1800, resident noted to be lethargic and shaking, stating ""I don't care."" repeatedly. C/O head and neck pain. T100.6. Given Tylenol with no relief of pain. Order received for Aleve and administered.. Assisted to bed as usual in evening. Monitored during night shift and noted to be resting comfortably/sleeping.. Noted agonal breathing at 4:10 AM 1/16/2021 , T 99.4, Absence of vital signs at 4:15AM 1/16/21 and death pronounced at 4:40AM 1/16/21."	No prior vaccinations for this event.
NECK PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood	No prior vaccinations for this event.

cultures x2 with gram positive cocci in clusters growing after 9 hours.

NECK PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Jan 3 vaccine administered, jan 4 started headaches, vomiting, pain in the back of the neck, Headaches, chills, loss of speech,	No prior vaccinations for this event.

NECK PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Same day as vaccination given, developed pain went from arm up to shoulder, to back, to neck to head - right side of body; chills/body aches	No prior vaccinations for this event.

NERVOUS SYSTEM DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of the MCA territory (TPA not recommended). CTA did show distal L M1/M2 occulsion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.	No prior vaccinations for this event.

NERVOUS SYSTEM DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.	No prior vaccinations for this event.	
NERVOUSNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient described feeling nervous, anxious the next morning (Wednesday) after the vaccine. He later fell in the bathroom after using the restroom, his legs gave out (his words) and consequently was on the ground for 23 hours before being transported to the hospital. That was Thursday afternoon. He was diagnosed with COVID-19 on Saturday night and died the following Friday morning.	No prior vaccinations for this event.	
NEURALGIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/29/21 patient began not feeling well and saw her provider. The doctor gave her fluids and tramadol for pain. They noticed increased confusion, but thought that could have been due to the tramadol. They also increased her gabapentin as she was experiencing nerve pain. Patient also developed a rash and was diagnosed with shingles on 2/1/21. Patient died on 2/3/21	No prior vaccinations for this event.	
NEUROLOGICAL SYMPTOM		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Vomit 30 minutes after administration. approx. 9 hours later, resident has Stroke-like symptoms. He was previously on Hospice before admitting to our facility and planned to be readmitted to hospice upon discharge.	No prior vaccinations for this event.
NEUROLOGICAL SYMPTOM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient woke up on the morning of 2/6 with symptoms of a stroke. Rushed to hospital where clot found in brain. Recovered from initial stroke but then had another major stroke on 2/8 and never recovered.	No prior vaccinations for this event.
NEUTROPHIL COUNT	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
NEUTROPHIL COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central	No prior vaccinations for this event.

line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral

central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

	NEUTROPHIL COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
	NEUTROPHIL COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73,		No prior vaccinations for this event.

2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

NEUTROPHIL COUNT INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."

No prior vaccinations for this event.

NEUTROPHIL COUNT INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1

No prior vaccinations for this event.

cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021

NEUTROPHIL COUNT NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.

No prior vaccinations for this event.

NEUTROPHIL COUNT NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

No prior vaccinations for this event.

NEUTROPHIL COUNT NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of

No prior vaccinations for

chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	this event.
NEUTROPHIL COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-	No prior vaccinations for this event.

ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2

through

	NEUTROPHIL PERCENTAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.		No prior vaccinations for this event.
	NEUTROPHIL PERCENTAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021		No prior vaccinations for this event.
	NEUTROPHIL PERCENTAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient		No prior vaccinations for this event.

passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.

NEUTROPHIL PERCENTAGE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
NEUTROPHIL TOXIC GRANULATION PRESENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
NIH STROKE SCALE SCORE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of	No prior vaccinations for this event.

the MCA territory (TPA not recommended). CTA did show distal L M1/M2 occulsion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.

NITRITE URINE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21	No prior vaccinations for this event.

NITRITE URINE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious,	No prior vaccinations for this event.

but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

NITRITE URINE ABSENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and

No prior vaccinations for this event.

pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib

fractures on the right at ribs 2 through

NODAL RHYTHM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.	No prior vaccinations for this event.
NUCLEATED RED CELLS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
NUCLEATED RED CELLS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
OCCULT BLOOD NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Received Moderna #1 on 1/12/2021. 1/15/2021 developed worsening shortness of breath. Went to hospital and diagnosed with anemia, 4 negative fecal tests, neg EGD and colonoscopy. Discharged and readmitted (circumstances unknown for this episode) then readmitted a third time 1/20/2021 for shortness of breath. Diagnosed covid + at third hospitalization and continued to get worse. He died 1/23/2021.	No prior vaccinations for this event.
OEDEMA	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.	No prior vaccinations for this event.
OEDEMA	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER	No prior vaccinations for this event.

prior to transfer.

	OEDEMA PERIPHERAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had Covid-19 in October of 2020. He recovered. He received the vaccination on 12/30/2020 with no complaints. On 01-05-2021 it was noted to he was incontinent of urine and bilateral lower extremity edema. Lab work was completed showed acute kidney injury. He had decreased blood pressure and oxygen saturations on 01-06-2021 He was admitted to the hospital with rapid progression of symptoms and suggested multi-system failure. He had a long cardiac history. On 01-14-2021 he passed away with a diagnosis of Cardiomyopathic CHF, A.Fib contributory.		No prior vaccinations for this event.
	OEDEMA PERIPHERAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
right arm swelling immediately after injection. followed by bilateral lower leg edema, chills and body aches that continued daily at 2 weeks post immunization admin 2/4/21 treated with dexamethasone 6mg PO x 7 days- this resolved his s/s 2/13/21 patient passed away at facility		No prior vaccinations for this event.
	OEDEMA PERIPHERAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema		No prior vaccinations for this event.

and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.

OEDEMA PERIPHERAL	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.	No prior vaccinations for this event.

OESOPHAGEAL DISORDER	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.	No prior vaccinations for this event.

OESOPHAGOGASTRODUODENOSCOPY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.	No prior vaccinations for this event.

OESOPHAGOGASTRODUODENOSCOPY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization	No prior vaccinations for this event.

(EUA)

OESOPHAGOGASTRODUODENOSCOPY NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Received Moderna #1 on 1/12/2021. 1/15/2021 developed worsening shortness of breath. Went to hospital and diagnosed with anemia, 4 negative fecal tests, neg EGD and colonoscopy. Discharged and readmitted (circumstances unknown for this episode) then readmitted a third time 1/20/2021 for shortness of breath. Diagnosed covid + at third hospitalization and continued to get worse. He died 1/23/2021.

No prior vaccinations for this event.

OMENTAL NECROSIS

COVID19 (COVID19 (MODERNA)) (1201)

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.

No prior vaccinations for this event.

OPHTHALMOPLEGIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early

No prior vaccinations for this event.

hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

OPIATES NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV

No prior vaccinations for this event.

push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

ORAL MUCOSAL BLISTERING

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

"The day after the 2nd shot, patient developed blisters on his lips and mouth. The care facility said that he had a nut allergy -- but he had never been allergic to nuts. He stopped eating and drinking and his BP had dropped to 60/40. By Jan 16th they called to say he was dying and he passed away on 1/18/21. Patient had COVID19 from Oct 29th - early November. By Nov 21st he had lost 40 lbs. He was 6'3"" and had gone from 189lbs to 149 lbs with COVID. By Nov 21st when we could visit, he had recovered from COVID, but was very thin and weak. He could not bathroom alone and kept falling. He didn't seem to have a bad reaction to the 1st COVID shot, But he immediately reacted to the 2nd shot and passed away within 6 days."

Shingles - Glaxo 8/22/2020, resulted in hospitalization and LTC.

ORAL PAIN

COVID19 (COVID19 (MODERNA)) (1201)

ON 02/08/2021 AROUND 0600 RESIDENTCOMPLAINED OF MOUTH PAIN AND RECEIVED OXYCODONE. DURING THE COURSE OF THE MORNING, RESIDENT EXHIBITED A FEW EPISODES OF LABORED/SHALLOW BREATHING AND SOB AT RESTING. 0XYGEN SATURATION RATE WAS 93-98% ON ROOM AIR, LUNG SOUNDS CLEAR IN ALL LOBES AND PULSE AND TEMPERATURE WITHIN NORMAL RANGE. AS THE DAY PROGRESSED, VITAL SIGNS REMAINED STABLE BUT RESIDENT CONTINUED TO HAVE PERIODS OF SOB/LABORED BREATHING.FAMILY AND NURSE PRACTIONER UPDATED AND THE ORDER WAS RECEIVED TO SEND PATIENT TO MEDICAL CENTER ER FOR EVALUATION PER AMBULANCE. RESIDENT TRANSPORTED AT 1425. RESIDENT RETURNED FROM THE ER AT 1830 ON HOSPICE CARE WITH THE DIAGNOSIS OF: ACURE RESPIRATORY FAILURE WITH HYPOXIA AND END OF LIFE DECISION MAKING. RESIDENT WAS MADE COMFORTABLE AND MONITORED DURING THE NIGHT AND EXPIRED AT 0630 ON 02/09/2021.

No prior vaccinations for this event.

OROPHARYNGEAL DISCOMFORT

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
The day following the vaccine, the patient complained of throat issues and anxiety. This was not new... however . That evening he reported difficulty breathing and was placed on oxygen; a COVID test was performed and was negative. On 12/30/2020, patient complained of sternal pressure and was transferred to the hospital. The patient died 12/31/2020 and records obtained from the hospital indicated the patient died from a massive myocardial infarction.	No prior vaccinations for this event.
OROPHARYNGEAL PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.	No prior vaccinations for this event.
OROPHARYNGEAL PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021.	No prior vaccinations for this event.

	OROPHARYNGEAL PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/15: Pfizer vaccine dose 1 administered 1/16: Fever, chills 1/22: Sore throat, coughing w/white phlegm, taking Tylenol and Mucinex. Fever and chills from 1/16 subsided. Had telehealth consultation with PA. Per her notes, patient said he gets these symptoms annually, requested for an antibiotic. PA referred him for a COVID test. Ordered hydrocodone/chlorphen ER suspension for his cough and an antibiotic. Antibiotic was recommended if symptoms do not subside. 1/23: COVID test administered 1/25: Reported positive for COVID 1/26: Telehealth session w/PA: she informed patient of his positive test, advised to quarantine and seek medical help at hospital if symptoms worsen. Patient reported that his sore throat mostly subsided but is still coughing at night. Said that the pharmacy didn't receive the prescription order for the antibiotic, so this was re-ordered. 1/31: Partner found him dead at 8:18AM on his bed. Death certificate issued by state says cause of death: COVID. Autopsy was not performed. Buried on 2/9/21.		No prior vaccinations for this event.

	OROPHARYNGEAL PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was found with no pulse no heart rate by a staff member around 11 pm. Earlier that day seen by myself for fatigue, sorethroat, nausea.		No prior vaccinations for this event.

	OROPHARYNGEAL PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
A few days after the vaccination my father had a sore throat and slight cough. This progressed into pneumonia like symptoms and he died on 2/11/21.		No prior vaccinations for this event.

ORTHOPNOEA	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off	No prior vaccinations for this event.

to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

ORTHOSTATIC HYPOTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or	No prior vaccinations for this event.

lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board

for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

OVARIAN CANCER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Day after receiving the vaccine, the patient complained of abdominal pain which worsened over the day. She went to the ED and was hospitalized. Abdominal pain complaints increased and continued, she decompensated rapidly, was intubated and subsequently died 3 days later. Imaging results showed, progressive ovarian cancer in the bowels. Blood culture revealed that she had E.Coli in her blood. It is thought that this is NOT related to the vaccine.	No prior vaccinations for this event.
OVARIAN NECROSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.	No prior vaccinations for this event.
OXYGEN SATURATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Is patient deceased: Yes; Low pulse; This is a spontaneous report from two contactable nurses reporting for a patient. A 70-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL0140 expiration date Mar2021) intramuscular on 22Dec2020 at 10:30 at single dose in right arm for COVID-19 immunisation. The patient was vaccinated at Nursing Home. Patient age at time of vaccination was 70 years. Patient's Medical History included ongoing Type 2 Diabetes Mellitus Without Complication onset	No prior vaccinations for this event.

date: admission 22Oct2020, ongoing morbid obesity due to excess calories onset date: admission 22Oct2020, cardiac disorder, essential hypertension, hypertension, schizophrenia, hyperlipidemia, benign prostatic hyperplasia (BPH), Gastrooesophageal reflux disease (GERD), depression, hypothyroid, epilepsy, pain, dry eyes, anxiety, restlessness, 17Jan2020 Slid out of chair to floor, no injury, on 27Jan2020, 28Jan2020, 29Jan2020 diarrhea noted. Concomitant medications included acetylsalicylic acid (ASPIRIN EC) for Cardiac Health, atenolol (ATENOLOL) for Essential Hypertension, atorvastatin calcium (ATORVASTATIN CALCIUM) for hyperlipidemia, finasteride (FINASTERIDE) for benign prostatic hyperplasia, tamsulosin hydrochloride (FLOMAX) benign prostatic hyperplasia, insulin glargine (LANTUS) for diabetes mellitus, lithium carbonate (LITHIUM CARBONATE) for Schizophrenia, losartan potassium (LOSARTAN POTASSIUM) for hypertension, lurasidone hydrochloride (LURASIDONE HYDROCHLORIDE) for Schizophrenia, omeprazole (OMEPRAZOLE) for gastrooesophageal reflux disease, sertraline hcl (SERTRALINE HCL) for depression, levothyroxine sodium (SYNTHROID) for hypothyroid, ergocalciferol (VIT D) for supplement, haloperidol (HALOPERIDOL) for Schizophrenia, levetiracetam (KEPPRA) for epilepsy, paracetamol (TYLENOL EXTRA-STRENGTH) for pain, propylene glycol (ARTIFICIAL TEARS) for dry eyes, lorazepam (ATIVAN) for a anxiety or restlessness. As antipyretic use was reported Tylenol ES (500 mg) Tab, 2 Tabs by Mouth Routine use three times a day given at time of vaccination and after. It was reported the patient was Covid+. He was tested on 21Dec2020 and was not admitted to hospital. Event Onset Date was reported as 24Dec2020 (clarification pending). On 30Dec2020 the patient was started on O2 at 2L for low pulse. O2 was increased over time to eventually O2 at 8L on 03Jan2021. Morphine Sulfate was started on 03Jan2021 at 5 mg sl/by mouth every 2 hours as needed for pain or airhunger. The patient deceased on 03Jan2021. The cause of death was unknown. It was not reported if an autopsy was performed. The AEs did not require a visit to Emergency Room or Physician Office. Outcome of Low pulse was unknown.; Sender's Comments: Based on the information available the events Death (unknown cause) and Heart rate decreased are attributed to patient's multiple underlying medical conditions including Type 2 Diabetes Mellitus, morbid obesity, cardiac disorder, hypertension, epilepsy etc. However, based solely on a vaccine-event chronological association, contributory role of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the above mentioned events cannot be completely excluded. The case will be reevaluated should additional information, including the cause of death, become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part

of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Is patient deceased: Yes

OXYGEN SATURATION ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the Moderna COVID vaccine 1/28/21. He was tested for COVID 19 on 1/29/31. Results were received 1/30/21, at which time he was evaluated and found to be hypoxic with tachycardia. He was sent to the local ER and returned this same day. On 2/2/21, he was evaluated by the provider, who sent him to the emergency room with acute respiratory distress and poor O2 sats	No prior vaccinations for this event.

OXYGEN SATURATION ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt with acute resp failure, COVID PNA, that developed symptoms 9 days prior to admit and ultimately received first vaccine 6 days prior toa admit, then shortly after progressed with other covid symptoms and was admitted. She decompensated while intp and was transferred to ICU for rising O2 needs, ultimately had to be intubated. Became hypotensive due to massive hamatoma 2' bleeding into abd rectus muscle. Sx and IR consulted and did beside exploration of hematoma. Initially blood pressure responded but overnight continued with refractory hypotension. Maxed out vasopressin and levophed, hemodynamics deteriorated. Pt passed soon after(2/2).	No prior vaccinations for this event.

OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident had body aches, a low O2 sat and had chills starting on 12/30/20. He had stated that they had	No prior vaccinations

slightly improved. On 1/1/21 he sustained a fall with a diagnosis of a displaced hip fracture. On 1/2/21 during the NOC shift his O2 sat dropped again. He later went unresponsive and passed away.

for this event.

OXYGEN SATURATION DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Weakness, Low O2, death. Positive for COVID on 1/12/21, dies on 1/16/21 No prior vaccinations for this event.

OXYGEN SATURATION DECREASED **COVID19 (COVID19 (MODERNA)) (1201)**

Patient obtained initial dose of Moderna vaccine on Thurday, Jan 14. No adverse effects reported during initial 15 minute post vaccine waiting period. Saturday morning (Jan 16), patient developed severe cough, labored breathing, and fever. Additionally patient mental status changed suddenly, became non-communicative (unable to speak, but would scream if she was touched). O2 status was irregular, dropping to 78. Sunday morning, EMT and then hospice was hospice called. Monday morning, after hospice emergency kit was initiated, patient passed away.

No prior vaccinations for this event.

OXYGEN SATURATION DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

On the evening of 10JAN2021, patient experienced a low grade fever, decreased oxygen saturation of 38%, heart rate of 124, confusion. Patient received oxygen via face mask, morphine and ativan. By 11JAN2021, patient was no longer verbal, able to eat or communicate and was kept on comfort measure only. On the morning of 17JAN2021, the patient passed away.

No prior vaccinations for this event.

OXYGEN SATURATION DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Resident received the first dose of Moderna Vaccine on 01/12/2021 and Tested for COVID-19 on

No prior vaccinations

01/12/2021. Resident tested positive on 01/13/2021. Resident was transferred to acute hospital on 01/19/2021 due to desaturation. Resident expired at Hospital on 01/24/2021.		for this event.
OXYGEN SATURATION DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient recieved vaccine 1 of covid 19 i 1/19/2021. She felt poorly on 1/20/2021. She felt dizzy and fell at 3 AM on 1/23/2021. She felt poorly and did not know her son's name which was not normal. She went to ER on 1/24. She was assessed as not having fractures. She was going to be transferred to a skilled nursing facility. She was not having respiratory complaints. She was awaiting transfer when her O2 levels started dropping substantially. She declined aggressive intervention and she died within a few hours.		No prior vaccinations for this event.
OXYGEN SATURATION DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Shortness of Breath, decreased oxygen saturation, irregular heart rhythm, hypertension, Positive for COVID, bilateral pneumonia		No prior vaccinations for this event.
OXYGEN SATURATION DECREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awake at 0300. When going into the room to get him ready for dialysis he was cold to touch, unresponsive other than to sound, and nonverbal. O2 sat was 67 via finger probe. Oxygen immediately initiated and a venturi mask retrieved and initiated. When unable to arouse him via sternal rub this RN called 911. Send to ED. Febrile 39.2 and hypotensive 58/43. Admitted. unknown after that as patient expired in hospital.		No prior vaccinations for this event.
OXYGEN SATURATION DECREASED		**COVID19 (COVID19**

	(MODERNA)) (1201)
2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.	No prior vaccinations for this event.
OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received his second dose of Moderna COVID vaccine on 2/6 at 12:40PM. Patient was observed for 15 minutes post-vaccination with no adverse events. On the evening of 2/6 (time unknown) the patient began to develop dry cough and fatigue. He was checked by a physician at that time (who was a family member). Patient continued to feel unwell into Sunday. His lungs were clear when checked Sunday afternoon (time unknown). At approximately 5:30pm on 2/7 the patient began experiencing sudden onset shortness of breath. A pulse ox was conducted at that time and it was 92%, and again shortly thereafter and it was 90% (as reported by family member). 9-1-1 was contacted at this time. CPR was initiated when he arrived at the emergency department, pulse ox was 60% (as reported by family member). The patient passed away shortly thereafter on 2/8/2021.	No prior vaccinations for this event.
OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time	No prior vaccinations for this event.

breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.

OXYGEN SATURATION DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient had Covid-19 in October of 2020. He recovered. He received the vaccination on 12/30/2020 with no complaints. On 01-05-2021 it was noted to he was incontinent of urine and bilateral lower extremity edema. Lab work was completed showed acute kidney injury. He had decreased blood pressure and oxygen saturations on 01-06-2021 He was admitted to the hospital with rapid progression of symptoms and suggested multi-system failure. He had a long cardiac history. On 01-14-2021 he passed away with a diagnosis of Cardiomyopathic CHF, A.Fib contributory.

No prior vaccinations for this event.

OXYGEN SATURATION DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

On 1/26 at breakfast table began vomiting. Continued thru am when at noon a caregiver did his O2 saturation and found it was 75%. This was confirmed, and resent sent to ER .

No prior vaccinations for this event.

OXYGEN SATURATION DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

1/31/2021 12:50 Nursing Note Note Text: Res had low BP, low O2 sats, 30 breaths per minute, eyes open wide, making confused utterances. Started supplemental oxygen via NC, 2L, then 3L. Sats went up to 93% for a while, Sprvsr called. Unable to auscultate Left lung sounds. Called to update Res daughter. Called to page NP, writer went back to assess Res and O2 sats were 88%, turned O2 to 4LPM, called 911 for transport to Hospital ED. Left around 1030. NP called back afterwards, was updated. Family updated that Res was sent to Hospital ED. Note Text: Received phone call from daughter as well as information from hospital. Resident

No prior vaccinations for this event.

has pneumonia with septic shock. She is on abx and had thoracentesis performed for large pleural effusion. [linked]

OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident tested NEGATIVE for COVID-19 last 1/25/2021. She was on monitoring for desaturation and low blood pressure on Jan. 27,2021	No prior vaccinations for this event.
OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from	No prior vaccinations for this event.

which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

OXYGEN SATURATION DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient received dose 1 of Moderna Vaccine on 1/14/21 administered by pharmacy. Patient was hospitalized on 1/31/21 due to shortness of breath and diminished O2 sats down to 88%. Patient was in atrial fibrillation. Patient discharged from hospital on 2/25/21 to home. Patient received dose 2 of Moderna Vaccine on 2/25/21 prior to discharge from hospital. Last hospital note stated that patient was pleasant and cooperative with good motivation. Patient passed away after discharge from the hospital on 2/26/21. Patient's son called the hospital to report his passing.

No prior vaccinations for this event.

OXYGEN SATURATION DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident became SOB, congested and hypoxic requiring oxygen, respiratory treatments and suctioning. Stabilized after treatment and for the next 72 hours with oxygen saturations in the 90s. On 1/3/2021 was found without pulse and respirations. Resident was a DNR on Hospice.

No prior vaccinations for this event.

OXYGEN SATURATION DECREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
3:07 pm lung sounds diminished oxygen sats 68%, oxygen applied Oxygen sats remained low for next 36 hours (patient on Hospice care) expired 6:22 am 1-8-21	No prior vaccinations for this event.	
OXYGEN SATURATION DECREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Three hours after receiving COVID 19 vaccination, Patient oxygen level decreased to a critical level and went into cardiac arrest. Staff performed full code but was unable to bring back patient from cardiac arrest.	No prior vaccinations for this event.	
OXYGEN SATURATION DECREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
increase weakness and fatigue, weakness in extremities, incontinent, jerky arm movements, within first 24 hours, continue to decline sent to hospital returned weaker, within 24 hrs hours BP dropped, low pulse oximeter reading, diaphoretic, lung sounds diminished, loss consciousness and passed away. 01-12-2021	No prior vaccinations for this event.	
OXYGEN SATURATION DECREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/11/21 at 8:57 Resident with fever and at 11 am saturation down to 83 O2 to 10 liters. Resident continued to decline until CTB on 1/14/2021 at 1325	No prior vaccinations for this event.	

OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
At approximately 12:15 pm the resident had a brief unresponsive episode that resolved quickly. Her Vital signs were stable and her mentation was at baseline. Later that evening approximately 10 pm she had labored respirations, shortness of breath, lethargy with bilateral crackles, Oxygen desaturated to 76% on room air, tachycardia and hypotension. She expired at 6:30 a.m. the following day.		No prior vaccinations for this event.
OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."		No prior vaccinations for this event.
OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Patient noted to have a change in status at 11:23PM that night. Her oxygen saturation had dropped from normal on room air to 82% and required oxygen. She was also noted to be lethargic with altered mental		No prior vaccinations for

status and not responding verbally. She then began to mottle. Her oxygen saturation worsened to 51% on 4Liters of oxygen by the next day and she expired on 1/14/21.		this event.
	OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client tested positive for COVID-19 by rapid test on 1/8/21. On 1/9/21 at 1405 his oxygen saturation dropped to 86% and oxygen was initiated at 2L per nasal cannula. A non-productive cough was noted on 1/10/21 and oxygen was increased to 3L. On 1/12/21 Client became non-responsive with 30 second periods of apnea. Dexamethasone was initiated on 1/13/21. Lung sounds were noted with crackles on 1/15/21 at 1158 and at 2120 Client was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.		No prior vaccinations for this event.
	OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient tested positive for COVID-19 by rapid test on 1/6/21. She began to demonstrate a dry cough on 1/11/21. On 1/12/21 at 1723 her oxygen saturation dropped to 79% and oxygen was applied at 4L per nasal cannula. On 1/19/21 at 2130 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.		No prior vaccinations for this event.
	OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began to demonstrate a cough the evening of 1/5/2021, after receiving the COVID-19 vaccine earlier in the afternoon. A rapid COVID-19 test was performed and was positive. She began to demonstrate		No prior vaccinations for

shortness of breath with exertion on 1/7/21, and lethargy on 1/12/21. Appetite and oral intake began to decline on 1/12/21, and Oxygen saturation dropped on 1/16/21 to 82%, and oxygen was initiated at 3L per nasal cannula. On 1/19/21 at 0414 patient was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.		this event.
	OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient tested Covid positive, cough, low oxygen levels, COVID Pneumonia, patient is now deceased		No prior vaccinations for this event.
	OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Note Text: Resident oxygen was going down to 74% during change of shift 3-11, oxygen initiated 3liters via nasal canula per standing order want up to 84-86% NP notified, ordered Prednisone 20mg stat, Rocephin 1gram IM stat administered, Per NP statement if pt's condition worsening sent him to ER, continue monitoring pt and his oxygen going to 82% increasing distress. Notified Nurses supervisor, 911 was called pt left building at 1819 to Hospital alert oriented. Vs bp. 165/60, temp. 98.3,m pulse 109, res 22, 02. 82%. Resident father notified.		No prior vaccinations for this event.
	OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1st COVID immunization 1/7/2021, COIVD positive results on 1/16/21, 1/24/21 O2 sats decreased to 78%, 1/24/21 reveived the Bamlanivimab infusion 50 ml/hr. 1/24/20 chest x ray 1/24/21 She was sent to		No prior vaccinations for this event.

hospital and admitted. 1/27/2021 Expired

OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.	No prior vaccinations for this event.
OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident passed away 2 days after receiving the vaccine. oxygen level has decreased shortly 1 day after receiving the vaccine.	No prior vaccinations for this event.
OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids	No prior vaccinations for this event.

were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

OXYGEN SATURATION DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

7 days after receiving the vaccine, patient suffered excessive diarrhea and slight coughing. 9 days after vaccine, patient was tested for Covid 19, and received positive results. Patient was transported to hospital via ambulance but hospital returned her to the nursing home since chest was clear, no respiratory issues, and no fever. 10 days after receiving the vaccine, patient was turned over to hospice care but still in the nursing home. Hospice was called in to provide better physician advice and access 24/7. 14 days after receiving vaccine, patient began experiencing excruciating body aches, coughing, low oxygen levels, and no appetite. 18 days after vaccine, patient died.

No prior vaccinations for this event.

OXYGEN SATURATION DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was not seen at our facilities prior to or after COVID-19 vaccination. Patient received first dose on 1/23/2021 and as reported by the family member, patient expired on 2/5/21. Symptoms were reported to have stared on 2/1/2021, 9 days after receiving the first dose with a drop in oxygen levels and fever. He was reported to also have a history of chronic lung disease. Patient's family member to be contacted if necessary.

No prior vaccinations for this event.

OXYGEN SATURATION DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low

No prior vaccinations for this event.

oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

SOB, DOE, oxygen desaturation, nausea. Ems transport to ER for eval No prior vaccinations for this event.

OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had sore arm on the day of vaccination. Per patient's nephew , the next morning patient experienced body pains, aches, headache . Onn Tuesday patient had fever. Patient's condition progressively got worse. He had difficulty breathing by Wednesday night. He had low oxygen levels at 80 per pulse ox reading. Patient was coughing up blood. Family took him to hospital on Thursday morning due	No prior vaccinations for this event.

to breathing difficulty and patient died 2.18.21 at 10 am

OXYGEN SATURATION DECREASED	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.	No prior vaccinations for this event.

OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Caller is nephew of patient. Patient was admitted to Hospital on 2/15/21 with Covid like symptoms and decreased O2 sat. He tested positive for Covid 2/15/21. Treated with Remdesivir. Patient status continued to decline and he passed away in hospital 2/22/21 0612.	No prior vaccinations for this event.
OXYGEN SATURATION DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/13/21 Patient had covid like symptoms 2/15/21 Patient admitted to Hospital with covid like sx and decreased O2 sat; tested positive for Covid on 2/15/21; treated with Remdesivir and convalesent Plasma. Sx worsened and patient died 2/26/21..	No prior vaccinations for this event.
OXYGEN SATURATION NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.

OXYGEN THERAPY	COVID19 (COVID19 (MODERNA)) (1201)
This patient has been under hospice care for over 2 years at the nursing home. She has had a steady decline with gradual weight loss. She was totally dependent in her care needs. She received the vaccine on 1/2/2021 as part of the facility vaccination campaign. No adverse events noted initially. On 1/3/2021 at 6:06 pm, she was noted on vital sign checks (done every 4 hours for first 72 hours after vaccination) with BP 64/52 but otherwise asymptomatic. Subsequent BP improved. On 1/4/2021 at 4:45 am, pt found with respiratory rate of 30 with otherwise normal vital signs. Tachypnea persisted, so she received liquid morphine 2.5 mg without improvement. Supplemental oxygen was applied. Tachypnea persisted. She had poor oral intake after that point had persistent tachypnea and worsening hypoxemia despite clear lungs on exam. She remained under hospice care and comfort measures were continued. No blood testing or imaging tests were done. She required increasing amounts of oxygen, became hypotensive, and died peacefully on 1/8/2021 at 7:45 pm.	No prior vaccinations for this event.

OXYGEN THERAPY	COVID19 (COVID19 (MODERNA)) (1201)
Death; kidney failure (unable to urinate); shortness of breath; required oxygen; A spontaneous report was received from consumer concerning an 87-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced shortness of breath, kidney failure and death. The patient's medical history included advanced kidney and heart disease. No relevant concomitant medications were reported. On 06 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 17 Jan 2021, the husband reported that the patient experienced adverse events. Symptoms included shortness of breath and kidney failure (unable to urinate). The patient was admitted to the hospital and discharged to hospice. Oxygen was administrated for shortness of breath. Action taken with mRNA-1273 in response to the events was not applicable. On 20 Jan 2021, the patient died. The cause of death was unknown. Autopsy details were unknown.; Reporter's Comments: This case concerns a 87-year-old, female patient with the medical history of advanced kidney and heart disease,	No prior vaccinations for this event.

who experienced fatal unexpected event of dyspnea, renal failure and death. The events of dyspnea and renal failure occurred 12 days and the event of death occurred 15 days after the first dose of mRNA-1273 (Lot: unknown). The patient was admitted to the hospital and discharged to hospice. Oxygen was administrated for shortness of breath. The cause of death was unknown. Autopsy details were unknown. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, the history of advanced kidney and heart disease may remain as confounder. Additional information has been requested.; Reported Cause(s) of Death: Unknown cause of death

OXYGEN THERAPY	**COVID19 (COVID19 (MODERNA)) (1201)**
"86yo female alert, stable with ankle abrasion eating 100% prior to vaccine in assisted living facility. On 2/1/2021, received Moderna vaccine. Starting thereafter, eating 50% on 2/2/21. Temperature was 98 tympanic. On 2/3, the leg abrasion started having moderate bleeding. On 2/4, the caregiver noted patient ""not looking good, unable to talk, arms moving aimlessly, grasping"". BP 95/41, temperature 98, oxygen on room air 92-93%. POA did not want hospital transfer. 2/5 Hospice started, oxygen given, morphine given. 2/5-2/8 comfort care given, patient responsive to tactile stimuli, resting, not taking oral medications or food. 2/8/2021 patient expired."	No prior vaccinations for this event.
OXYGEN THERAPY	**COVID19 (COVID19 (MODERNA)) (1201)**
Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed	No prior vaccinations for this event.

away at 2127

OXYGEN THERAPY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client tested positive for COVID-19 by rapid test on 1/8/21. On 1/9/21 at 1405 his oxygen saturation dropped to 86% and oxygen was initiated at 2L per nasal cannula. A non-productive cough was noted on 1/10/21 and oxygen was increased to 3L. On 1/12/21 Client became non-responsive with 30 second periods of apnea. Dexamethasone was initiated on 1/13/21. Lung sounds were noted with crackles on 1/15/21 at 1158 and at 2120 Client was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.	No prior vaccinations for this event.

OXYGEN THERAPY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also	No prior vaccinations for this event.

received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

OXYGEN THERAPY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.

No prior vaccinations for this event.

PACEMAKER GENERATED RHYTHM

COVID19 (COVID19

	(MODERNA)) (1201)
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).	No prior vaccinations for this event.
PACKED RED BLOOD CELL TRANSFUSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Fever 101.1, unresponsive episode. Transferred to Hospital on 1/28. Diagnosis there was anemia and CHF, aware that he had vaccine day prior. Transfused with 2 units pRBC's. Transferred back to Nursing Home on 1/30 and passed away 0140 1/31/2021	No prior vaccinations for this event.
PACKED RED BLOOD CELL TRANSFUSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to	No prior vaccinations for this event.

ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy

(albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

PAIN

COVID19 (COVID19 (MODERNA)) (1201)

Resident had body aches, a low O2 sat and had chills starting on 12/30/20. He had stated that they had slightly improved. On 1/1/21 he sustained a fall with a diagnosis of a displaced hip fracture. On 1/2/21 during the NOC shift his O2 sat dropped again. He later went unresponsive and passed away.

No prior vaccinations for this event.

PAIN

COVID19 (COVID19

(MODERNA)) (1201)

Found dead at home slumped on the floor; Loss of appetite; Body aches; Feverish; A spontaneous report was received from a physician, concerning a 65-years-old male patient, who received Moderna's COVID-19 Vaccine and experienced feverish, body aches, loss of appetite, and death. The patient's medical history, as provided by the reporter, included diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia. Concomitant medications reported included metformin, glimepiride, lisinopril, atorvastatin, aspirin, methimazole, propranolol, and cilostazol. On 05 Jan 2021, prior to the onset of events, the patient received the first of two planned doses of mRNA-1273 (lot number 037k20a) for COVID-19 infection prophylaxis. On an unknown date in Jan 2021, some time after receiving the vaccine, the patient was feeling feverish with body aches and loss of appetite. On 09 Jan 2021 at approximately 21:30, the patient was found dead at home slumped on the floor. According to the paramedics, the patient was dead longer than when his wife found him, and no resuscitation was performed. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events, feverish, body aches, loss of appetite, was considered resolved. The patient died on 09 Jan 2021. The cause of death was not reported. The reporter assessed the event, death, as not related to Moderna's COVID-19 Vaccine. The reporter did not provide assessment for the events, feverish and body aches, in relation to Moderna's COVID-19 Vaccine.; Reporter's Comments: This case concerns a 65 year old male patient with medical history of diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia, who experienced the serious unexpected event of death, non-serious unexpected event of loss of appetite, and non-serious expected events of fever and body pain. The event of death occurred 5 days after the first dose of mRNA-1273. The events of fever, body pain and loss of appetite occurred an unspecified period of time after the first dose of mRNA-1273. Very limited information regarding these events has been provided at this time. Based on temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Definitive causal association is confounded by age and medical history of diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and

No prior vaccinations for this event.

hypertriglyceridemia.

	PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
"Client came to nursing station about 2pm to report she ""was not feeling well"". Nurses took vital signs, then referred her to the vaccination clinic that was onsite. She was observed by vaccination team for a period of time. She reported shoulder pain radiating into shoulder blade in arm vaccine was received. Vaccination team offered ice pack to her, observed for a period of time, and released back to work. About 10pm that evening, she sent a text to another coworker that her pain was ""off the charts"" and that she had pain covering her whole left side of her body. She did not come to work in the morning and did not contact work. Well being check was performed at approximately 9am on 2/2/2021 and she was found dead in her home. 911 was immediately called and authorities took over the scene."		No prior vaccinations for this event.

	PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
1-2 days after vaccine, pt developed weakness, fatigue, body aches, nausea, headache and poor appetite. Pt was admitted to the hospital on 2/5/21 and death occured on 2/6/21		No prior vaccinations for this event.

	PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
I video chatted with her Thursday after receiving the vaccine. My mom was in poor health but she was talking in complete sentences and responded appropriately. She was upright in bed and made eye contact. She smiled and denied pain. By Sunday, she was extremely weak and unable to sip water with a straw. Her health had changed dramatically and rapidly. She moaned in pain and was very fatigued. Her condition continued to deteriorate over the week and she stopped talking and was constantly sleeping. They started antibiotics for the oozing cancer lesion and then morphine for pain and end of life care. She passed away on January 22nd		No prior vaccinations for this event.

which was 15 days post vaccination.

	PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
	Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.	No prior vaccinations for this event.
	PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
	Pt was hospitalized Jan 18, 2021 after he had fallen outside overnight and lay there approximately 12 hours until he was found. Hypothermic & rhabdomyolis diagnosis. Gradually improved w/ strength & mental status - was in swing bed @ hospital. He got his first Covid 19 shot on 2-8-21. Was fine @ 0300 on 2-9-21 and @ 0430 he was found unresponsive. Dx: probable arrythmia & pronounced dead @ 0454. Noted on pain scale @ 2/8/21 @ 21:11, clients pain was a 7/10 They offered pain med & he refused They repositioned & distracted him @ 2047 on 2/8/21 Pain had decreased to 3/10 and nothing given. Then @ 0300 check he was sleeping and @ 0430 unresponsive.	No prior vaccinations for this event.
	PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
	Individual developed severe body aches, severe shoulder discomfort, high fevers (documented max temp.	No prior vaccinations

103.7 F). Daughter reported that she became non-responsive with high fevers, and when the fevers decreased she was more lucid. Her condition rapidly progressed to nausea vomiting, diarrhea and patient died on 2/9/2021.		for this event.
	PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
pt woke up at 0400 with fever, chills, and body aches progressing over 4 hours to the point when she became unresponsive. husband called 911, pt was declared dead at the time of EMS arrival around 1200		No prior vaccinations for this event.
	PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen		No prior vaccinations for this event.

levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.		
PAIN		**COVID19 (COVID19 (MODERNA)) (1201)**
Do not know if patient informed her physician that she received vaccine on 1/29/2021. She had appt at 3:15 pm on 1/29 and afterwards stated she received the Moderna vaccine. Reporter is uncertain if this was at a health office or clinic. She drove herself to the ER at about 3am on 1/30/2021 with increased cramping and pain.		No prior vaccinations for this event.
PAIN		**COVID19 (COVID19 (MODERNA)) (1201)**
"Possible heart attack on 2/5/21. Complaint: "" On Feb 5th I believe I experienced a mild hear attack"" (Comment: He said he felt ""clammy, sweaty, excruciating pain on my left side - including his left arm, and left leg, dizzy, exhausted."" This happened after work, and after taking a shower. He said that was the first time he's experienced it, and that it has not happened since then. He said he has constant headaches, ""It just went away yesterday.""""		No prior vaccinations for this event.

	PAIN	**COVID19 (COVID19 (MODERNA)) (1201)**
	Died at home; Gasping for air/difficulty breathing; Soreness; A spontaneous report was received from a physician concerning a 45 years-old, female patient who experienced soreness/MedDRA PT: pain, gasping for air/difficulty breathing/MedDRA PT: dyspnoea and subsequently died/MedDRA PT: death. The patient's medical history included blood pressure (disorder not specified), thyroid disorder, depression and anxiety. Concomitant product use included blood pressure medication, thyroid medication and possibly depression and anxiety medication. On 28 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot #007M20A) (route of administration and injection site not provided) for prophylaxis of COVID-19 infection. On 28 Jan 2021, following the vaccination, the patient was fine but had experienced some soreness. Per patient's coworker, the patient did not take any medication as it made the patient sick. The physician was not aware of any complaints from the vaccine. On 13 Feb 2021 at 3:31am, the patient called 911. Per the 911 call, the patient was gasping for air on the call and having difficulty breathing. The patient subsequently died on 13 Feb 2021 at home. The physician inquired whether Moderna gets involved with the autopsy and logistics of the death of patients and wanted to know the time frame for reporting a death of a patient who received the vaccine. The physician did not know who administered the patient's vaccine. Action taken with mRNA-1273 in response to the events was not applicable as the patient deceased. The event died was fatal. The outcome for the events soreness and gasping for air/difficulty breathing was unknown. The patient died on 13 Feb 2021. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter's Comments: Very limited information regarding the event of dyspnea and death has been provided at this time. Further information has been requested. Patient's medical history of blood pressure is considered a risk factor. Based on the current available information and temporal association between the use of the product and the onset of the pain, a causal relationship cannot be excluded.; Reported Cause(s) of Death: Died at home	No prior vaccinations for this event.
	PAIN	**COVID19 (COVID19**

(MODERNA)) (1201)

EXTREME PAIN, STOPPED EATING/DRINKING -- STARTED MORPHINE No prior vaccinations for this event.

PAIN **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

No adverse effects from vaccination seen on 1/2/21. On 1/6/21 resident was seen by Dr and her baclofen pump was refilled with 20 ml Baclofen 4,000mcg/ml. ITB Rate increased by 6% to 455.5 mcg/day simple continuous rate over 3 days. On 1/8/21 at 0615 resident was shaking, lower extremities mottled, Sa02 70%, pulse 45. Oxygen started at 2 L/m per NC. At 0715 her primary physician was notified as well as her daughter. Oxygen increased to 4 L/min, sats at 83%. SOA noted, reported all over pain. At 0850 when they attempted to reposition the resident, she was not responsive. Licensed nurse assessed her and no heartbeat heard or pulse found. No prior vaccinations for this event.

PAIN **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

54 y/o M with PMH of HTN, HLD, Alcoholic Cirrhosis, Aortic Valve Stenosis, and angina BIBA as a Medical Alert for cardiac arrest noted PTA. Per EMS, the patient called because he was having constant, diffuse abdominal pain x 1 day that radiated to his chest. On scene, the patient had a witnessed arrest with EMS starting CPR. He was given 3 rounds of epi without ROSC. Pt had no associated shockable rhythm. Of note, pt's wife, had noted pt had received covid vaccine the prior day. No prior vaccinations for this event.

PAIN **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever No prior vaccinations for

and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away		this event.
	PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/9/2021 observed with elevated respirations of 38-42 per minute, BP manually 72/50. pulse is jumping rapidly between 110-16 bpm. oxygen sat 76% RA, resident refusing oxygen at first attempt, allowed oxygen to be placed, is now 84% on 4L. resident shaking head yes that he is hurting, and yes that he would take medication for pain. Dr. notified, branch block. Received order for morphine 2mg per hr as needed for elevated respirations and pain. Dr. also gave orders to D/C Tamsulosin and finasteride. Resident continue with decreased O2 sats and elevated respirations. Absence of vital signs on 1/10/21 at 826PM.		No prior vaccinations for this event.
	PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic. Client tested positive for COVID-19 by rapid testing on 1/21/21, with c/o hurting all over and loose stools. She became non-verbal on 1/23/21 with poor intake. On 1/24/21 at 0537 Client was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.		No prior vaccinations for this event.
	PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Same day as vaccination given, developed pain went from arm up to shoulder, to back, to neck to head - right side of body; chills/body aches	No prior vaccinations for this event.
PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/29/21 patient began not feeling well and saw her provider. The doctor gave her fluids and tramadol for pain. They noticed increased confusion, but thought that could have been due to the tramadol. They also increased her gabapentin as she was experiencing nerve pain. Patient also developed a rash and was diagnosed with shingles on 2/1/21. Patient died on 2/3/21	No prior vaccinations for this event.
PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
view 2/5/2021 09:23 e Progress Note Note Text: Patient passed away in the facility this morning. view 2/5/2021 08:39 Orders - Administration Note Note Text: Resident passed. view 2/5/2021 08:33 Nurses Note Note Text: Body released to funeral home at this time. Personal effects sent with resident include: 1 pair of glasses, 1 yellow wedding band, 1silver spoon ring, 1 ring with black and clear stones. Resident has own teeth view 2/5/2021 08:32 Nurses Note Note Text: cause of death per CRNP failure to thrive. view 2/5/2021 07:44 Orders - Administration Note Note Text: Take and document temp & PO2 every 4 hours for MONITORING Resident passed. view 2/5/2021 06:49 Nurses Note Note Text: Son returned call and was updated of resident's passing this am view 2/5/2021 06:33 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Unknown Resident expired @ 0604 [linked] view 2/5/2021 06:06 Nurses Note Note Text: Res found without pulse or respirations. Pronounced at 0604. Updated. N/o's for RN to pronounce, release body to funeral home, dispose of medications per facility policy. Daughter updated. Funeral Home called to release body. view 2/5/2021 05:26 Orders - Administration Note Note	No prior vaccinations for this event.

Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Pulse ox 60% on O2 @ 5L/min via mask. Resps 44 per minute. view 2/5/2021 01:57 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/5/2021 00:52 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Residents resps are 40 per minute, pulse ox 76% on O2 @ 5L/min via mask. Resps are labored, shallow and rapid. view 2/5/2021 00:48 Nurses Note Note Text: Nonresponsive to verbal and tactile stimulation. Appears comfortable. view 2/4/2021 22:01 Nurses Note Note Text: Resident resting comfortably, breathing becoming increasingly shallow, wearing O2 via mask at 5L via mask, no dyspnea noted, feet are mottled, oral and peri care provided Q2H. No s/s of pain or discomfort. view 2/4/2021 21:40 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective [linked] view 2/4/2021 19:32 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger medicated for air hunger, RR 28 to 32/ min view 2/4/2021 19:22 Nurses Note Note Text: Daughter updated on N/O to increase Morphine Sulfate 20mg/mL 0.25mL to Q2H prn from Q6H prn. view 2/4/2021 18:06 Nurses Note Note Text: POA Daughter and daughter aware of residents current condition. view 2/4/2021 11:58 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/4/2021 11:13 Nurses Note Note Text: Pt. noted to be lethargic at this time. Does respond to verbal and tactile stimuli by opening her eyes but non verbal currently. Skin warm and dry. No mottling or apnea observed at this time. O2 sat 88% with O2 at 2 LPM via n/c. On increased to 3 LPM via mask as pt. noted to be mouth breathing. Respirations 28. F/U O2 sat 93%. HOB elevated. Pt. medicated with morphine by LPN. Daughter updated on pt.'s condition. Does not want pt. sent out to hospital and would like comfort measures to continue. Daughter also in agreement with delay in d/c d/t pt.'s condition.CRNP updated on pt.'s condition, delay in d/c and daughter's wishes. No n/o's at this time. view 2/4/2021 10:56 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB Resident

showing s/s of discomfort. SOB at this time and high respirations. Repositioned, changed for incontinence care and mouth care provided. view 2/4/2021 10:34 Progress Note Note Text: Spoke with RN regarding change in condition. Updated Sr Living regarding change. Recommendation to cancel d/c/transfer for today, see how resident does through the weekend and re-evaluate on Monday. Daughter updated on cancellation of d/c today. view 2/4/2021 10:04 Nurses Note Note Text: Daughter aware that resident's O2 sat was 88% on room air on 3-11 shift and that oxygen was applied via nasal cannula. view 2/4/2021 10:03 Nurses Note Note Text: N/O: Discharge 2/4/21 with scripts to Sr. Living. Daughter aware. view 2/4/2021 09:53 Nurses Note Note Text: Pt. to be d/c'd to another facility this am as per MD order. Pt. alert and responsive. Skin assessment done as per facility policy. No pressure areas noted at this time. No s/sx of pain or discomfort observed at this time. V.S. 97.0 67 20 O2 sat 95% with O2 at 2 LPM via n/c. view 2/4/2021 07:45 Nurses Note Note Text: Resident seen by Dr. for discharge. Orders pending at this time. view 2/4/2021 07:36 Nurses Note Note Text: CRNP and Dr. updated on O2 sat 88% on RA with f/u of 93% with O2 on at 2 LPM as well as rest of VS, 3-11 shift 2/3/21. No n/o's at this time. view 2/3/2021 21:17 Nurses Note Note Text: Resident Sp02 88% on RA. Pulse 124. Respirations 40. PRN morphine given and O2 applied via NC at 2L/min. After recheck pulse ox up to 93%, pulse 100, and respirations 22. Resident appears comfortable at this time. view 2/3/2021 20:05 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective [linked] view 2/3/2021 19:48 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN given for SOB after elevation of HOB not effective. view 2/3/2021 11:51 Nurses Note Note Text: CRNP updated rapid COVID test done for d/c tomorrow was negative. No n/o's at this time. view 2/3/2021 11:44 Nurses Note Note Text: Daughter notified of rapid covid swab being negative. view 2/3/2021 09:50 Orders - Administration Note Note Text: Obtain Rapid Covid test on 2/3/2021 for discharge. Please give copy of results to Social Worker every day shift for covid testing for 1 Day Completed and negative. view 2/3/2021 08:45 Skilled Nursing Note Reason for skilled service: Therapy describe skilled service: Nursing, therapy assessment: V.S. 97.8 79 18 138/84 Orientation: Oriented to self only. Oxygen: O2 sat 94% on RA Edema: Trace edema noted BLE. Pedal pulses present. Pain: Denies pain or discomfort at this time. Nursing note: Pt. alert and responsive. Skin warm and dry. Lung sounds diminished. No respiratory distress observed at

this time. Abdomen soft. BS+ in all 4 quads. Continent/Incontinent of B&B. 1 assist with ambulation, transfers. 1 assist with ADL's. Working with therapy on gait training, therapeutic exercise, therapeutic activities & neuromuscular reeducation. view 2/2/2021 14:37 Progress Note Note Text: Per health professional at Sr Living, prepared to accept patient to their Memory Care Unit 2/4. Transportation arranged for 11 AM per family request. Daughter (POA) updated on d/c time on 2/4/21. Facility requesting rapid COVID test completed prior to d/c and results sent to them. All other information sent for continuity of care.

PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
7 days after receiving the vaccine, patient suffered excessive diarrhea and slight coughing. 9 days after vaccine, patient was tested for Covid 19, and received positive results. Patient was transported to hospital via ambulance but hospital returned her to the nursing home since chest was clear, no respiratory issues, and no fever. 10 days after receiving the vaccine, patient was turned over to hospice care but still in the nursing home. Hospice was called in to provide better physician advice and access 24/7. 14 days after receiving vaccine, patient began experiencing excruciating body aches, coughing, low oxygen levels, and no appetite. 18 days after vaccine, patient died.	No prior vaccinations for this event.

PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
right arm swelling immediately after injection. followed by bilateral lower leg edema, chills and body aches that continued daily at 2 weeks post immunization admin 2/4/21 treated with dexamethasone 6mg PO x 7 days- this resolved his s/s 2/13/21 patient passed away at facility	No prior vaccinations for this event.

PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.	No prior vaccinations for this event.
PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
(02/15/2021): vaccine (02/16/2021) : severe body aches and weakness, increased congestion and mucous production. (02/16-17/2021) : death possibly during the night	No prior vaccinations for this event.
PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease	No prior vaccinations for this event.

progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or

if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

PAIN

COVID19 (COVID19 (PFIZER-BIONTECH))

		(1200)
Resident received the 2nd dose of the Covid vaccine approximately around 1105 by pharmacy through the pharmacy LTC partnership vaccination program. Resident had no adverse effects until around 8:00 pm she began complaining of body aches, and chills, Tylenol was given at this time. Around 9:30pm resident was sleeping in bed. Around 12:00 am the CNA called nurse into room to assess resident as the resident stated she did not feel good. Temperature at that time was 102.2, and vomiting. RN came to assess @ 1220 am She was noted to be vomiting, diaphoretic, pale and having trouble breathing. Temp was 97.3 after vomting, Pulse 53, Resp 20, o2 sats were 40-45%, unable to obtain Blood pressure, Applied 5 L of oxygen at this time and had LPN call 911 immediately. Resident was repsonsive and able to follow staff members instructions but was only answering yes or no simple questions at the time time of assessment. Paramedics arrived at 0040 and resident was sent to Hospital. @ 0130 ER nurse called to nursing facility to notify resident had coded in the ER and passed away @ 0110.		No prior vaccinations for this event.
	PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had sore arm on the day of vaccination. Per patient's nephew , the next morning patient experienced body pains, aches, headache . Onn Tuesday patient had fever. Patient's condition progressively got worse. He had difficulty breathing by Wednesday night. He had low oxygen levels at 80 per pulse ox reading. Patient was coughing up blood. Family took him to hospital on Thursday morning due to breathing difficulty and patient died 2.18.21 at 10 am		No prior vaccinations for this event.
	PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient felt achy, tired starting the day after the vaccine. Per his wife, he was very tired and ""losing		No prior vaccinations for

stamina"". On 2/13/21, he woke up feeling dizzy and weak. His wife asked him if he wanted to go to the doctor and he declined. He ate breakfast and went to rest in his easy chair. He passed away an hour later."		this event.
	PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Pt he reports he developed chills SOB body aches the same night as receiving the COVID vaccine on 1.26.2021-pt is currently reporting CheSt tightness and SOB Admitted to hosp: ICU with Bilateral Pulmonary Emboli, LLE DVT, NSTEMI, Arrhythmia.		No prior vaccinations for this event.
	PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient, age 101, was having a period of declining health prior to vaccine administration. This continued after the vaccine to include increased pain, inability to swallow and ultimately Patient passed away on 1/9/2021. The physician does not believe this is due to vaccine administration, however family asked that this information be reported for record keeping.		No prior vaccinations for this event.
	PAIN IN EXTREMITY	**COVID19 (COVID19 (MODERNA)) (1201)**
on 12/24/2020 the resident was sleepy and stayed in bed most of the shift. He stated he was doing okay but requested pain medication for his legs at 250PM. At 255AM on 12/25/2020 the resident was observed in bed lying still, pale, eyes half open and foam coming from mouth and unresponsive. He was not breathing and with no pulse		No prior vaccinations for this event.

PAIN IN EXTREMITY		**COVID19 (COVID19 (MODERNA)) (1201)**
"1-2-2021 10:30 PM Complained Right arm/back hurt - took Tylenol 1-3-2021 Complained Right arm hurt, dizzy 1-4-2021 Felt better - did laundry, daughter found her deceased at 3:30 pm. Dr. at hospital said it was ""cardiac event"" according to death certificate."	No prior vaccinations for this event.	
PAIN IN EXTREMITY		**COVID19 (COVID19 (MODERNA)) (1201)**
My dad got the Moderna Vaccine on Tuesday, January 12, 2021 in his left arm at the Mall injection site for the Health Department. He was told that the side effects could mean his arm hurting, tiredness, headache, and even a low grade fever. Additionally, the site informed us both (as I was with him to get the injection) that this was all normal and not to seek medical attention unless these symptoms last longer than 72 hours. That evening, my dad was experiencing all of those symptoms, and went to bed at 7pm. A little after 10am on Wednesday, January 13, 2021, when he awoke, my dad went to the bathroom vomiting. This was where he collapsed and went into cardiac arrest. Fire/Rescue was dispatched about 10:30am after my mom started CPR. County Fire Rescue EMTs and Paramedics continued CPR and other attempts at reviving him all the way to Hospital Emergency Department. He was pronounced dead at 12:14pm on Wednesday, January 13, 2021. We have no doubt my dad, following the instructions of the injection facility, thought he was just experiencing the side effects of the vaccine. He had no chance. Had this injection been done in the RIGHT arm, perhaps he could have recognized the arm numbness being that of an impending heart attack. We really miss Dad. He served this country with distinction for over 50 years, and we believe his country failed him.	No prior vaccinations for this event.	
PAIN IN EXTREMITY		**COVID19 (COVID19 (MODERNA)) (1201)**
Death Narrative: Patient received the first COVID-19 dose on 12/23. Afterwards, patient complained of localized pain on L deltoid area where the vaccine was administered; his temperature was 98.1 F. On 12/26-	No prior vaccinations	

27, staff reported that patient appeared more fatigued than usual and was shivering on 12/27, which seized after blanket was given. On 12/28, patient presented with fever (Tmax 100.2 F) and acetaminophen was administered for alleviation of fever. ADR was reported for the fever on 12/29. Patient continued to decline and was placed back on hospice care on 12/29; on 12/30. the symptoms reported on nursing note include erythema and pain on whole L arm. Lidocaine was applied. Patient's family and provider mutually agreed not to administer the second dose of vaccine. He continued to decline and was started on end-of-life care around 1/4 and passed on 1/20 1417.		for this event.
	PAIN IN EXTREMITY	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient texted a friend on 2/7/2021 c/o arm pain and feeling tired. I don't know if he was taken to a hospital. Autopsy today.		No prior vaccinations for this event.
	PAIN IN EXTREMITY	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received vaccination on 2/4. Patient's wife reported that he felt a slight soreness in his arm the day following the shot, but had no other symptoms. On 2/8 he passed away. Wife reports that it was related to his heart and they never made it to a hospital. The wife also reported that the patient had been in poor health prior to the vaccination		No prior vaccinations for this event.
	PAIN IN EXTREMITY	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had the first Moderna Covid vaccine on Thursday 1/21/2021. She had a bit of sore arm on that day and the day after. On Saturday 1/23/2021, she had a fever of 100.5 F (11AM), nausea, light headache and chills. The temperature went down after she took ibuprofen. Patient's husband enrolled her to V-Safe to report all the adverse effects she experienced. On Sunday 1/24/2021, her temperature was 98.3F. She still had		No prior vaccinations for this event.

nausea and no appetite. She and her husband watched a football game in their bedroom upstairs. Husband noticed that his wife was pacing around the room many times. At 7Pm, Husband went downstairs for dinner but she refused to come down to eat. He went upstairs around 8pm, TV was still on. He turned off TV and went down stairs again thinking his wife felt as sleep while watching TV. He went back upstairs for bed around 10:30 PM. Husband said his wife had a deviated septum so she would snore very loudly when asleep. He didn?t hear her snoring so he went to check on her and found her not responsive. Husband called emergency services. Paramedic came at 10:45 and said patient was passed. Husband sent many texts to V-safe after that to report the incident. No response was received from V-safe. Patient?s doctor told her husband that she died due to cardiac arrest.

PAIN IN EXTREMITY

COVID19 (COVID19 (MODERNA)) (1201)

"The patient came to the Emergency Room at approx 3:30 am on 02/03/2021 with pain in right arm (same arm the COVID vaccine had been administered in approx 12 hours earlier) and feeling generally unwell. Patient was concerned about possibility of gout flare or that something was wrong with her arm. Elevated blood pressure was noted; this was attributed to anxiety. She was evaluated, given 500 mg Tylenol, and discharged since the pain was decreasing and blood pressure was stabilized. Patient instructed to follow-up with physician. The next day, on 02/04/2021, the patient arrived at the Emergency Room by ambulance; cardiac arrest was the chief complaint. The patient's daughter stated the patient had been ""feeling generally poor and then suddenly collapsed."" Daughter described ""gurgling respirations"" and being unresponsive. 911 was called, police arrived within 5 minutes and initiated CPR. Epinephrine, atropine, lidocaine and bicarb administered after arrival to Emergency Room. Shockable rhythm never demonstrated. Patient never recovered spontaneous respiration or movement. The death was called at 23:04. Coronary artery disease with cardiac arrest is the cause from the ER records; the coroner is putting COVID-19 vaccination in Part 1 of the death certificate."

No prior vaccinations for this event.

PAIN IN EXTREMITY

COVID19 (COVID19

	(MODERNA)) (1201)
2/12/2021 woke up with sore arm and back. 2/13/2021 woke up with headache around 1am. Headache and nausea all morning. Mid-late afternoon started having seizures. Admitted to Hospital 2/15/2021 expired. Reported per wife on 2/25/2021.	No prior vaccinations for this event.
PAIN IN EXTREMITY	**COVID19 (COVID19 (MODERNA)) (1201)**
"Possible heart attack on 2/5/21. Complaint: "" On Feb 5th I believe I experienced a mild hear attack"" (Comment: He said he felt ""clammy, sweaty, excruciating pain on my left side - including his left arm, and left leg, dizzy, exhausted."" This happened after work, and after taking a shower. He said that was the first time he's experienced it, and that it has not happened since then. He said he has constant headaches, ""It just went away yesterday.""""	No prior vaccinations for this event.
PAIN IN EXTREMITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Arm hurting used his oxygen at time of bed appeared vomited. No prior vaccinations for this event.	
PAIN IN EXTREMITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Same day as vaccination given, developed pain went from arm up to shoulder, to back, to neck to head - right side of body; chills/body aches	No prior vaccinations for this event.
PAIN IN EXTREMITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

she was hurting at her chest/ Chest pain; on her left arm hurt real bad that's what the clot on her left arm; on her left arm hurt real bad that's what the clot on her left arm; She passed away; heart attack; This is a spontaneous report from a contactable consumer. An 87-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Jan2021 at single dose for COVID-19 immunisation. Medical history included diabetes mellitus, for which she was taking a pill like an hour before she would take her meal. On Monday (Jan2021) the patient experienced was hurting at her chest/ chest pain, her left arm hurt real bad as she had a blockage in her left arm/clot on her left arm, and they wanted to put in a stent and after the surgery it went well and she all go home in two days. The patient was hospitalized in Jan2021 due to the events. She had a heart attack and that the chamber between the dividers had a hole in it and her heart tissue was too thin so much thin she couldn't repair it. The patient passed away on 26Jan2021. The patient was tested negative for COVID-19 on unknown date. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: She passed away

No prior vaccinations for this event.

PAIN IN EXTREMITY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

her arm was sore but no other adverse reactions until Saturday, Feburary 6th 2021 she had stroke between 4 and 6pm. She died within 6 to 7 hours later.

No prior vaccinations for this event.

PAIN IN EXTREMITY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Swollen leg/pain- taken to urgent care- became unresponsive - CPR initiated- expired

No prior vaccinations for this event.

PAIN IN EXTREMITY

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia	No prior vaccinations for this event.
PAIN IN EXTREMITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall; fatigued; arm pain; AML; Sepsis secondary to AML; This is a spontaneous report from a contactable consumer. An 88-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EL3249), via an unspecified route of administration on 19Jan2021 17:30 in right arm at single dose for covid-19 immunization. Medical history included hypertension, hyperlipidemia, OA (osteoarthritis), cognitive impairment. No other vaccine in four weeks was administrated. Concomitant medication in two weeks included atorvastatin, aspirin, calcium, gabapentin, losartan and memantine hydrochloride (NAMENDA). The patient previously took lisinopril and tetracycline and both experienced allergies. The patient had no covid prior vaccination. The patient initially had no symptoms but arm pain in Jan2021, no bleeding or bruising from injection. On 31Jan2021 19:00, patient felt fatigued. Patient suffered fall on 01Feb2021. She was admitted to hospital. All cell lines were down in Feb2021. She was diagnosed with AML (acute myeloid leukemia) in 2021. She expired 07Feb2021. Events resulted in emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event) and patient died. The patient received the treatment of blood and platelet transfusions, bone marrow biopsy, cytogenetic testing, antibiotics, intubation for events. The patient died on 07Feb2021 due to sepsis secondary to AML. An autopsy was not performed. Outcome of events were fatal.; Reported Cause(s) of Death: arm pain; fatigued; fall; Sepsis secondary to AML; Sepsis secondary to AML	No prior vaccinations for this event.

	PAIN IN EXTREMITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had COVID in Sept. Minimal symptoms. Received 1st dose 1/18 without adverse reactions. Second dose on 2/8-had complaints of arm soreness several days after then appeared in usual state of health. On 2/14 @ 2 hours after having lunch, patient was found unresponsive with Respirations 60, pulse 130, PO 84%, blood pressure 105/68. Patient with lots of white foam coming out of mouth. Temperature to 101.3. Patient DNR B and family deferred transfer, wanted comfort measures only. Nursing received order for MSIR. Patient continued with temps in 99-100 range with tylenol suppositories. Patient passed on 2/16.		No prior vaccinations for this event.
	PAIN IN EXTREMITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had sore arm on the day of vaccination. Per patient's nephew , the next morning patient experienced body pains, aches, headache . Onn Tuesday patient had fever. Patient's condition progressively got worse. He had difficulty breathing by Wednesday night. He had low oxygen levels at 80 per pulse ox reading. Patient was coughing up blood. Family took him to hospital on Thursday morning due to breathing difficulty and patient died 2.18.21 at 10 am		No prior vaccinations for this event.
	PAIN IN EXTREMITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was into the clinic on the afternoon of 2/23/21 for a COVID-19 vaccine. He had a podiatry clinic visit after his vaccine same day. It was reported by the patients family physician that patient stated he didn't feel well and suddenly collapsed at home at approximately 4:45 pm. Emergency medical personnel were not		No prior vaccinations for this event.

able to revive him. Patient died at approximately 4:45 pm on 2/23/21.

PAIN IN EXTREMITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had only complained of a sore arm after receiving the vaccine- pt died on 2/25/21 from what they feel was a massive heart attack- unsure if related to vaccine at all	No prior vaccinations for this event.
PAIN IN EXTREMITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Minor arm pain on 2nd day of each vaccine Diarrhea 3 days after 2nd vaccine Massive heart attack (left ventricle) 8 days (2/24/21) after vaccine Home hospice 3:30pm 2/24/21 Stopped breathing 5:45 am, pronounced dead at 8:22 am on 2/25/21	No prior vaccinations for this event.
PAIN IN JAW	**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation	No prior vaccinations for this event.
PALLOR	**COVID19 (COVID19**

	(MODERNA)) (1201)
on 12/24/2020 the resident was sleepy and stayed in bed most of the shift. He stated he was doing okay but requested pain medication for his legs at 250PM. At 255AM on 12/25/2020 the resident was observed in bed lying still, pale, eyes half open and foam coming from mouth and unresponsive. He was not breathing and with no pulse	No prior vaccinations for this event.
PALLOR	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second dose of COVID vaccine on 01/20/2021 at 1430. At 1600 Pt developed a wet productive cough with coarse crackles. Pt ate dinner at 5 pm cough persisted. At 18:30 the nurse went to Pt's room to give him his medications. Pt still had a cough, denied shortness of breath. Pt was in a good mood and joking with staff. Pt asked to be shaved. At 19:45 Pt was sitting in the lounge and a CNA noticed that Pt was pale/white in color and clammy. 02 Sat was 85%. Respirations were labored. Pt was placed on 4 L of 02. Increased to 5 L via face mask and 02 sat was 89-90%. Ambulance was called at unknown time. Pt arrived at Medical Center at 2120 and was pronounced dead at 2127.	No prior vaccinations for this event.
PALLOR	**COVID19 (COVID19 (MODERNA)) (1201)**
ON 1/21/2020 RESIDENT WAS EXPERINCING CHILLS AND LOOSE STOOLS. FOLLOWING THIS EPISODE BECAME UNRESPONSIVE, PALE, DIAPHORETIC AND BRADYCARDIC. PALLIATIVE CARE WAS PROVIDED. RESIDENT PASSED AWAY APPROX. 10 HOURS LATER.	No prior vaccinations for this event.
PALLOR	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to the Emergency Department complaining of chest pain, pale, cool diaphoretic, and	No prior vaccinations for

hypotensive. The patient was discovered to have a large saddle pulmonary embolism, went into cardiac arrest and expired. Of note, the patient received her second Moderna COVID vaccine on 1/23, which would place her first one approximately 12/25 if she received them at the appropriate interval. This information is from the patient's daughter and the ED record, the information is not available in CAIR. Per the daughter, the patient started feeling ill on 1/21, improved on 1/25, and then acutely worsened on 1/27, resulting in the ED visit.		this event.
	PALLOR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was okay, but he was very agitated; reported as not like this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for		No prior vaccinations for this event.

vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away		
	PALLOR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 10 minutes after receiving the COVID- 19 vaccine resident displayed seizure activity, staring straight ahead and strong allover muscle jerking of both the up and lower extremities, color became gray, activity lasted approximately 3 minutes, resident then became relaxed, color returned to normal, BP-140/80, 97.8, 60, 16, sleeping the remainder of the shift,. Resident continued to decline until resident CTB on 1/19/21		No prior vaccinations for this event.
	PALLOR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began feeling nauseated on 1/18/21 around 6pm, and had uncontrolled diarrhea, reported that she		No prior vaccinations for

did not feel right. Staff reported to this writer, that her skin tone was gray in tone and she just didn't look good. She was transferred to the HOSPITAL ER VIA AMBULANCE.

this event.

PALLOR

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident received the 2nd dose of the Covid vaccine approximately around 1105 by pharmacy through the pharmacy LTC partnership vaccination program. Resident had no adverse effects until around 8:00 pm she began complaining of body aches, and chills, Tylenol was given at this time. Around 9:30pm resident was sleeping in bed. Around 12:00 am the CNA called nurse into room to assess resident as the resident stated she did not feel good. Temperature at that time was 102.2, and vomiting. RN came to assess @ 1220 am She was noted to be vomiting, diaphoretic, pale and having trouble breathing. Temp was 97.3 after vomting, Pulse 53, Resp 20, o2 sats were 40-45%, unable to obtain Blood pressure, Applied 5 L of oxygen at this time and had LPN call 911 immediately. Resident was repsonsive and able to follow staff members instructions but was only answering yes or no simple questions at the time time of assessment. Paramedics arrived at 0040 and resident was sent to Hospital. @ 0130 ER nurse called to nursing facility to notify resident had coded in the ER and passed away @ 0110.

No prior vaccinations for this event.

PALLOR

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pale, Short of Breath, Hypoxic, Lethargic within minutes became unresponsive and died.

No prior vaccinations for this event.

PALLOR

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pale, not eating, no urine output After 1st covid vaccine

PALPITATIONS **COVID19 (COVID19 (MODERNA)) (1201)**

"Patient is reported to have died at home, the day after his COVID test. Family member states that he did good the afternoon and evening after his COVID-19 injection, but that he started not feeling good the next day. The patient ""was having palpitations"". The family tried to convince him to go to the Emergency Room, but he refused. Patient died at home."

No prior vaccinations for this event.

PALPITATIONS **COVID19 (COVID19 (MODERNA)) (1201)**

Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021and felt poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM CHLORIDE 1000 MG ONCE

No prior vaccinations for this event.

PALPITATIONS **COVID19 (COVID19 (MODERNA)) (1201)**

Patient had no symptoms or adverse events until the next evening after shot (1/29/21) where daughter reported her having heart palpitations. Family told her to rest and did not seek medical attention. Saturday afternoon (1/30/2021), patient started experiencing labored breathing. Daughter called 911 and before the

No prior vaccinations for this event.

ambulance arrived, the patient's breathing became more and more shallow. Patient was taken to the local hospital and passed away Saturday evening around 5:30 pm.

PALPITATIONS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Symptoms: Palpitations & Syncope Treatment: EPINEPHRINE 1 MG ONCE ,EPINEPHRINE 1 MG ONCE ,SODIUM BICARBONATE 50 ML ONCE	No prior vaccinations for this event.

PALPITATIONS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/28/2021- Seen by FNP for indigestion, chest pressure and palpitations. EKG reviewed and referral made to Cardiology. 1/29/2021-1800 Presented to ED in cardiac arrest-onset PTA. Patient was found unresponsive by his wife at their home. The last known well was at 1530 when she called him on the phone. The patient was pronounced at ~1850.	No prior vaccinations for this event.

PANCYTOPENIA	**COVID19 (COVID19 (MODERNA)) (1201)**
High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like	No prior vaccinations for this event.

chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

	PANCYTOPENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.		No prior vaccinations for this event.
	PANCYTOPENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM		No prior vaccinations for this event.
	PANIC DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.	No prior vaccinations for this event.
PARACENTESIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death ""cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its components or a severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed. MDs recommending hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative	No prior vaccinations for this event.

status. 1/29 Pt passed away."

	PARALYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.		No prior vaccinations for this event.

	PARALYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)		No prior vaccinations for this event.
	PAROSMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.		No prior vaccinations for this event.
	PATIENT ISOLATION	**COVID19 (COVID19 (MODERNA)) (1201)**
This is the patient who passed away 2d after his second COVID vaccine. Of note, the 2/8 telephone note makes it sound like he was hospitalized at time of death - that is incorrect. His daugther listed as EM contact works in the eye clinic here. He had mild illness, completed 10d isolation but missed his scheduled booster dose on 2/2 due to isolation. He was called on 2/5 when there was a booster visit cancellation and received his booster dose on that day. His daugther reported that he was doing fine and looking well on 2/7 AM, ate breakfast, shortly after stood up and just collapsed.		No prior vaccinations for this event.
	PCO2 DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR		No prior vaccinations for this event.

status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

PCO2 INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

PCO2 INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis

No prior vaccinations for this event.

involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

PCO2 NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.
PEMPHIGOID	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient (now deceased) received 1st dose of Pfizer-BioNTech vaccine around December 21, 2020 and was noticed to be scratching, fatigued, and unresponsive by a family member on December 24, 2020. He received the second dose of the same vaccine around January 22, 2021. Pockmarks and bleeding scratch marks were noted by a family member on the patient's face prior to this second dose. On January 28, 2021 a family member was alerted that the patient was suffering from severe bullous pemphigoid- a skin condition that has never been experienced by the patient, has been reported to be related to COVID-19 viral infection, and to T-	No prior vaccinations for this event.

cell responses promoted by vaccines. A corticosteroid was given, but did not work. Blisters developed to the point hands had to be dressed.

PERICARDIAL EFFUSION		**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.	

PERICARDIAL EFFUSION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion; On 21Feb he went to the ER after vomiting and passing out; On 21Feb he went to the ER after vomiting and passing out; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; fever; headache; stomach upset; This is a spontaneous report from a contactable consumer reporting for the father: A 75-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EL3428) at single dose at left arm on 03Feb2021 for Covid-19 immunisation. Medical history included type 2 diabetes mellitus. No known allergies. The patient had not experienced Covid-19 prior vaccination. Concomitant medication in 2 weeks included amitriptyline hydrochloride (manufacturer unknown) 10 mg, atorvastatin (manufacturer unknown) 20 mg, dutasteride (manufacturer unknown) 0.5 mg, linaclotide (LINZESS) 290 mcg, gabapentin (manufacturer unknown) 300 mg, montelukast (manufacturer unknown) 10 mg, ramipril (manufacturer unknown) 5 mg, insulin degludec (TRESIBA) 100 unit/ml, liraglutide (VICTOZA) 18 mg/3ml solution. No other vaccine in 4 weeks. The patient experienced cardiac arrest due to pericardial effusion on 21Feb2021 14:15, fever on 13Feb2021, headache on 13Feb2021, stomach upset on 13Feb2021, on 19feb, he began to feel ill again with a fever, he felt worse on 20feb on 19Feb2021, on 21feb he went to	No prior vaccinations for this event.	

the ER after vomiting and passing out on 21Feb2021. Events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of cardiac arrest due to pericardial effusion. Course of events: In Feb2021, 10 days after his 1st injection, the patient developed fever, headache, and stomach upset. He went for a rapid Covid-19 test (nasal swab) and it was negative on 11Feb2021. The doctor told him he might be having a delayed reaction to the vaccination. After a couple of days, he improved. On 19Feb2021, he began to feel ill again with a fever. He felt worse on 20Feb2021. On 21Feb2021 he went to the ER after vomiting and passing out and received treatment: IV fluids, diagnostic testing at ER. Rapid Covid test (nasal swab) at ER came back negative again on 21Feb2021. His heart arrested suddenly and he could not be resuscitated. CT scan results, that came back after death, showed Covid like pneumonia and pericardial effusion. The patient died on 21Feb2021 14:15. Cause of death was cardiac arrest due to pericardial effusion. An autopsy was not performed. The outcome of cardiac arrest due to pericardial effusion was fatal, of fever, headache, stomach upset was recovering, of he began to feel ill again with a fever, he felt worse was not recovered, of he went to the ER after vomiting and passing out was unknown.; Reported Cause(s) of Death: cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion		
PERICARDITIS		**COVID19 (COVID19 (MODERNA)) (1201)**
"The decedent experienced severe chest pain and dyspnea approximately nine days following the first series of the vaccine. He reported to family members that he was having a ""severe reaction"" to the vaccine and believed it was acute pericarditis due to the same symptoms he experienced prior. He reported that on 2/1/21 around 0300 hours, the symptoms were the most severe and he was going to seek medical attention, but did not. He waited till the convenient store opened and purchased OTC Tylenol for relief of symptoms. He continued to have dyspnea and chest pain up until 2/9/21, when he called 911 complaining of chest pain and was found to have a STEMI; subsequently died at Hospital in the ER."	No prior vaccinations for this event.	
PERIORBITAL OEDEMA		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely.""

No prior vaccinations for this event.

1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan

10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

PERIPHERAL COLDNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awake at 0300. When going into the room to get him ready for dialysis he was cold to touch, unresponsive other than to sound, and nonverbal. O2 sat was 67 via finger probe. Oxygen immediately initiated and a venturi mask retrieved and initiated. When unable to arouse him via sternal rub this RN called 911. Send to ED. Febrile 39.2 and hypotensive 58/43. Admitted. unknown after that as patient expired in hospital.		No prior vaccinations for this event.
PERIPHERAL COLDNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received COVID19 vaccine at clinic at 11:52 am, discharge post treatment stable. Got home around 2:30 pm went to bed. He usually got tired post dialysis. He did not wake up at 6 pm. His wife went check on him. found patient cold and unresponsive. 911 pulseless PEA. ER Medical hospital. Pronounced death at 7:40 pm		No prior vaccinations for this event.
PERIPHERAL COLDNESS		**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival.		No prior vaccinations for this event.

CPR was continued until family could be reached and decision was made to stop resuscitation.

	PERIPHERAL COLDNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On December 17, 2020, my husband, received his first BioNTech BNT162b2 COVID-19 vaccination. On Thursday January 7, 2021, he received this second COVID-19 vaccination. The following three days after his second vaccination, he felt fine. The fourth day, on Sunday January 10, my husband felt extremely fatigued. On Monday the 11th and Tuesday the 12th, he worked a full shift but complained of extreme fatigue and extreme chills to the point that his teeth were chattering while on the phone with me. He decided to work through it. When he got home on Monday night, he started vomiting. On Wednesday January 13, he woke up and had swollen eyes. Once again, he felt extremely fatigued, even after a full nights rest. He had the day off but had an early meeting. After his meeting, he was still tired so he went back to sleep. I left to get lunch, and drop off our kids, and upon my return, I found him on the walk in closet floor, face up, having passed away. He felt as cold as ice. The rapid test done after they called the paramedics resulted in a negative COVID-19 test for him.		No prior vaccinations for this event.

	PERIPHERAL COLDNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21- N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol		No prior vaccinations for this event.

administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

PERIPHERAL COLDNESS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On the evening of 2/23/221 at 9:00 pm, resident reported feeling SOB, BP 80/44, Pulse 53, O2Sat 95% on 3L oxygen, hands cold, pulse weak. Temp 92.5F MD notified. EMS activated. EMS arrival and HR 20. Family refused transport to ER. Resident expired at 2:40 am on 2/24/21 Meds continued: duloextine, VITd2,hydralazine, synthroid, lisinopril, mag ox, folplex, pantoprazole, potassium chloride, ellipta, ensure, hydrocortisone cream, boost, deprox, xanax, morphine, lorazepam, tylenol, albuterol inhlation, ventolin inh.

No prior vaccinations for this event.

PERIPHERAL SWELLING

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Legs started swelling and shortness of breath Thursday January 21 2021 Was rushed to hospital with kidney failure and fluid build up around lungs and entire body Blood pressure dropped and had multiple organ failure	No prior vaccinations for this event.	
PERIPHERAL SWELLING		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Swollen leg/pain- taken to urgent care- became unresponsive - CPR initiated- expired	No prior vaccinations for this event.	
PERIPHERAL SWELLING		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia	No prior vaccinations for this event.	
PERIPHERAL SWELLING		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
right arm swelling immediately after injection. followed by bilateral lower leg edema, chills and body aches that continued daily at 2 weeks post immunization admin 2/4/21 treated with dexamethasone 6mg PO x 7 days- this resolved his s/s 2/13/21 patient passed away at facility	No prior vaccinations for this event.	

	PERIPHERAL SWELLING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.		No prior vaccinations for this event.
	PERIPHERAL SWELLING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was into the clinic on the afternoon of 2/23/21 for a COVID-19 vaccine. He had a podiatry clinic visit after his vaccine same day. It was reported by the patients family physician that patient stated he didn't feel well and suddenly collapsed at home at approximately 4:45 pm. Emergency medical personnel were not able to revive him. Patient died at approximately 4:45 pm on 2/23/21.		No prior vaccinations for this event.
	PERIPHERAL SWELLING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to		No prior vaccinations for this event.

death of patient prior to lab company arrival.

	PERIPHERAL SWELLING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting	No prior vaccinations for this event.

to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away

PERITONEAL LAVAGE

COVID19 (COVID19 (MODERNA)) (1201)

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.

No prior vaccinations for this event.

PETECHIAE

COVID19 (COVID19 (MODERNA)) (1201)

Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

No prior vaccinations for this event.

PETECHIAE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also

No prior vaccinations for this event.

started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.

PH URINE NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

PH URINE NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT

No prior vaccinations for this event.

revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

PH URINE NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency

No prior vaccinations for this event.

department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

PHARYNGEAL SWELLING

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On Saturday, 1/16/2021, Patient went to the grocery store. Upon her return, she indicated she was experiencing N/V and some throat swelling. Patient subsequently collapsed and expired before she could be brought to an emergency room. During investigation by Coroners Office, it has been reported that Patient may have gotten some takeout food while she was out. Labs are pending and the Coroners

No prior vaccinations for this event.

investigation is ongoing. Spouse believes that her death was caused by the vaccine.

PHARYNGEAL SWELLING	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
73-year-old man s/p first dose of Pfizer at 10:20 AM Ambulated comfortably to exit after 20 minutes in observation but 10:45 collapsed while exiting the building 10:47 CPR initiated 10:49 medical team/EMS found no pulse, agonal respirations, ventricular fibrillation Paramedics and team performed ACLS; of note patient was intubated 7.5 ETT with bilateral breath sounds on ventilation; paramedic reported easy intubation with no apparent throat swelling; 11:02 transported to Emergency Department 11:30 Pronounced dead at Emergency Department	No prior vaccinations for this event.

PHYSICAL EXAMINATION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also	No prior vaccinations for this event.

received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

PLATELET COUNT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.

No prior vaccinations for this event.

PLATELET COUNT DECREASED

COVID19 (COVID19

(MODERNA)) (1201)

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.

No prior vaccinations for this event.

PLATELET COUNT DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

patient developed autoimmune thrombocytopenia No prior vaccinations for this event.

PLATELET COUNT DECREASED **COVID19 (COVID19 (MODERNA)) (1201)**

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

PLATELET COUNT DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.

No prior vaccinations for this event.

PLATELET COUNT DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

jaundice->hemolytic anemia-> hemorrhagic shock->multi organ failure->death pt admitted to ICU 2/16 with Hgb=3.4, treated with steroids, supportive care , pressors, pt died 2/20/21	No prior vaccinations for this event.
PLATELET COUNT DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.
PLATELET COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the	No prior vaccinations for this event.

evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

PLATELET COUNT DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care

No prior vaccinations for this event.

center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

PLATELET COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received dose #1 of COVID-19 vaccine (Pfizer-BioNTech) on 12/18/20 and dose #2 (Pfizer-BioNTech) on 1/8/21. On 1/30, patient was evaluated at urgent care due to back pain. No bloodwork done; metronidazole prescribed for 7 days. On 2/8, patient was admitted to outside hospital due to ongoing symptom progression. At time of admission, hgb 5 g/dL and plt 9k. Per Dr. (hematology/oncology), pt with schistocytes, LDH 1500, and elevated reticulocyte count consistent with thrombotic thrombocytopenic purpura (TTP). SCr >2 mg/dL. Patient immediately treated with plasma exchange and steroids, however continued to decline. Patient expired on 2/14/21.	No prior vaccinations for this event.
PLATELET COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.	No prior vaccinations for this event.
PLATELET COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.	No prior vaccinations for this event.
PLATELET COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
PLATELET COUNT INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.	No prior vaccinations for this event.
PLATELET COUNT NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to emergency room on 2/1/2021 with a chief complaint of having a chronic headache and fatigue following receipt of the Moderna vaccine 10 days prior. Following examination by the physician, the patient was diagnosed with an acute subdural hematoma. The patient subsequently underwent decompressive surgery, however demonstrated worsening neurologic status over the next several days and ultimately expired on 2/4/2021.	No prior vaccinations for this event.

PLATELET COUNT NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE,

No prior vaccinations for this event.

no acute PE.

PLATELET COUNT NORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021		No prior vaccinations for this event.
PLATELET COUNT NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.		No prior vaccinations for this event.
PLATELET COUNT NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p		No prior vaccinations for

multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.		this event.
	PLATELET COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21		No prior vaccinations for this event.
	PLATELET COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA		No prior vaccinations for this

1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	**PLATELET COUNT NORMAL**	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)** event.
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.	**PLATELET COUNT NORMAL**	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)** No prior vaccinations for this event.
Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.	**PLATELET COUNT NORMAL**	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	**PLATELET COUNT NORMAL**	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)** No prior vaccinations for this event.
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension.	**PLATELET COUNT NORMAL**	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)** No prior vaccinations for this event.

Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement

of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

PLATELET COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently	No prior vaccinations for this event.

to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

	PLATELET COUNT NORMAL	**COVID19 (COVID19 (UNKNOWN)) (1202)**
5 days after receiving his COVID vaccination the patient had a spontaneous (nontraumatic) subarachnoid hemorrhage which was fatal. The patient had previously been stable on his coumadin dosing with therapeutic INRs for the past several months per his wife. At time of presentation his blood pressure in the ER was elevated to 223/94 and his INR was risen to 3.1		No prior vaccinations for this event.
	PLATELET TRANSFUSION	**COVID19 (COVID19**

	(MODERNA)) (1201)
It was reported to staff that this gentleman suffered thrombocytopenia following his vaccine, a platelet infusion was done and he expired on 2-14-21	No prior vaccinations for this event.
PLEURAL EFFUSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29	No prior vaccinations for this event.
PLEURAL EFFUSION	**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"	No prior vaccinations for this event.
PLEURAL EFFUSION	**COVID19 (COVID19 (MODERNA)) (1201)**
1/31/2021 12:50 Nursing Note Note Text: Res had low BP, low O2 sats, 30 breaths per minute, eyes open wide, making confused utterances. Started supplemental oxygen via NC, 2L, then 3L. Sats went up to 93% for a while, Sprvsr called. Unable to auscultate Left lung sounds. Called to update Res daughter. Called to	No prior vaccinations for this event.

page NP, writer went back to assess Res and O2 sats were 88%, turned O2 to 4LPM, called 911 for transport to Hospital ED. Left around 1030. NP called back afterwards, was updated. Family updated that Res was sent to Hospital ED. Note Text: Received phone call from daughter as well as information from hospital. Resident has pneumonia with septic shock. She is on abx and had thoracentesis performed for large pleural effusion. [linked]

	PLEURAL EFFUSION	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.		No prior vaccinations for this event.
	PLEURAL EFFUSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.		No prior vaccinations for this event.
	PLEURAL EFFUSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Several days after vaccination his left arm turned red. He was taken to the hospital where he was evaluated and admitted with a diagnosis of left axillary vein thrombosis. A chest X-ray was taken and he		No prior vaccinations for this event.

presented bibasilar atelectasis and pneumonia with pleural effusions.

PLEURAL EFFUSION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Patient with past medical history of CAD, CKD, sCHF, LGL Leukemia admitted to Hospital on 1/19 with pleural effusion. Pt expired on 2/1/2021. Hs of essential HTN, complete heart block, T2Diabetes,thyroid issues, stroke, papillary CA of thyroid, dyslipidemia, anemia, hypercalcemia, pulmonary nodule, hypoparathyroidism, pacemaker, bilat carotid stenosis, afib, pleural effusion, pancytopenia, cardiomyopathy, severe aortic stenosis, sick sinus syndrome, Dressler syndrome, empyema, ESRD	No prior vaccinations for this event.

PLEURAL EFFUSION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the	No prior vaccinations for this event.

emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

PLEURAL EFFUSION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.

PLEURAL EFFUSION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to	No prior vaccinations for this event.

decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

PNEUMONIA

COVID19 (COVID19 (MODERNA)) (1201)

Resident became lethargic and reports of blood coming from resident's nose and mouth on the morning of 1/13/21. Resident went out to ER for eval, and came back to facility with dx of pneumonia and recommendations for resident to be placed on hospice. Resident deceased on 1/14/21. Unknown if vaccine related, but with timeline of events I was advised to report this per medical director of facility, as well as Pharmacy who administered the vaccine.

No prior vaccinations for this event.

PNEUMONIA

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied

No prior vaccinations for this event.

about her symptoms on the day of vaccination to get the shot.

	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
	Shortness of Breath, decreased oxygen saturation, irregular heart rhythm, hypertension, Positive for COVID, bilateral pneumonia	No prior vaccinations for this event.
	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
	Death on 1/17/21. Death certificate reports: Septic Shock, UTI, Pneumonia, Chronic Renal Failure	No prior vaccinations for this event.
	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
	The patient, who was a pharmacist, developed fatigue and shortness of breath hours after receiving vaccine. Two days later, on 01/28/2021, the patient went to local urgent care for worsening shortness of breath and was referred to Hospital for worsening dyspnea and hypoxia. The patient was admitted to the hospital We was found to have bilateral pulmonary infiltrates and treated for pneumonia with Rocephin and azithromycin. He was tested for COVID-19 multiple times, but each of the results were negative. Despite the negative results, there was high clinical suspicion for COVID-19 and the patient was started on Remdesivir and Decadron. The patient's oxygen requirements continued to worsen and the patient was transferred to another facility for higher level of care. There his hypoxia worsened and he required mechanical ventilation. Patient then developed hypotension and required vasopressors for blood pressure support. Furthermore, patient developed acute renal failure requiring hemodialysis. Despite mechanical ventilation with FiO2 100%, and for vasopressors, patient clinically deteriorated and family decided to palliatively extubate on 02/05/2021.	No prior vaccinations for this event.

	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
EARLY SUNDAY MORNING THE PATIENT BEGAN VOMITTING AND SHORT OF BREATH AND CHEST AND BACK PAIN. SHE CODED WHEN SHE GOT IN THE ER AND LATER PASSED AWAY THE MONDAY. DIAGNOSIS WAS PNEUMONIA AND HEART FAILURE PER STEP DAUGHTER.		No prior vaccinations for this event.
	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
He had not been feeling well after his second Covid vaccination (on 01/23/2021) and was found unresponsive in his room at the nursing home (late evening on 02/02/2021). He was taken to a hospital where they did tests and he had pneumonia and kidney failure, but he was being transferred to a larger hospital when he arrested and died (02/03/2021)		No prior vaccinations for this event.
	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received vaccine at Public Health Clinic. Patient ended up having a seizure 3 days later and ended up in the hospital. Found to have right lobe pneumonia and low depakote level. Patient noted to have multiple seizures at hospital, issues with stabilizing HR and BP, and passed away on 1/20/21.		No prior vaccinations for this event.
	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
1/31/2021 12:50 Nursing Note Note Text: Res had low BP, low O2 sats, 30 breaths per minute, eyes open wide, making confused utterances. Started supplemental oxygen via NC, 2L, then 3L. Sats went up to 93% for a while, Sprvsr called. Unable to auscultate Left lung sounds. Called to update Res daughter. Called to page NP, writer went back to assess Res and O2 sats were 88%, turned O2 to 4LPM, called 911 for transport		No prior vaccinations for this event.

to Hospital ED. Left around 1030. NP called back afterwards, was updated. Family updated that Res was sent to Hospital ED. Note Text: Received phone call from daughter as well as information from hospital. Resident has pneumonia with septic shock. She is on abx and had thoracentesis performed for large pleural effusion. [linked]

	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Fever by the next day, difficulty breathing, pneumonia, and then DEATH within a few days. (Died 02/01/2021)		No prior vaccinations for this event.
	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.		No prior vaccinations for this event.
	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident getting rehab therapy in the facility and has a long history of Parkinson's Disease. On 01/29/21, he received the COVID vaccine on left deltoid, resident was recently hospitalized due to Pneumonia and was on antibiotic IV and was recently placed on GT feeding due to severe dysphagia from his Parkinson's disease. On 01/31/21, started having increased congestion. On 02/02/21, started having increased temperature and WBC went up >20,000 on 02/03/21, started on Vancomycin IV on 02/04/21 but was transferred to the		No prior vaccinations for this event.

hospital. Facility was notified today (02/18/21) that resident expired in the hospital.

	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was admitted to hospital on 2-9-21 for urinary tract infection and tested positive for Covid. Developed pneumonia and expired on 2-12-21.		No prior vaccinations for this event.
	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
1-25-2021- Phone call: pt had cold and cough prior to vaccine. cough worsened 1-28-2021 Phone call: pt requesting provider visit, cough is same and taking tessalon pearls 1-29-2021 Provider in office visit: pt complain of cough and SOB for 6 days. Getting worse. Temp 101.2, pulse ox 87%, BP 128/70. level of distress- leaning forward to breath. appeared ill. diffuse rales throughout both lung fields, more at bases. Diagnosis Pneumonia due to COVID 19 virus. Sent to ER		No prior vaccinations for this event.
	PNEUMONIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Several days after vaccination his left arm turned red. He was taken to the hospital where he was evaluated and admitted with a diagnosis of left axillary vein thrombosis. A chest X-ray was taken and he presented bibasilar atelectasis and pneumonia with pleural effusions.		No prior vaccinations for this event.
	PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
COVID-19; COVID-19; Pneumonia; respiratory failure; This is a spontaneous report from a contactable		No prior vaccinations for

consumer. An 80-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 02Jan2021 for COVID-19 immunization. Medical history included Alzheimer's and others. No known allergies. Concomitant medications included unspecified medications. The reporter's mother in law was tested for COVID-19 at a nursing facility on 25Dec2020 and she was negative. On 02Jan2021, she received the first dose of Pfizer vaccine. On 04Jan2020, she developed a high fever, needed oxygen and was positive for COVID-19. Date of death was 04Jan2021. The cause of her death was listed as pneumonia, respiratory failure and COVID-19. No autopsy performed. No treatment received. No one knew if the vaccination contributed to her death. It was hard to know if her death was due to the administration of the vaccine or it exacerbated the COVID19 symptoms which led to her death. Since this was unknown, it could have been a possibility. The reporter wanted to give us this information because we might want to consider having high risk population, patients with underlying conditions, older population tested for COVID-19 prior to the vaccination, as this is not currently a recommendation or a requirement. All is very new and they are all learning so the reporter wanted to share this information with us. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There are medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. The outcome of the events was fatal. Information about Lot/Batch has been requested.; Sender's Comments: The association between the fatal event lack of effect (pneumonia, respiratory failure and COVID-19) with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19

this event.

PNEUMONIA

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
patient suddenly developed pneumonia 7 days after vaccination and died the evening of developing pneumonia	No prior vaccinations for this event.
PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient expired 1/15/2021; had been treated as outpatient for pneumonia, likely COVID-19 but no positive test result in December 2020. PMH diabetes	No prior vaccinations for this event.
PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.	No prior vaccinations for this event.
PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some	No prior vaccinations for this event.

shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."

PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"	No prior vaccinations for this event.

PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for	No prior vaccinations for this event.

a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

	PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Early in the shift on January 31 resident was noticed to be more tired than usual and was not eating well. Lung sounds were crackly and resident was found to be hypotensive. He was evaluated in emergency department. He was diagnosed with pneumonia. Received a loading dose of antibiotic and returned to facility.		No prior vaccinations for this event.
	PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Four days after being vaccinated, she developed pneumonia and died 8 days later.		No prior vaccinations for this event.
	PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver failure, pneumonia, and DIC>"	No prior vaccinations for this event.	
PNEUMONIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19.""	No prior vaccinations for this event.	

Patient expired 1/24/2021."

PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.	No prior vaccinations for this event.
PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient developed pneumonia Admitted to hospital on 12/25. Determined to have pseudomonas bacteremia and passed away on 12/27.	No prior vaccinations for this event.
PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Grandmother had trouble breathing the night she got the vaccine. She went to the hospital. They found pneumonia and a partial bowel obstruction. The obstruction cleared but she died from the pneumonia on 2/16/21.	No prior vaccinations for this event.
PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
A few days after the vaccination my father had a sore throat and slight cough. This progressed	No prior vaccinations for this event.

into pneumonia like symptoms and he died on 2/11/21.

	PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.

	PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.	No prior vaccinations for this event.

	PNEUMONIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival	No prior vaccinations for this event.

he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was

diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

PNEUMONIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient hospitalized with shortness of breath and pneumonia (from 2/15/2021 to 2/21/2021) and patient died at another facility on 3/2/2021.

No prior vaccinations for this event.

PNEUMONIA ASPIRATION

COVID19 (COVID19 (MODERNA)) (1201)

aspiration pneumonia/death No prior vaccinations for this event.

PNEUMONIA ASPIRATION COVID19 (COVID19 (MODERNA)) (1201)

On 1/26 at breakfast table began vomiting. Continued thru am when at noon a caregiver did his O2 saturation and found it was 75%. This was confirmed, and resent sent to ER .	No prior vaccinations for this event.	
PNEUMONIA ASPIRATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient did not have any adverse reaction to the COVID vaccine, but we were asked by our health dept to submit a VAERS report since the patient died between his first and second dose. Received Pfizer Dose #1 12/17/2020. No side effects or adverse events noted; lived in 24/7 care facility and monitored twice daily for reaction. Date of death 12/23/2020 from aspiration pneumonia complicated by end-stage heart failure and ischemic cardiomyopathy. Death was anticipated and not sudden.	No prior vaccinations for this event.	
PNEUMONIA ASPIRATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness; respiratory distress Narrative: Patient tolerated his 1st dose of the COVID-19 vaccine well, on 12/16/2020, and received his 2nd dose on 1/6/2021. Patient had some mild clinical decline the past few days prior to 2nd vaccination, with a decreased appetite and some increased fatigue per nursing report, but no significant changes. He experienced nausea on the evening of 1/6/21, which was effectively managed, but by early morning he spiked a fever of 102.9 with a sat of 86.1%. He continued to deteriorate from that point on and died 1/7/21 @13:20. Clinically, the presentation was most consistent with an aspiration pneumonia.	No prior vaccinations for this event.	
PNEUMONIA ASPIRATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I	No prior vaccinations for	

(person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.

this event.

PNEUMONIA ASPIRATION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

emesis bright yellow in color, liquid BM, increased respirations No prior vaccinations for this event.

PNEUMONIA ASPIRATION **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

My father was in weak condition to begin with. He didn't get out of bed for the next few days after receiving the vaccine. The little amount that he ate was consumed in bed. He began aspirating his food which lead to pneumonia. He wasn't strong enough to fight off the pneumonia even with antibiotics. He died on 1/23/21. While he might have passed soon in any case, I believe that the vaccine may possibly have increased his weakness/exhaustion thereby hastening his demise.

No prior vaccinations for this event.

PNEUMONIA ASPIRATION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status:

No prior vaccinations for this event.

SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

PNEUMONIA ASPIRATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Death Narrative: Patient received first dose of COVID vaccine on 1/30/21. Reported by his wife to agency that he passed away at an outside hospital on 2/14/21. By report of his wife: ""due to sepsis (related to bed sores) and aspiration pneumonia"""	No prior vaccinations for this event.
PNEUMONIA BACTERIAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Approximately 2 weeks after the first COVID vaccine she developed shortness of breath that was much more significant than she had previously. This was the first time she had expressed this symptom to me as being something she was concerned about and difficult for her to manage (we have spoken almost daily for many years). Within 24 hours of the second dose of the mRNA vaccine, they called an ambulance to get her and she was taken to the hospital and diagnosed with bacterial pneumonia. The doctors said it was	Breathing issues ~2 weeks after first dose of mRNA vaccine in the series but were not nearly as acute or severe as they were fol

unrelated, but I found a study with a different vaccine (LAIV) that also seemed to increase the incidence of bacterial pneumonia. They hypothesized through diverting the immune system. So while I don't think the vaccine gave her the bacteria, I do think it may have caused her immune system to be temporarily compromised allowing the bacteria to grow out of control. I feel this is important to report to look for these types of patterns as perhaps it can help others avoid the death spiral that happened to my mother. There were also intervening events between her hospitalization and her death including two successful surgeries (one for a broken hip and another to put in stents in her leg). So to summarize, the first vaccine was within about 2 weeks of the onset of her breathing problems. Within 24 hours of the second vaccine she was hospitalized and diagnosed with bacterial pneumonia. As she was battling bacterial pneumonia in the hospital she broke her hip and was found to have reduced peripheral circulation and had 2 surgeries to correct those. They were successful according to the surgeons, however she died within a week or so of the surgeries. She had other comorbidities as well which I'm sure predisposed her such as diabetes, hypertension and cancer for many years.

PNEUMONITIS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized

No prior vaccinations for this event.

further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib

fractures on the right at ribs 2 through

PNEUMONITIS CHEMICAL	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20	No prior vaccinations for this event.

without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending

work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

	PNEUMOTHORAX	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a	No prior vaccinations for this event.

result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away

PO2 INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

PO2 NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was

No prior vaccinations for this event.

at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

PO2 NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration

No prior vaccinations for this event.

pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

POISONING

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.
POLLAKIURIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1-12-21 Resident is complaining of heart pain. Resident blood pressure is 228/105. 1-22-21 Dx UTI 1-13-21 His nurse called MD at approximately 0645, reported to him that it was reported to this nurse that resident has not slept in 2 days and night, has an increased blood pressure, reports severe pain in lower back, and appears to be uncomfortable Resident is able to verbalize his pain and where it is at, but is unable to	No prior vaccinations for this event.

explain the quality of the pain or give a number on the 0/10 pain scale.

	POLYCHROMASIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
	POLYMERASE CHAIN REACTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.		No prior vaccinations for this event.
	POLYMERASE CHAIN REACTION POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.

No prior vaccinations for this event.

POLYNEUROPATHY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.

Influenza Vaccine

POLYURIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He

No prior vaccinations for this event.

complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA,

Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

POOR PERIPHERAL CIRCULATION

COVID19 (COVID19 (MODERNA)) (1201)

Approximately 2 weeks after the first COVID vaccine she developed shortness of breath that was much more significant than she had previously. This was the first time she had expressed this symptom to me as being something she was concerned about and difficult for her to manage (we have spoken almost daily for many years). Within 24 hours of the second dose of the mRNA vaccine, they called an ambulance to get her and she was taken to the hospital and diagnosed with bacterial pneumonia. The doctors said it was unrelated, but I found a study with a different vaccine (LAIV) that also seemed to increase the incidence of bacterial pneumonia. They hypothesized through diverting the immune system. So while I don't think the vaccine gave her the bacteria, I do think it may have caused her immune system to be temporarily compromised allowing the bacteria to grow out of control. I feel this is important to report to look for these types of patterns as perhaps it can help others avoid the death spiral that happened to my mother. There were also intervening events between her hospitalization and her death including two successful surgeries (one for a broken hip and another to put in stents in her leg). So to summarize, the first vaccine was within about 2 weeks of the onset of her breathing problems. Within 24 hours of the second vaccine she was hospitalized and diagnosed with bacterial pneumonia. As she was battling bacterial pneumonia in the hospital she broke her hip and was found to have reduced peripheral circulation and had 2 surgeries to correct those. They were successful according to the surgeons, however she died within a week or so of the surgeries. She had other comorbidities as well which I'm sure predisposed her such as diabetes, hypertension

Breathing issues ~2 weeks after first dose of mRNA vaccine in the series but were not nearly as acute or severe as they were fol

and cancer for many years.

POSTHAEMORRHAGIC HYDROCEPHALUS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."	No prior vaccinations for this event.
POSTOPERATIVE WOUND INFECTION	**COVID19 (COVID19 (MODERNA)) (1201)**

Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse	No prior vaccinations for this event.

POSTURE ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Staff reported that patient was found Friday morning (Jan 8) sitting at a table with his head tilted forward and unresponsive to verbal or physical stimuli. Staff lowered patient to floor and started CPR. EMS was called and continued CPR at scene, however they were not able to revive patient. Patient was pronounced dead at the scene. Staff written statements following the death of patient show that he had a fall about 1 hr. prior. It is unknown if this fall contributed to patient's death. An autopsy has been requested.	No prior vaccinations for this event.

POSTURE ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
patient received vaccine on 1/20/2121, later that night husband found her slumped in chair, called EMS and patient was taken to Hospital where she died on 1/21/2021	No prior vaccinations for this event.

POSTURE ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Veteran was found by family slumped over and unresponsive at the breakfast table on 1/13/21, had expired	No prior vaccinations for this event.
POSTURE ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
passed away; cough; This is a spontaneous report from a contactable consumer, the patient's daughter. A 92-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration in the left arm on 13Jan2021 at 11:00 (at the age of 92-years-old) as a single dose for COVID-19 immunization. Ongoing medical history included nursing home resident, admitted to hospice on 13Jan2021 (prior to vaccination), and oxygen supplementation (due to low oxygen levels) from a few days prior to the vaccine (Jan2021). Other relevant medical history included congestive heart failure from Dec2020 and sulfa allergy. Prior to the vaccination, the patient was tested numerous times (as reported) for COVID-19 and was negative. There were no concomitant medications. The patient did not receive any other vaccines within four weeks prior to the vaccination. A few days before the vaccination, her oxygen level had gone down, and she had been placed on oxygen. Prior to receiving the vaccine, the patient was reported as being 'fine'. On 13Jan2021, the patient received the vaccine at 11:00. The patient coughed maybe 5 or 6 times and then dropped her head. Resuscitation was not performed as patient had a do not resuscitate (DNR) order. The patient passed away on 13Jan2021 at 13:05. The cause of death was not reported. An autopsy was not performed. The clinical outcome of the cough was unknown at the time of death. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Reported Cause(s) of Death: passed away	No prior vaccinations for this event.
POSTURING	**COVID19 (COVID19 (MODERNA)) (1201)**

Rapid decline in health status, Elevated BP&P, posturing, loss of consciousness, Glasgow coma Scale 4 starting 2/1/2021, Deceased 2/3/21

No prior vaccinations for this event.

POSTURING

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

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POSTURING

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known

No prior vaccinations for this event.

Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

PREALBUMIN	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for	No prior vaccinations for this event.

CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

PRESYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
Moderna Vaccine Lot 029K20A Patient received second dose of vaccine on 2/2/21. Within 30 minutes patient had a near syncopal episode. She felt lightheaded and shortly after had episode of nonbloody vomiting. Hypotensive 81/69 and started on levophed. Alert and orientated. Lungs clear, abdomen benign on admission. Patient had no reaction when received first dose of the vaccine. Patient developed worsening shortness of breath, tachypnea, Afib with RVR, hypotension and required intubation and multiple pressors.	No prior vaccinations for this event.

PRESYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per EMS, the patient was last seen walking and talking to wife 10 minutes prior to EMS arrival. EMS reports via patients wife, that patient was upstairs to change for his doctor appointment then patient's wife found	No prior vaccinations for this event.

him down. The patient received his COVID-19 vaccine on 1/25/21. EMS states they gave 5 rounds of EPI then patient moved into vfib then was shocked once but returned to asystole. In ED, the patient initially in asystole CPR was started immediately. The patient was given 3 rounds EPI, 1 round bicarb. The patient stayed in PEA throughout. Patient was given tPA. Patient continued to be in asystole and time of death was called at 11:35 am.

PROCALCITONIN DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass	No prior vaccinations for this event.

away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

PROCALCITONIN INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied

No prior vaccinations for this event.

about her symptoms on the day of vaccination to get the shot.

	PROCALCITONIN INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.		No prior vaccinations for this event.

	PROCALCITONIN INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR		No prior vaccinations for this event.

unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."

PROCALCITONIN INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral	No prior vaccinations for this event.

pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some

time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

PROCALCITONIN INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable

No prior vaccinations for this event.

to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

PROCALCITONIN INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.

No prior vaccinations for this event.

PROCALCITONIN INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)

No prior vaccinations for this event.

PROCALCITONIN INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
PROCTITIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.
PRODUCT USE ISSUE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice, memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200	No prior vaccinations for this event.

mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation: tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed, metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil

exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral patchy opacities

PRODUCTIVE COUGH

COVID19 (COVID19 (MODERNA)) (1201)

Pt received second dose of COVID vaccine on 01/20/2021 at 1430. At 1600 Pt developed a wet productive cough with coarse crackles. Pt ate dinner at 5 pm cough persisted. At 18:30 the nurse went to Pt's room to give him his medications. Pt still had a cough, denied shortness of breath. Pt was in a good mood and joking with staff. Pt asked to be shaved. At 19:45 Pt was sitting in the lounge and a CNA noticed that Pt was pale/white in color and clammy. 02 Sat was 85%. Respirations were labored. Pt was placed on 4 L of 02. Increased to 5 L via face mask and 02 sat was 89-90%. Ambulance was called at unknown time. Pt arrived at Medical Center at 2120 and was pronounced dead at 2127.

No prior vaccinations for this event.

	PRODUCTIVE COUGH	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident expired on 2/5/21 at 03:35pm, about 25 hours after second dose of vaccine. At breakfast, resident was spitting a lot of secretions, coughing up liquids from nose and phlegm, facial swelling, which were all symptoms that he was struggling with prior to both doses of COVID vaccine, but had increased more than prior incidences on 2/5/21. Gurgling noted in upper airways, hyscolamine given, bath given to loosen secretions, morphine given. Family notified and came into facility for compassionate care visit around 1300. 1400 HR was 3 and RR was 2, but increased back to 60 and 12 within 20 minutes. Then resident expired at 1535.		No prior vaccinations for this event.
	PRODUCTIVE COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21		No prior vaccinations for this event.
	PRODUCTIVE COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19		No prior vaccinations for

on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back

this event.

to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

PRODUCTIVE COUGH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/15: Pfizer vaccine dose 1 administered 1/16: Fever, chills 1/22: Sore throat, coughing w/white phlegm, taking Tylenol and Mucinex. Fever and chills from 1/16 subsided. Had telehealth consultation with PA. Per her notes, patient said he gets these symptoms annually, requested for an antibiotic. PA referred him for a COVID test. Ordered hydrocodone/chlorphen ER suspension for his cough and an antibiotic. Antibiotic was recommended if symptoms do not subside. 1/23: COVID test administered 1/25: Reported positive for COVID 1/26: Telehealth session w/PA: she informed patient of his positive test, advised to quarantine and seek medical help at hospital if symptoms worsen. Patient reported that his sore throat mostly subsided but is still coughing at night. Said that the pharmacy didn't receive the prescription order for the antibiotic, so this was re-ordered. 1/31: Partner found him dead at 8:18AM on his bed. Death certificate issued by state says cause of death: COVID. Autopsy was not performed. Buried on 2/9/21.

No prior vaccinations for this event.

PRODUCTIVE COUGH

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.	No prior vaccinations for this event.
PRODUCTIVE COUGH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.	No prior vaccinations for this event.
PROGRESSIVE BULBAR PALSY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia	No prior vaccinations

and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.		for this event.
	PROSTATE CANCER METASTATIC	**COVID19 (COVID19 (MODERNA)) (1201)**
chills 1 day after vaccine administration; found dead by family 1/18/2021 Narrative: Per patient family report, patient said the next day after vaccination that he didn't feel well because of chills. Patient was found dead at home by his family on January 18th. He was a 74yo man with castrate resistant prostate cancer and liver and bone metastases with rising PSA, status post intravenous chemotherapy 1/7/21		No prior vaccinations for this event.
	PROSTATIC SPECIFIC ANTIGEN INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
chills 1 day after vaccine administration; found dead by family 1/18/2021 Narrative: Per patient family report, patient said the next day after vaccination that he didn't feel well because of chills. Patient was found dead at home by his family on January 18th. He was a 74yo man with castrate resistant prostate cancer and liver and bone metastases with rising PSA, status post intravenous chemotherapy 1/7/21		No prior vaccinations for this event.
	PROTEIN ALBUMIN RATIO INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"		No prior vaccinations for this event.

PROTEIN TOTAL	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"	No prior vaccinations for this event.

PROTEIN TOTAL	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21	No prior vaccinations for

reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	this event.
PROTEIN TOTAL DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass	No prior vaccinations for this event.

away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

PROTEIN TOTAL INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration

No prior vaccinations for this event.

PROTEIN TOTAL NORMAL

COVID19 (COVID19

(MODERNA)) (1201)

Patient has end stage renal disease and rapidly worsening dementia, family could no longer care for him at home, and he was admitted for 14-day quarantine prior to admission to inpatient hospice. Received vaccine on 1/12 without apparent adverse reactions. Patient started refusing oral intake on 1/16, and CMP on 1/17 showed hypernatremia 165 (new issue). His BUN 138 CREAT 6.93 K 5.2 were his baseline. He was found to be deceased on 1/18 at 11:18 pm.

No prior vaccinations for this event.

PROTEIN TOTAL NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

PROTEIN TOTAL NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push

No prior vaccinations for this event.

1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

PROTEIN TOTAL NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
PROTEIN TOTAL NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.	No prior vaccinations for this event.
PROTEIN URINE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of	No prior vaccinations

chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

for this event.

PROTEIN URINE PRESENT

COVID19 (COVID19 (MODERNA)) (1201)

Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29

No prior vaccinations for this event.

PROTEIN URINE PRESENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o

No prior vaccinations

some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or for this event.

multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

PROTHROMBIN TIME PROLONGED

COVID19 (COVID19 (MODERNA)) (1201)

"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."

No prior vaccinations for this event.

PROTHROMBIN TIME PROLONGED

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

PROTHROMBIN TIME PROLONGED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.
PROTHROMBIN TIME PROLONGED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
PROTHROMBIN TIME PROLONGED	**COVID19 (COVID19 (UNKNOWN)) (1202)**

5 days after receiving his COVID vaccination the patient had a spontaneous (nontraumatic) subarachnoid hemorrhage which was fatal. The patient had previously been stable on his coumadin dosing with therapeutic INRs for the past several months per his wife. At time of presentation his blood pressure in the ER was elevated to 223/94 and his INR was risen to 3.1

No prior vaccinations for this event.

PRURITUS

COVID19 (COVID19 (MODERNA)) (1201)

began itching within 24 hours, within 5 days couldn't move on her own, by 6th day was having respiratory issues, by day 7 unresponsive, by day 8 dead

No prior vaccinations for this event.

PRURITUS

COVID19 (COVID19 (MODERNA)) (1201)

itchy skin, swelling, disorientation that led to a fall No prior vaccinations for this event.

PRURITUS **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient (now deceased) received 1st dose of Pfizer-BioNTech vaccine around December 21, 2020 and was noticed to be scratching, fatigued, and unresponsive by a family member on December 24, 2020. He received the second dose of the same vaccine around January 22, 2021. Pockmarks and bleeding scratch marks were noted by a family member on the patient's face prior to this second dose. On January 28, 2021 a family member was alerted that the patient was suffering from severe bullous pemphigoid- a skin condition that has never been experienced by the patient, has been reported to be related to COVID-19 viral infection, and to T-cell responses promoted by vaccines. A corticosteroid was given, but did not work. Blisters developed to the point hands had to be dressed.

No prior vaccinations for this event.

PRURITUS

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Day After - severe headache, 2 days after headache continues, itchy scalp, day 3 rash visible at hair line headache continues, more confusion than normal, day 4 on site nurses check rash and think it is dermatitis, day 5 continues to get work nurse practitioner was to visit next day, day 6 NP thinks that she has UTI and sends her to hospital (2/11/21). Hospital determines - Rash is Shingles, UTI present, - MRSA is now present in shingles which is on right back of head and right neck and face. Next Sepsis is diagnosed. Since 2/11/21 patient was not conscious. 2/20/21 famiy is notified that she should be moved to Hospice. Moved to hospice on 2/20/21. The patient, my mother, died on 2/23/21 official cause of death is UTI.

No prior vaccinations for this event.

PSEUDOMONAL BACTERAEMIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient developed pneumonia Admitted to hospital on 12/25. Determined to have pseudomonas bacteremia and passed away on 12/27.

No prior vaccinations for this event.

PSYCHOMOTOR HYPERACTIVITY

COVID19 (COVID19 (MODERNA)) (1201)

Patient had the first Moderna Covid vaccine on Thursday 1/21/2021. She had a bit of sore arm on that day and the day after. On Saturday 1/23/2021, she had a fever of 100.5 F (11AM), nausea, light headache and chills. The temperature went down after she took ibuprofen. Patient's husband enrolled her to V-Safe to report all the adverse effects she experienced. On Sunday 1/24/2021, her temperature was 98.3F. She still had nausea and no appetite. She and her husband watched a football game in their bedroom upstairs. Husband noticed that his wife was pacing around the room many times. At 7Pm, Husband went downstairs for dinner but she refused to come down to eat. He went upstairs around 8pm, TV was still on. He turned off TV and went down stairs again thinking his wife felt as sleep while watching TV. He went back upstairs for bed around 10:30 PM. Husband said his wife had a deviated septum so she would snore very loudly when asleep.

No prior vaccinations for this event.

He didn?t hear her snoring so he went to check on her and found her not responsive. Husband called emergency services. Paramedic came at 10:45 and said patient was passed. Husband sent many texts to V-safe after that to report the incident. No response was received from V-safe. Patient?s doctor told her husband that she died due to cardiac arrest.

PULMONARY CONGESTION

COVID19 (COVID19 (MODERNA)) (1201)

Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face, increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia

No prior vaccinations for this event.

occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

PULMONARY CONGESTION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.

No prior vaccinations for this event.

PULMONARY CONGESTION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

REPORTING ONLY AS RESIDENT EXPIRED ON 1/17/2021 3 DAYS AFTER. S/S HYPOXIA/CONGESTED LUNG SOUNDS

No prior vaccinations for this event.

PULMONARY CONGESTION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident is a Hospice patient. On 1-23-2021 am shift resident was observed by nursing have chest congestion and had a emesis times 1 with SOB, Zofran 4 mg was given. HOB (02 sats 88%) was elevated resident on 02 via nasal canula with 02 sat now @ 90% . no respiratory distress noted. MD was called with response pending for orders. @ 1400 resident with no signs of life. vs 90%-24-97/71-97.6. Hospice on site and time of death 1436

No prior vaccinations for this event.

PULMONARY EMBOLISM

COVID19 (COVID19

(MODERNA)) (1201)

Not sure if it has to do with the COVID vaccine but her caregiver reported to me today (1/27/20201) that she passed away on 01/16/2021 from a pulmonary embolism that was 18 days after vaccine	No prior vaccinations for this event.

PULMONARY EMBOLISM

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to the Emergency Department complaining of chest pain, pale, cool diaphoretic, and hypotensive. The patient was discovered to have a large saddle pulmonary embolism, went into cardiac arrest and expired. Of note, the patient received her second Moderna COVID vaccine on 1/23, which would place her first one approximately 12/25 if she received them at the appropriate interval. This information is from the patient's daughter and the ED record, the information is not available in CAIR. Per the daughter, the patient started feeling ill on 1/21, improved on 1/25, and then acutely worsened on 1/27, resulting in the ED visit.	No prior vaccinations for this event.

PULMONARY EMBOLISM

COVID19 (COVID19 (MODERNA)) (1201)

Rapid decline in health status, Elevated BP&P, posturing, loss of consciousness, Glasgow coma Scale 4 starting 2/1/2021, Deceased 2/3/21	No prior vaccinations for this event.

PULMONARY EMBOLISM

COVID19 (COVID19 (MODERNA)) (1201)

"Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive	No prior vaccinations for this event.

MI, PE or ruptured AAA"". Death certificate notes indicate ""signficant conditions contributing to death after cardiac arrest; ASCVD""."

PULMONARY EMBOLISM

COVID19 (COVID19 (MODERNA)) (1201)

Vaccine was administered 2/1/2021 at approximately 9am. Due to self reporting of allergic reaction (hives) to Augmentin, patient was monitored on site for 30 minutes. After the monitoring period, she was cleared to go with no issues reported at the time. We were later informed that the patient passed away from a pulmonary embolism on 2/12/2021.

No prior vaccinations for this event.

PULMONARY EMBOLISM

COVID19 (COVID19 (MODERNA)) (1201)

9 days after vaccination, the patient was found deceased in his home, sitting on his couch. Determined to be due to pulmonary embolism.

No prior vaccinations for this event.

PULMONARY EMBOLISM

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient reported to Emergency room on 01/23/2021 with complaint of nausea. According to ER record patient reported he received a COVID 19 vaccine Pfizer the day before. Work up in the ER (CT ABD PELVIS) reveal a clotted of SMA. CT CHEST REVEALED BILATERAL PULMONARY EMBOLUS. THE PATIENT WAS TRANSFERRED TO THE STATE HOSPITAL. HE WAS SCHEDULED FOR EMERGENT VASCULAR SURGERY WHICH WAS CANCELLED AS THE PATIENT DIED SHORTLY AFTER HIS ARRIVAL.

No prior vaccinations for this event.

PULMONARY EMBOLISM

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia	No prior vaccinations for this event.
PULMONARY EMBOLISM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Pt he reports he developed chills SOB body aches the same night as receiving the COVID vaccine on 1.26.2021-pt is currently reporting CheSt tightness and SOB Admitted to hosp: ICU with Bilateral Pulmonary Emboli, LLE DVT, NSTEMI, Arrhythmia.	No prior vaccinations for this event.
PULMONARY EMBOLISM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left	No prior vaccinations for this event.

ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first

dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

PULMONARY FIBROSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was	No prior vaccinations for this event.

admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

PULMONARY GRANULOMA

COVID19 (COVID19 (MODERNA)) (1201)

started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.

No prior vaccinations for this event.

PULMONARY HILUM MASS

COVID19 (COVID19 (MODERNA)) (1201)

started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with

No prior vaccinations for

complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		this event.
	PULMONARY HYPERTENSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient passed away from chronic respiratory failure with cardiogenic shock 24 hours from 2nd dose of vaccine. Patient with longstanding history of pulmonary HTN and heart failure with desire for comfort care only. Entering into VAERS out of abundance of caution.		No prior vaccinations for this event.
	PULMONARY IMAGING PROCEDURE ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.		No prior vaccinations for this event.
	PULMONARY MASS	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.

	PULMONARY OEDEMA	**COVID19 (COVID19 (MODERNA)) (1201)**
At approximately, 1855, I was alerted by caregiver, resident was not responding. Per caregiver, she was doing her rounds and found resident in bed, unresponsive, mouth open, observed gurgling noises and tongue hanging out of mouth. This primary caregiver observed resident at baseline and ambulating after dinner at approximately, 1800 less than an hour prior to incident. This PCG called 911 for EMS and gave report of incident. Resident was taken to Medical Center Emergency Department. At ER, CT scan and X-ray was performed. Per report from ER RN, CT scan and x-ray revealed an intracranial aneurysm and fluid in the lungs. Per RN, resident was still unresponsive and was admitted to Medical Center for observation and comfort measures. This primary caregiver reported to RN, resident recently received the first dose of COVID-19 vaccine on 1/2/21. Primary caregiver received a call from Castle RN at 0700, resident expired at 0615.		No prior vaccinations for this event.
	PULMONARY OEDEMA	**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29		No prior vaccinations for this event.
	PULMONARY OEDEMA	**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid		No prior vaccinations for this event.

thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"

	PULMONARY OEDEMA	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.		No prior vaccinations for this event.

	PULMONARY OEDEMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some		No prior vaccinations for this event.

interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with

radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

PULMONARY OEDEMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Legs started swelling and shortness of breath Thursday January 21 2021 Was rushed to hospital with kidney failure and fluid build up around lungs and entire body Blood pressure dropped and had multiple organ failure	No prior vaccinations for this event.

PULMONARY OEDEMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to

No prior vaccinations for this event.

urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

PULMONARY OEDEMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.	No prior vaccinations for this event.

PULMONARY OEDEMA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Elevated heart rate, flushing of the face and ears, vomiting, trouble breathing, pulmonary edema	No prior vaccinations for this event.

PULMONARY OEDEMA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
pulmonary edema; Low heart rate; chest pain; This is a spontaneous report from a contactable pharmacist. An 80-years-old male patient received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in left arm on 28Jan2021 at single dose for COVID-19 Immunisation. Medical history included dementia, high blood pressure, COVID prior vaccination. He had no known allergies. Concomitant medication included diltiazem hydrochloride (CARDIZEM), anastrozole (ARIMIDEX), simvastatin and lorazepam. Historical Vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 07Jan2021 (at the age of 80-years-old) at single dose for COVID-19 Immunization. There was no other vaccine received in four weeks. The patient experienced pulmonary edema, low heart rate and chest pain on 26Feb2021. The events resulted in hospitalization and patient died. The patient was hospitalized from 26Feb2021 for 1 day. Treatment received for the events included Epinephrine, morphine, nitroglycerine. The patient underwent lab tests and procedures which included Covid test Nasal Swab post vaccination on 26Feb2021 indicated Negative. The patient died on 26Feb2021. An autopsy was not performed. information on the lot/batch number has been requested.; Sender's Comments: Pulmonary edema, low heart rate, and chest pain, all reported as fatal, are deemed unrelated to BNT162B2 vaccine, being rather accidental occurrences, likely favored by the patient's age and by the mentioned high blood pressure, known risk factor for cardiovascular diseases. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Low heart rate; pulmonary edema; chest pain		No prior vaccinations for this event.
PULMONARY PNEUMATOCELE		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely.""

No prior vaccinations for this event.

1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan

10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure""""

PULMONARY VASCULAR DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"	No prior vaccinations for this event.
PULSE ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On the evening of 2/23/221 at 9:00 pm, resident reported feeling SOB, BP 80/44, Pulse 53, O2Sat 95% on 3L oxygen, hands cold, pulse weak. Temp 92.5F MD notified. EMS activated. EMS arrival and HR 20. Family refused transport to ER. Resident expired at 2:40 am on 2/24/21 Meds continued: duloextine, VITd2,hydralazine, synthroid, lisinopril, mag ox, folplex, pantoprazole, potassium chloride, ellipta, ensure, hydrocortisone cream, boost, deprox, xanax, morphine, lorazepam, tylenol, albuterol inhlation, ventolin inh.	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (MODERNA)) (1201)**
on 12/24/2020 the resident was sleepy and stayed in bed most of the shift. He stated he was doing okay but requested pain medication for his legs at 250PM. At 255AM on 12/25/2020 the resident was observed in bed	No prior vaccinations

lying still, pale, eyes half open and foam coming from mouth and unresponsive. He was not breathing and with no pulse	for this event.	
PULSE ABSENT		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident exhibited no adverse events during 30 minute monitoring following vaccine administration. Resident found without pulse at 1900.	No prior vaccinations for this event.	
PULSE ABSENT		**COVID19 (COVID19 (MODERNA)) (1201)**
No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.	No prior vaccinations for this event.	
PULSE ABSENT		**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient was found ""acting abnormal"" on 1/9/2021 at 1215. VS HR 20-30's. EMS activated. EMS arrived and patient was found pulseless in PEA/ asystole, CPR and ACLS initiated and then transported to the MC. Unsuccessful resuscitation and expired on 1/09/2021 at 1348. Clinical impression Cardiopulmonary arrest."	No prior vaccinations for this event.	
PULSE ABSENT		**COVID19 (COVID19 (MODERNA)) (1201)**

Resident found unresponsive and without pulse at 05:45am. No prior vaccinations for this event.

PULSE ABSENT **COVID19 (COVID19 (MODERNA)) (1201)**

On 1/13/2021, resident had sudden emesis. Immediately following emesis he was noted without a pulse and pronounced deceased. No acute symptoms noted prior to this episode. Resident does have a significant cardiac history.

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (MODERNA)) (1201)

Resident was noted to have increase weakness on 1/15/2021. Resident was warm to touch with low grade fever of 99.3 F. Resident was up propelling self in w/c on 1/16/2021 he was pleasant, accepted medications and ate lunch. He was found slumped over in his w/c not responding and vital signs absent.

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (MODERNA)) (1201)

Patient woke apx 0200 complaining of nausea to group home staff. Vitals were checked at that time and WNL. Patient went back to bed. When staff went to wake patient apx 0530, he was unresponsive and had no pulse. Chest compressions were started and EMS called.

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (MODERNA)) (1201)

"Patient was tested positive for Covid-19 on 12/9/20. Patient received Covid Vaccine on 1/21/21. Patient was observing for 15 minutes in treatment room by Nursing staff. Patient denied any signs/symptoms adverse effect: headache, dizziness & weakness, difficulty breathing, muscle pain, chills, nausea and vomiting, and fever . Patient seated on treatment table appeared to be relaxed, respiration even and unlabored. Health

No prior vaccinations for this event.

teaching provided. Patient educated to report any changes in condition to staff immediately. Patient verbalized understanding and able to verbalize signs and symptoms and adverse effects to be aware of related vaccine. On 1/22/21: patient was seen by medical provider for ""altered behavior"". Per medical provider's documentation: ""Patient was fallen on 1/2/21 and was sent out to outside hospital on 1/4/21. CT head: no intracranial abnormality, age-related changes. Patient had labs (B12, RPR, folate) were within normal limit"". We did MMSE today: 22/30 score ""mild dementia"" On 1/23/20: ""Patient was inside his cell. He was walking towards cell door to obtain his breakfast, when custody witnessed him collapse and activated the alarm. Nursing staff arrived at cell front at 06:34 am and found the patient pulseless and unresponsive, and CPR was immediately initiated. AED was attached at 06:35 am and no shock advised. AMR then arrived and patient did not have ROSC, and was pronounced dead at 06:54 am.""""	
PULSE ABSENT	**COVID19 (COVID19 (MODERNA)) (1201)**
UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless and breathless and was pronounced. Autopsy currently pending.	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presented to ER via EMS at 1556 3 days after receiving vaccine. pt was breathing approximately 50 times a minutes and o2 sats in the 70's upon arrival. NP decided to intubate, Rocuronium and Versed given. Pt	No prior vaccinations for this event.

became bradycardic and 1 amp of Atropine was given without improvement. No pulse felt, CPR started per ACLS protocol. 7 Epi's given. Time of death- 1632. After TOD pt was swabbed for COVID-19 and the results were positive.

PULSE ABSENT

COVID19 (COVID19 (MODERNA)) (1201)

Resident passed away at 8:15 am on 1/28/21-found to be without pulse/respirations/DNR order in place.

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (MODERNA)) (1201)

DISCOVERED UNRESPONSIVE WITHOUT PULSE, RESPIRATIONS, HEART BEAT ON 2/7/21 AT 0435 A.M. RESIDENT WAS DNR STATUS.

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (MODERNA)) (1201)

Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19

	(MODERNA)) (1201)
2/7/2021 at 0630, resident found in recliner without pulse or respirations. Resident had not been found to have any adverse reactions to the vaccine between the time of the vaccine on 2/4 until found deceased on 2/7.	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received COVID19 vaccine at clinic at 11:52 am, discharge post treatment stable. Got home around 2:30 pm went to bed. He usually got tired post dialysis. He did not wake up at 6 pm. His wife went check on him. found patient cold and unresponsive. 911 pulseless PEA. ER Medical hospital. Pronounced death at 7:40 pm	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident reviewed for incident. Resident received the second dose of the Moderna Covid-19 vaccine lot# 016M20A Exp 5/2/2021 on 2/5/2021 from clinic through pharmacy. Resident had her temp/O2 taken on AM shift and was 98.6/93%, beginning PM shift 98.4/95%. A few hours later noted that resident to have chills and was shaking RN assessment completed and vitals taken resident noted to have temp of 102.2, oxygen 95%, pulse 110. Resident alert and oriented at that time and talking to staff. Reported findings to APNP with order to send to ER. 911 called, residents brother updated. Upon EMT arrival RN went down to residents room with EMT and resident had an emesis as resident was getting cleaned up resident went unresponsive. Pulse noted to still be present at that time, resident did briefly respond to sternal rub and then went unresponsive again. Resident full code and EMT transferred to gurney and said that if they lost a pulse in route that they would transfer to hospital B instead of hospital A being the closest facility. RN called brother and gave update. Facility notified from Hospital that resident had passed away.	No prior vaccinations for this event.

	PULSE ABSENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Short version The patient has long-standing health issues. The patient received the first dose of Moderna COVID-19 vaccine on 1/16/2021 (unknown location). The patient suffered an event in his home on 1/24/2021. CPR and treatment was begun and he was transported to the ED. He was pronounced dead in the ED at 0846. Long version 70-year-old male with past medical history of CAD with pacemaker, A. fib, COPD, hypertension/hyperlipidemia presenting in cardiac arrest. 911 call at 0724. Per EMS, patient was witnessed by family to have seizure-like activity and then collapsed and became unresponsive. Patient was noted by family to be pulseless and CPR was started right away. Patient received two doses of epi by police were on scene first (AED defibrillation x2) and six doses of epi (plus 6 more AED shocks) by EMS when they arrived. Patient had CPR performed for 45 minutes prior to arriving at the hospital. On route, patient had episodes of paced rhythm and V. fib. Patient received one amp of bicarb and one amp of calcium en route. Patient also received 300 mg of amiodarone en route. Arrived in ED at 0810 Patient received ongoing compressions, shocks and additional medications (epinephrine x6, lidocaine IV, sodium bicarbonate) until time of death called at 0846 in the ED.		No prior vaccinations for this event.
	PULSE ABSENT	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.		No prior vaccinations for this event.
	PULSE ABSENT	**COVID19 (COVID19**

	(MODERNA)) (1201)
"Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive MI, PE or ruptured AAA"". Death certificate notes indicate ""signficant conditions contributing to death after cardiac arrest; ASCVD""."	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Moderna COVID vaccine administered 2/9/21. Patient expired in home on 2/10/21, at around 2100. Patient had h/o CVA in2001 with long standing sequelae. On day of administration, team attempted to draw lab specimen with vein finder, but patient was possibly Narrative: Moderna COVID vaccine administered 2/9/21. Patient expired in home on 2/10/21, at around 2100. Patient had h/o CVA in2001 with long standing sequelae. On day of administration, team attempted to draw lab specimen with vein finder, but patient was possibly dehydrated. CG/wife reported to APRN on 2/10/21, patient was sleeping and snoring and then began to sleep more quietly. She checked on patient and found that he had no pulse and had passed away	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was found unconscious without a pulse. Patient remained in asystole without pulse or respirations despite CPR.	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (MODERNA))**

(1201)

Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (MODERNA)) (1201)

Found lying face down without respiration or pulse, believed to be within 5 minutes of event. ACLS procedures unsuccessful. Unable to get autopsy. Believed to be heart attack secondary to COVID infection, but unconfirmed. Relative contribution of recent vaccination unknown.

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (MODERNA)) (1201)

Since I was not with my husband I can only tell you what was told to me. He walked out of the store toward our car. Someone watched him, concerned, because he was walking very slowly (normally has a slow gait because of leg braces and toe amputations so I don't know if it was unusually slow). The woman saw him fall and she ran to help-administered CPR immediately-and told me he died instantly. Medics tried to resuscitate and failed to bring a pulse. (My husband left our home around 11:15 to drop a package off at store. The store is one mile from our home. At around 12:30 a deputy came to my door and when I saw him my knees buckled. I knew something horrible happened.

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (MODERNA)) (1201)

Patient received Covid Vaccine Moderna at 1145, multiple syncopal episodes at pharmacy, sent to ER. Outcome Death	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Hypoxia, Decreased responsiveness, Narrative: 86yo male with PMHx HTN, Afib not on AC after head trauma, CVA, and colon cancer who was brought to the ED by his family on 2/17. Per documentation the pt was in his usual state of health until 2/16. Received Moderna covid vaccine #2 on 2/16/21 at 0900, and was monitored for 15 minutes following immunization no noted issues. Later that night, had myalgias and took Tylenol. Per the family he slipped on the ice and fell on his butt. Overnight, had several dark stools and vomitus. was brought to the ED by his family because he was being less responsive. Pt arrived to the emergency department in extremis. No pulse identified. CPR immediately initiated for several rounds lasting about 25-30 minutes. ROSC unable to be achieved. Patient expired on 2/17 at 1941. Of note, per previous documentation had waxing and waning mental status at baseline. No symptoms noted with 1st dose of Moderna vaccine, which was administered on 1/16/21.	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg	No prior vaccinations for this event.

epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

PULSE ABSENT

COVID19 (COVID19 (MODERNA)) (1201)

ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident found unresponsive without pulse, respirations at 04:30 CPR performed, expired at 04:52 by Rescue

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident became SOB, congested and hypoxic requiring oxygen, respiratory treatments and suctioning. Stabilized after treatment and for the next 72 hours with oxygen saturations in the 90s. On 1/3/2021 was found without pulse and respirations. Resident was a DNR on Hospice.	No prior vaccinations for this event.	
PULSE ABSENT		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"The resident received is vaccine around 11:00 am and tolerated it without any difficulty or immediate adverse effects. He was at therapy from 12:36 pm until 1:22 pm when he stated he was too tired and could not do anymore. The therapist took him back to his room at that time and he got into bed himself but stated his legs felt heavy. At 1:50 pm the CNA answered his call light and found he had taken himself to the bathroom. She stated that when he went to get back into the bed it was ""abnormal"" how he was getting into it so she assisted him. At that time he quit breathing and she called a RN into the room immediately. He was found without a pulse, respirations, or blood pressure at 1:54 pm. He was a DNR."	No prior vaccinations for this event.	
PULSE ABSENT		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt last seen at 1200 by nurse for ID band check. No visible signs of distress noted. Pt states ""I just want to be left alone"". 1230 nurse was called to pt room. Pt was noted unresponsive, no pulse and respiration noted. CPR started immediately, at 1239 first shock given. 1245 EMT took over, at 1319 EMT called time of death"	No prior vaccinations for this event.	
PULSE ABSENT		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient went to bed around 11pm on Saturday PM and sometime between then and 1:30am on Sunday morning got up and went into the living room without waking up her husband (which is normal). At 1:30am, the husband got up to use the restroom and she was out of bed then, but the husband did not know if she was having any problems at this time. When he got up at 7:45am, she was in the recliner and did not move or anything, which is normal for her. At 8:45am, the husband went back into the living room and tried to wake his wife and that is when he noticed there was no pulse and he called 9-1-1 at this time. EMS got on scene and did CPR for 30 mins and she was pronounced dead at 9:21am.	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Cardiac Arrest; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; This is a spontaneous report from a contactable other healthcare professional (HCP). A 66-year-old female patient (pregnant at the time of vaccination: no) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284) via intramuscular at left arm on 11Jan2021 12:15 PM at single dose for COVID-19 immunization. Medical history included diastolic CHF, spinal stenosis, morbid obesity, epilepsy, pulmonary hypertension and COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19). The patient received medication within 2 weeks of vaccination included amiodarone, melatonin, venlafaxine hydrochloride (EFFEXOR), ibuprofen, aripiprazole (ABILIFY), lisinopril, cranberry capsules, diltiazem, paracetamol (TYLENOL), famotidine, furosemide (LASIX [FUROSEMIDE]), ipratropium bromide, salbutamol sulfate (IPRATROPIUM/ALBUTEROL), buspirone, senna alexandrina leaf (SENNA [SENNA ALEXANDRINA LEAF]), polyethylene glycol 3350 and morphine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient used took Penicillin, propranolol, quetiapine, topiramate, Lamictal and had allergy to them. Patient used took the first dose of BNT162B2 (lot number: EJ1685) via intramuscular at right arm on 21Dec2020 12:00 PM at single dose for COVID-19 immunization. Since the vaccination, the patient been tested for COVID-19 (Sars-cov-2 PCR) via nasal swab	No prior vaccinations for this event.

on 06Jan2021, covid test result was negative. Patient was found pulseless and breathless 20 minutes following the vaccine administration (11Jan2021 12:30 AM). MD found no signs of anaphylaxis. Patient died on 11Jan2021 12:30 AM because of cardiac arrest. No treatment received for the events. Outcome of pulseless and breathless was unknown. the autopsy was performed, and autopsy remarks was unknown. Autopsy-determined cause of death was unknown. It was reported as non-serious, not results in death, Life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.; Sender's Comments: Based on the available information this patient had multiple underlying medical conditions including morbid obesity, diastolic CHF, epilepsy, pulmonary hypertension and COVID-19 diagnosed prior to vaccination. All these conditions more likely contributed to patients cardiac arrest resulting in death. However, based on a close temporal association (""Patient was found pulseless and breathless 20 minutes following the second dose of BNT162B2 vaccine administration, contributory role of BNT162B2 vaccine to the onset of reported events cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Cardiac arrest; Autopsy-determined Cause(s) of Death: autopsy remarks was unknown. Autopsy-determined cause of death was unknown"

PULSE ABSENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

No adverse effects from vaccination seen on 1/2/21. On 1/6/21 resident was seen by Dr and her baclofen pump was refilled with 20 ml Baclofen 4,000mcg/ml. ITB Rate increased by 6% to 455.5 mcg/day simple continuous rate over 3 days. On 1/8/21 at 0615 resident was shaking, lower extremities mottled, Sa02 70%, pulse 45. Oxygen started at 2 L/m per NC. At 0715 her primary physician was notified as well as her daughter. Oxygen increased to 4 L/min, sats at 83%. SOA noted, reported all over pain. At 0850 when they

No prior vaccinations for this event.

attempted to reposition the resident, she was not responsive. Licensed nurse assessed her and no heartbeat heard or pulse found.

	PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
54 y/o M with PMH of HTN, HLD, Alcoholic Cirrhosis, Aortic Valve Stenosis, and angina BIBA as a Medical Alert for cardiac arrest noted PTA. Per EMS, the patient called because he was having constant, diffuse abdominal pain x 1 day that radiated to his chest. On scene, the patient had a witnessed arrest with EMS starting CPR. He was given 3 rounds of epi without ROSC. Pt had no associated shockable rhythm. Of note, pt's wife, had noted pt had received covid vaccine the prior day.		No prior vaccinations for this event.
	PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"83yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, the patient reportedly got up in the middle of the night with c/o feeling ""blah"", restlessness, and nausea. VS normal, no other s/sx. At 4:15am, the patient was asked to go back to bed, assisted by a nurse and GNA. At 6am, GNA was going to do morning VS and found the patient unresponsive, no pulse, no respirations. GNA notified the nurse. At 6:03am, CPR started and EMS called. At 6:15am, EMS arrived and took over. At or around 6:30am, EMT called time of death"		No prior vaccinations for this event.
	PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Had no immediate issues with the vaccine. He had returned from the hospital on 12/21 and had some		No prior vaccinations for

concerns about his weight which were shared with his physician on 1/4/21. On 1/5/21 had a visit with his cardiologist for a pacemaker check. On 1/8/21 staff were called to his room, he was on the floor, bluish skin color. No vital signs found, no heart rhythm heard at 2200.

this event.

PULSE ABSENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 1/17/2021 at 4:35 am resident found apneic and pulseless, at 4:40am death confirmed

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient with inoperable pancreatic cancer received second Pfizer vaccine approximately 12:30 pm on 1/27/21. At approximataely 16:30, patient complained of abdominal pain and was given Levsin 0.125mg and morphine 5mg orally. At approximately 19:30 patient was found on the floor covered in a large amount of emesis, unresponsive without a pulse.	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Heart stopped; Could not swallow; This is a spontaneous report from a contactable nurse (patient's wife). An 85-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 21Jan2021 at a single dose for COVID-19 immunization. Medical history included blood pressure abnormal (verbatim: blood pressure) from an unknown date and unknown if ongoing, neuropathy from an unknown date and unknown if ongoing, weight issue from an unknown date and unknown if ongoing, diabetes from an unknown date and unknown if	No prior vaccinations for this event.

ongoing, walker user from an unknown date and unknown if ongoing. Concomitant medications included insulin aspart (NOVOLOG) taken for diabetes from an unspecified date to an unspecified date; and he was taking a long acting one as well. The patient previously received the influenza vaccine (MANUFACTURER UNKNOWN) for immunization on unknown dates (""had flu shots before with no reactions and everything, nothing before""). On 24Jan2021, the patient's heart stopped (death, medically significant), and could not swallow (medically significant). The clinical course was reported as follows: The patient's wife stated the patient was taking insulin aspart (NOVOLOG) and he was taking a long acting one as well. The reporter, the patient's wife and a retired registered nurse (RN) stated, her husband (patient) just died and she thought he died from the COVID vaccine (later clarified the reason of death was-heart stopped). The patient had the vaccine on 21Jan2021, which was on a Thursday, and he was fine. On the following Sunday around 1:30 (on 24Jan2021), the patient was feeling a little weak, however, the patient's wife thought maybe his blood sugar was low. The patient's wife checked, and the patient's blood sugar was 91. The patient's wife went to get some yogurt to feed him in order to get his blood sugar up a little; ""which was a normal thing for him, it was not that low for him."" Then, suddenly, the patient fell, and the patient's wife could not get a pulse or anything. The patient's wife called an unspecified number and she started compressions; however, he was dead. The patient's wife stated the patient just had his heart test, a three hour long one, and it was ""perfect three weeks ago."" The patient had just gone to the doctor the other day and his blood pressure was ""fine and everything."" The patient's wife stated that other than his diabetes, ""which he had for (sentence incomplete)."" Regarding lab tests, the patient's wife stated, ""No, he had it before but not in the last two weeks. He was going for one because we just went to the doctor last week and he was going to call yesterday to make the appointment request to get his blood work done. Blood work has been good except his A1C was always high, but other than that everything was good"" (as reported). Regarding causality, the patient's wife stated, ""I do, because he was fine until about half an hour before he died. He said to me, I feel a little weak today and then I was talking to him that your upper body strength is really good and then I said, we just have to work on your weight a little more because he did have neuropathy. And then, I went out of the room and all of a sudden I just heard him fall and that is when I just went in to check his blood sugar and it was 91 and I got him yogurt and he started eating that and then that was it, he started spitting it out and he said, I could not swallow and that was it, he just died."" The patient's wife further added, ""I just

wanted other people to know that things like this happen and I am sure it was from that because he was healthy as could be. He was walking with his walker, the day before outside and he felt fine."" The clinical outcome of the event, heart stopped, was fatal. The clinical outcome of the event, could not swallow, was unknown. The patient died on 24Jan2021 due to ""heart stopped."" An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: Heart stopped"

	PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Myocardial infarction Narrative: PMH significant for aortic valve stenosis, mitral valve stenosis, CKD, CHF, DM, HTN, obesity, hypothyroidism and dyslipidemia. Per report from primary care - the patients wife reports that the patient went on Saturday (1/30/21 - about 1050) morning to receive his COVID vaccine. He returned home and told her about the experience and denied any side effects. He then proceeded to sit in his easy chair for a while and around 1:30, she asked him if he wanted any lunch. The patient's wife reports he ""grumbled"" at her, and then got up to go to the bathroom. She then heard a loud crash and found him lying on the floor of the bathroom, with his head knocking hole in the wall as he fell. She could not detect a pulse. She called 911 and began compressions. First responders to the scene likewise tried to revive him but were not successful in her efforts. Per primary care documentation - Uncertain if related to Pfizer vaccine; vaccine administered on 1/30/21 and approximately 3 hours later suffered fatal MI at home."		No prior vaccinations for this event.

	PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient expired. Per Emergency MD note: ""This is a 72-year-old male with what sounds like diabetes, atrial fibrillation, and hypertension who presents via EMS in cardiac arrest. It sounds like he received his		No prior vaccinations for this event.

Covid vaccine last week. Initially he had some mild effects from it. However over the last day or so he has felt very unwell. He apparently called his wife today and told her that he was not feeling well and so she returned home. Shortly thereafter he attempted to get up from his chair. He then collapsed and fell forward onto his face. Sounds like his wife had some difficulty rolling him over to perform CPR. When EMS arrived they found him in PEA. He received a total of 5 rounds of epinephrine. At some point they did have return of spontaneous circulation. However just prior to arriving in the emergency department they lost pulses again. The patient was intubated with an 8 oh endotracheal tube prior to arrival."""

PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care	No prior vaccinations for this event.

center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

	PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	73-year-old man s/p first dose of Pfizer at 10:20 AM Ambulated comfortably to exit after 20 minutes in observation but 10:45 collapsed while exiting the building 10:47 CPR initiated 10:49 medical team/EMS found no pulse, agonal respirations, ventricular fibrillation Paramedics and team performed ACLS; of note patient was intubated 7.5 ETT with bilateral breath sounds on ventilation; paramedic reported easy intubation with no apparent throat swelling; 11:02 transported to Emergency Department 11:30 Pronounced dead at Emergency Department	No prior vaccinations for this event.

	PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids	No prior vaccinations for this event.

were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

	PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and ACLS guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and ACLS guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.		No prior vaccinations for this event.
	PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia,		No prior vaccinations for this event.

COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent

after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

PULSE ABSENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient found unresponsive in room with no pulse or respirations. She was pronounced dead by paramedics at 06:25am on 2/5/2021.

No prior vaccinations for this event.

PULSE ABSENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful

No prior vaccinations for this event.

ventilation and acls protocol. Code was stopped.

	PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received the vaccine at an outside healthcare facility on 2/11/21. At approximately 1 pm she screamed out and fell out of her chair. EMS was called and patient was found to be in Vfib. ACLS was performed for approximately 42 minutes prior to arrival at ED. At that time the patient had been pulseless for 25 minutes. Patient received 450 mg of amiodarone, epinephrine x7, sodium bicarbonate x2, and 7 AED shocks. In the ED 3 more doses of epinephrine were given, one more dose of sodium bicarbonate, and 5 additional shocks. ROSC was not achieved and time of death was called at 1416.		No prior vaccinations for this event.

	PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My dad received the Pfizer vaccination on 2/5/21. He was admitted into the hospital the next day for C-Diff bacterial infection. He had been on dialysis treatments for kidney failure treatment since 2017 and had recently been diagnosed with stage 3 colon cancer in June 2020. He had completed his final treatment of chemotherapy on 2/4/21 and several weeks prior had been determined cancer free. On Tuesday 2/9/21 he was released from the hospital and went home. Early Thursday morning 2/11/21 @ approximately 1:30 am CST his eyes rolled back in head and he stopped breathing and was non responsive. My mother called 911 and attempted CPR. Paramedics arrived and were able to successfully get a pulse then transferred him to the hospital. He was put on a ventilator @ the hospital and then transferred to a different hospital a few hours later. He lost pulse/heartbeat several times @ the 2nd hospital he was transferred to. We were not allowed to travel with him or see him b/c of all of the COVID restrictions. We were communicating with the ICU doctor by phone who ultimately communicated to us that there was nothing further that could be done		No prior vaccinations for this event.

to save his life. He subsequently passed away @ approximately 8:55 am CST on 2/11/21.

PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was found with no pulse no heart rate by a staff member around 11 pm. Earlier that day seen by myself for fatigue, sorethroat, nausea.	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA.	No prior vaccinations for this event.

Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The recipient was feeling well immediately after the vaccination, all day on 2.8 and in the morning of 2.9. His daughter in law text him at 0930 and he did not respond to the text (atypical) and then he missed a morning meeting. His wife was downstairs in a meeting herself and after the meeting was over she called to him and he did not respond. She found him with no pulse and was not breathing. She called 911 and attempted CPR. They did not complete an autopsy, they stated that they believe the cause of death was either an embolism, Heart attack or aneurism. The wife stated that she does not believe the death was due to the vaccination; however, there were no tests completed to prove or disprove.	No prior vaccinations for this event.
PULSE ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Expired within 30days of vaccination. Received vaccine 1/22/21 did not have any complaints, during a bed check she was found on the floor with no apparent injury, no pulse or respirations.	No prior vaccinations for this event.
PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (MODERNA)) (1201)**
Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the	No prior vaccinations

emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021and felt poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM CHLORIDE 1000 MG ONCE		for this event.
PULSELESS ELECTRICAL ACTIVITY		**COVID19 (COVID19 (MODERNA)) (1201)**
"85 year old patient with multiple medical problems. PEA/asystolic arrest 5 days after receiving vaccine, hospitalized. Patient died on 2/1/2021. It is not clear whether the vaccine administration led to the patient's death or not. ""...healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event)"""		No prior vaccinations for this event.
PULSELESS ELECTRICAL ACTIVITY		**COVID19 (COVID19 (MODERNA)) (1201)**
CARDIAC ARREST, DEATH Narrative: The patient presents to the emergency department in cardiopulmonary arrest. CPR was continued upon arrival. The Combi tube was removed and an endotracheal tube was placed without complications. ROSC was obtained multiple times but the patient continued to go into PEA. The patient was seen in the emergency department by both critical care and Cardiology. EKG shows ST elevations, but the patient was unstable to go to catheterization. The patient had 1 episode of asystole. Despite best efforts and multiple attempts we were unable to resuscitate the patient. Time of death 1253 on 1/24/21.		No prior vaccinations for this event.

PULSELESS ELECTRICAL ACTIVITY		**COVID19 (COVID19 (MODERNA)) (1201)**
Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.		No prior vaccinations for this event.
PULSELESS ELECTRICAL ACTIVITY		**COVID19 (COVID19 (MODERNA)) (1201)**
pt received vaccine on 2/3. early on 2/4 developed chest pain, dyspnea, and was seen in ED and diagnosed with acute exacerbation of CHF and NSTEMI type 2, and anemia. on 2/5 transfusion was started and pt developed worsening dyspnea and then PEA arrest. Pt achieved ROSC and was transferred to the cardiac intensive care unit where he required vasopressor support. he subsequently declined and died on 2/7		No prior vaccinations for this event.
PULSELESS ELECTRICAL ACTIVITY		**COVID19 (COVID19 (MODERNA)) (1201)**
Received first 1/15/2021 with no adverse reaction. Received 2nd dose 2/9 @ 0846 with no adverse reaction or report of feeling ill. Traveled to store and arrived approx. 2 hours after receiving vaccine. Daughter stated patient felt well and had to go to the restroom to have BM. Collapsed in bathroom. Transported by ambulance to Hospital @ 1439 in cardiac arrest. Was in PEA and went in v fib back to PEA. Resuscitation efforts initiated and patient expired with time noted at hospital records at 15:11.		No prior vaccinations for this event.

PULSELESS ELECTRICAL ACTIVITY		**COVID19 (COVID19 (MODERNA)) (1201)**
"Was given vaccine around 1:30Pm on 2-11-2021. He and his wife waited in the building for 15 minutes and then left. he denied complaint. (He was waiting to have both Covid shots before he went to cardiologist Re: CAD.) He had an alarm going off in his house, was going to basement to check it out. Police officer heard alarm, came into house, & heard a thud when Doc fell. He was in PEA (Pulseless Electrical Activity) when brought into ER. Given 5 ""rounds of Epinephrine with no response."	No prior vaccinations for this event.	
PULSELESS ELECTRICAL ACTIVITY		**COVID19 (COVID19 (MODERNA)) (1201)**
"""Feeling Hot"" without fever and nausea 10 hours post vaccine and resolved within 1 hour. Seizure, Hypotension, Unresponsive followed shortly by cardiac arrest and pulseless electrical activity 21 hours post vaccine. Pronounced dead 22 hours post vaccine"	No prior vaccinations for this event.	
PULSELESS ELECTRICAL ACTIVITY		**COVID19 (COVID19 (MODERNA)) (1201)**
92 yo female who received her first dose of Moderna vaccine on 1/11/2021 with no known adverse effects. Admitted to the hospital on 1/17/21 with a spine compression fracture. Discharged and readmitted on 1/19 /21 with nausea and vomiting. Found to have new atrial flutter and elevated troponin attributed to NSTEMI. Discharge on Aspirin and Plavix. No cath. Second dose of Moderna vaccine 2/25/21. No immediate reaction. One hour later began to feel progressively weak. EMS called shortly after getting home. Intubated in the field. Died at 0658 on 2/26/21 s/p PEA arrest without ROSC.	No prior vaccinations for this event.	
PULSELESS ELECTRICAL ACTIVITY		**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

She had the first dose of Pfizer vaccine at the Campus on Friday 1/15 at 4:30 pm. After the vaccine, she had no new symptoms or signs of vaccine reaction and MD friend reports that he checked her pulse which was not elevated from baseline. On 1/16, she awakened and continued to feel at her recent baseline. However, in the early afternoon, she complained of headache, nausea/epigastric pain, and chest heaviness. These apparently were not unusual symptoms for her to feel intermittently. Per her niece, who has a home O2 sat device, her 02 sat that morning was 97 with a HR of 87 irregularly irregular. She was afebrile. (continue on page 2)

No prior vaccinations for this event.

PULSELESS ELECTRICAL ACTIVITY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

No prior vaccinations for this event.

PULSELESS ELECTRICAL ACTIVITY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

This is a 94-year-old male who is brought in by ambulance after being found on the floor with unknown downtime. He was in asystole upon EMS arrival. He remains in asystole. No advanced airway is in place. The patient is getting compressions from Lucas device upon arrival. It was reported that he was last talked

No prior vaccinations for this event.

to by family at 2 PM. The patient got his SARS-CoV-2 vaccination this morning. The patient is evaluated emergently. CPR was ongoing with 3 rounds of epinephrine given. The patient remains in asystole. He has rigor mortis. The patient's pupils are fixed and dilated. The patient has compressions paused and ultrasound is used to evaluate for cardiac activity. None is detected. The patient has no electrical activity on monitor. The patient's time of death is 2113.

PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (	No prior vaccinations for this event.

PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"CC:full arrest HPI:HPI and ROS limited due to patient's condition. History is via EMS, medical record, and son. Per Son patient had Covid vaccine on Saturday morning. Slept all day Sunday. Woke up Sunday night	No prior vaccinations for this event.

a bit ""like coming out of a deep sleep per son, around 10 pm. Shortly after that patient was having a hard time breathing. Emergency called. Arrested around the time EMS arrived. King airway, I/O and CPR initiated. Patient has been in v fib. Was shocked multiple times, given 4 rounds of epi, bicarb and amiodarone. ACLS continued on arrival. Multiple rounds of epi, and attempted defib. Patient given epi, bicarb. Rhythms included fine v fib, asystole, and PEA. Unrecoverable with no cardiac motion. Time of death 11:50 pm."

	PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per EMS, the patient was last seen walking and talking to wife 10 minutes prior to EMS arrival. EMS reports via patients wife, that patient was upstairs to change for his doctor appointment then patient's wife found him down. The patient received his COVID-19 vaccine on 1/25/21. EMS states they gave 5 rounds of EPI then patient moved into vfib then was shocked once but returned to asystole. In ED, the patient initially in asystole CPR was started immediately. The patient was given 3 rounds EPI, 1 round bicarb. The patient stayed in PEA throughout. Patient was given tPA. Patient continued to be in asystole and time of death was called at 11:35 am.		No prior vaccinations for this event.

	PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After being observed for approximately 20 minutes and patient walked to her car without assistance I was called to assess the patient in the parking lot for troubles breathing. EMS was called as I made my way outside. Upon my arrival patient was leaning out of the car and stating that she could not breath. She was able to tell me that she was allergic to penicillin. Oxygen was immediately placed on the patient with minimal relief. Lung sounds were coarse throughout. She then began to vomit about every 20-30 seconds.		No prior vaccinations for this event.

Epipen was administered in the right leg with no relief. Patient continued to complain of troubles breathing and vomiting. A second epipen was administered in the patients right arm again with no relief. A few minutes later patient was given racemic epinephrine through the oxygen mask. There appeared to be mild improvement in her breathing as she appeared more comfortable, but still complaining of shortness of breath and vomiting. When EMS arrived patient was unable to transport herself to the stretcher. When EMS and clinical staff transferred patient to the stretcher she became unresponsive. She appeared to still be breathing. She did not respond to verbal stimuli. Per ED report large amount of fluid was suctioned from the patients lungs following intubation in the ambulance. When patient arrived to the ED she was extubated and re-intubated without difficulty and further fluid was suctioned. At that time patient was found to be in PEA, shock was delivered. Shortly thereafter no cardiac activity was found and patient pronounced dead.

PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"Patient expired. Per Emergency MD note: ""This is a 72-year-old male with what sounds like diabetes, atrial fibrillation, and hypertension who presents via EMS in cardiac arrest. It sounds like he received his Covid vaccine last week. Initially he had some mild effects from it. However over the last day or so he has felt very unwell. He apparently called his wife today and told her that he was not feeling well and so she returned home. Shortly thereafter he attempted to get up from his chair. He then collapsed and fell forward onto his face. Sounds like his wife had some difficulty rolling him over to perform CPR. When EMS arrived they found him in PEA. He received a total of 5 rounds of epinephrine. At some point they did have return of spontaneous circulation. However just prior to arriving in the emergency department they lost pulses again. The patient was intubated with an 8 oh endotracheal tube prior to arrival."""

No prior vaccinations for this event.

PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.
PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was	No prior vaccinations for this event.

mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.		
	PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia		No prior vaccinations for this event.
	PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient was not vaccinated at hospital. Caregiver reports that patient was vaccinated with second dose on Monday 2/15/21. Tuesday patient experienced n/v/d. Went to an ED on Wednesday and was cleared and sent home. Thursday reported shortness of breath to her caregiver and then collapsed. Patient was brought to as PEA arrest and ultimately died.		No prior vaccinations for this event.
	PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with		No prior vaccinations for

cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

this event.

PULSELESS ELECTRICAL ACTIVITY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient had an unwitnessed cardiac arrest while outside walking his dog. AED in the field initially advised shock and was shocked 3 times without effect. At the time EMS ALS arrived, patient was in PEA arrest. He

No prior vaccinations for this event.

was transferred to Hospital with CPR in progress. Time of death called at 1857.

PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Presented to ED via EMS c/o increasing shortness of breath, O2 sat mid to high 80s on 4L. When EMS arrived , pt was in distress, intubated by EMS and transported to ED. Pt had a PEA arrest en route but resuscitated w/ return of spontaneous circulation after receiving a dose of epinephrine and chest compressions. Pt was hypotensive on arrival to ED. He was started on sepsis protocol , volume resuscitation and empiric antibiotics. Once stabilized, he was admitted to icu at hospital. Removed from respirator 2/22/21	No prior vaccinations for this event.
PULSELESS ELECTRICAL ACTIVITY	**COVID19 (COVID19 (UNKNOWN)) (1202)**
Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2 diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated) then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and was intubated. Transported to hospital. SARS CoV-2 and influenza negative.	No prior vaccinations for this event.
PUPIL FIXED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1	No prior vaccinations for this event.

mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

PUPIL FIXED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient did not display any obvious signs or symptoms; the vaccination was administered at approximately 10:00 AM and the patient continued throughout her day without any complaints or signs of adverse reaction. Patient was helped to bed by the nursing assistant estimated at around 9:00 PM. The facility received notification from the lab around 11:00 PM that the patient's COVID-19 specimen collection from Sunday, 1/3/21, detected COVID-19. When the nursing staff went to the room to check on the resident and prepare her to move to a COVID-19 care area the patient was found unresponsive, no movement, no chest rises, noted regurgitated small amount of food to mouth left side, lying on left side. Pupils non reactive.

No prior vaccinations for this event.

PUPIL FIXED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On day due for 2nd dose, Patient was found unresponsive at work in the hospital. Patient pupils were fixed and dilated. Full ACLS was initiated for 55 minutes with multiple rounds of bicarb, calcium chloride, magnesium, and epinephrine. Patient was intubated. Patient continued into V. Fib arrest and was shocked multiple times.	No prior vaccinations for this event.
PUPIL FIXED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
PUPIL FIXED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
This is a 94-year-old male who is brought in by ambulance after being found on the floor with unknown downtime. He was in asystole upon EMS arrival. He remains in asystole. No advanced airway is in place. The patient is getting compressions from Lucas device upon arrival. It was reported that he was last talked to by family at 2 PM. The patient got his SARS-CoV-2 vaccination this morning. The patient is evaluated emergently. CPR was ongoing with 3 rounds of epinephrine given. The patient remains in asystole. He has rigor mortis. The patient's pupils are fixed and dilated. The patient has compressions paused and ultrasound is used to evaluate for cardiac activity. None is detected. The patient has no electrical activity on monitor. The patient's time of death is 2113.	No prior vaccinations for this event.

	PUPIL FIXED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was an 87 y/o female admitted for septic shock. She was started on and eventually maxed on 3 pressors. CT abd showed colonic obstruction with dilatation of large and small bowel. Patient was made DNR in the ED. Palliative care consulted on case. Family opted for comfort care. Patient was asystole on monitor. No spontaneous breath/cardiac sounds ausculted. Patient did not withdraw to pain. Pupils fixed and dilated. She was pronounced and 1230 on 1/28/21		No prior vaccinations for this event.
	PUPIL FIXED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received vaccination at 9:12 am, she was monitored and checked at the 15 minute interval 9:27 am, reassessed, vitals were fine. Within 20 (9:32 am) minutes of receiving the vaccine she was unresponsive, pupils were fixed at 9:45 am, no vital signs noted; hospice came out and reported her time of death 10:21 am. This person was on hospice.		No prior vaccinations for this event.
	PUPILLARY DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448		No prior vaccinations for this event.

with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

PUPILLARY LIGHT REFLEX TESTS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
PUPILLARY LIGHT REFLEX TESTS ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known	No prior vaccinations for this event.

Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

PUPILLARY LIGHT REFLEX TESTS ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative.

No prior vaccinations for this event.

Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

PUPILLARY REFLEX IMPAIRED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (

No prior vaccinations for this event.

PUPILLARY REFLEX IMPAIRED

COVID19 (COVID19

(PFIZER-BIONTECH))
(1200)

"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

No prior vaccinations for this event.

PURPURA

COVID19 (COVID19 (PFIZER-BIONTECH))
(1200)

Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.

No prior vaccinations for this event.

PYREXIA

COVID19 (COVID19 (MODERNA)) (1201)

Fever, RespDepression & COVID positive REMDESIVIR (EUA) 200 mg x1 then 100 mg daily

No prior vaccinations for this event.

PYREXIA

COVID19 (COVID19 (MODERNA)) (1201)

Resident was noted to have increase weakness on 1/15/2021. Resident was warm to touch with low grade fever of 99.3 F. Resident was up propelling self in w/c on 1/16/2021 he was pleasant, accepted medications and ate lunch. He was found slumped over in his w/c not responding and vital signs absent.

No prior vaccinations for this event.

PYREXIA

COVID19 (COVID19 (MODERNA)) (1201)

My dad got the Moderna Vaccine on Tuesday, January 12, 2021 in his left arm at the Mall injection site for the Health Department. He was told that the side effects could mean his arm hurting, tiredness, headache, and even a low grade fever. Additionally, the site informed us both (as I was with him to get the injection) that this was all normal and not to seek medical attention unless these symptoms last longer than 72 hours. That evening, my dad was experiencing all of those symptoms, and went to bed at 7pm. A little after 10am on Wednesday, January 13, 2021, when he awoke, my dad went to the bathroom vomiting. This was where he

No prior vaccinations for this event.

collapsed and went into cardiac arrest. Fire/Rescue was dispatched about 10:30am after my mom started CPR. County Fire Rescue EMTs and Paramedics continued CPR and other attempts at reviving him all the way to Hospital Emergency Department. He was pronounced dead at 12:14pm on Wednesday, January 13, 2021. We have no doubt my dad, following the instructions of the injection facility, thought he was just experiencing the side effects of the vaccine. He had no chance. Had this injection been done in the RIGHT arm, perhaps he could have recognized the arm numbness being that of an impending heart attack. We really miss Dad. He served this country with distinction for over 50 years, and we believe his country failed him.

PYREXIA		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient obtained initial dose of Moderna vaccine on Thurday, Jan 14. No adverse effects reported during initial 15 minute post vaccine waiting period. Saturday morning (Jan 16), patient developed severe cough, labored breathing, and fever. Additionally patient mental status changed suddenly, became non-communicative (unable to speak, but would scream if she was touched). O2 status was irregular, dropping to 78. Sunday morning, EMT and then hospice was hospice called. Monday morning, after hospice emergency kit was initiated, patient passed away.		No prior vaccinations for this event.
PYREXIA		**COVID19 (COVID19 (MODERNA)) (1201)**
Found dead at home slumped on the floor; Loss of appetite; Body aches; Feverish; A spontaneous report was received from a physician, concerning a 65-years-old male patient, who received Moderna's COVID-19 Vaccine and experienced feverish, body aches, loss of appetite, and death. The patient's medical history, as provided by the reporter, included diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia. Concomitant medications reported included metformin, glimepiride, lisinopril, atorvastatin, aspirin, methimazole, propranolol, and cilostazol. On 05 Jan 2021, prior to the onset of events, the patient received the first of two planned doses of		No prior vaccinations for this event.

mRNA-1273 (lot number 037k20a) for COVID-19 infection prophylaxis. On an unknown date in Jan 2021, some time after receiving the vaccine, the patient was feeling feverish with body aches and loss of appetite. On 09 Jan 2021 at approximately 21:30, the patient was found dead at home slumped on the floor. According to the paramedics, the patient was dead longer than when his wife found him, and no resuscitation was performed. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events, feverish, body aches, loss of appetite, was considered resolved. The patient died on 09 Jan 2021. The cause of death was not reported. The reporter assessed the event, death, as not related to Moderna's COVID-19 Vaccine. The reporter did not provide assessment for the events, feverish and body aches, in relation to Moderna's COVID-19 Vaccine.; Reporter's Comments: This case concerns a 65 year old male patient with medical history of diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia, who experienced the serious unexpected event of death, non-serious unexpected event of loss of appetite, and non-serious expected events of fever and body pain. The event of death occurred 5 days after the first dose of mRNA-1273. The events of fever, body pain and loss of appetite occurred an unspecified period of time after the first dose of mRNA-1273. Very limited information regarding these events has been provided at this time. Based on temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Definitive causal association is confounded by age and medical history of diabetes, hypertension, Hashimoto's, smoker, cataracts, atrioventricular block, occasional premature ventricular contractions, and hypertriglyceridemia.

PYREXIA

COVID19 (COVID19 (MODERNA)) (1201)

Fever Feeling tired short of breath all night and morning after the vaccine My grandma had to be intubated and then passed away to a heart distress we think it was the vaccine because she was fine even with dialysis. When she got the vaccine it took hours and her health conditions changed.

No prior vaccinations for this event.

PYREXIA

COVID19 (COVID19

	(MODERNA)) (1201)
On the evening of 10JAN2021, patient experienced a low grade fever, decreased oxygen saturation of 38%, heart rate of 124, confusion. Patient received oxygen via face mask, morphine and ativan. By 11JAN2021, patient was no longer verbal, able to eat or communicate and was kept on comfort measure only. On the morning of 17JAN2021, the patient passed away.	No prior vaccinations for this event.
PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received Moderna COVID vaccine on 12/30/2020 at a Pharmacy clinic where he was a resident. Nurses at the facility reported that he was responsive and showed no signs of any adverse effects until 1/2/2021 when he was observed slightly unresponsive and staring at the ceiling and trembling. He had a fever of 101F at this time. The facility ordered labs and a rapid COVID test (all of which came back normal) and started IV antibiotics. A few hours later, patient began bleeding from his eyes, nose, and mouth and was sent to the local ER. The patient refused being admitted to the ICU for possible sepsis/hemorrhage and died the following day on 1/3/2021. All healthcare professionals involved agreed that this was not likely due to the vaccine, but needed to be reported nonetheless.	No prior vaccinations for this event.
PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2	No prior vaccinations for this event.

with gram positive cocci in clusters growing after 9 hours.

PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
ON 1/14/2021 TYPICAL UTI SYMPTOMS FOR RESIDENT DEVELOPED INCLUDING FEVER AND RIGIDITY. RESIDENT IS NON-VERBAL. IV ANTIBIOTICS WERE STARTED. FREQUENT UTI'S ARE COMMON FOR THIS RESIDENT.	No prior vaccinations for this event.

PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face, increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious	No prior vaccinations for this event.

unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Fever 101.1, unresponsive episode. Transferred to Hospital on 1/28. Diagnosis there was anemia and CHF, aware that he had vaccine day prior. Transfused with 2 units pRBC's. Transferred back to Nursing Home on 1/30 and passed away 0140 1/31/2021		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine given on 01-25-2021. Wife reported on 01-29-2021 that patient had a ran a fever on 01-26-2021, Was better on 01-27-2021. She found him dead when she came home work on the evening of 01-28-2021.		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Death Narrative: Patient received the first COVID-19 dose on 12/23. Afterwards, patient complained of localized pain on L deltoid area where the vaccine was administered; his temperature was 98.1 F. On 12/26-27, staff reported that patient appeared more fatigued than usual and was shivering on 12/27, which seized		No prior vaccinations for this event.

after blanket was given. On 12/28, patient presented with fever (Tmax 100.2 F) and acetaminophen was administered for alleviation of fever. ADR was reported for the fever on 12/29. Patient continued to decline and was placed back on hospice care on 12/29; on 12/30. the symptoms reported on nursing note include erythema and pain on whole L arm. Lidocaine was applied. Patient's family and provider mutually agreed not to administer the second dose of vaccine. He continued to decline and was started on end-of-life care around 1/4 and passed on 1/20 1417.

	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awake at 0300. When going into the room to get him ready for dialysis he was cold to touch, unresponsive other than to sound, and nonverbal. O2 sat was 67 via finger probe. Oxygen immediately initiated and a venturi mask retrieved and initiated. When unable to arouse him via sternal rub this RN called 911. Send to ED. Febrile 39.2 and hypotensive 58/43. Admitted. unknown after that as patient expired in hospital.		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood		No prior vaccinations for this event.

pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.

	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had the first Moderna Covid vaccine on Thursday 1/21/2021. She had a bit of sore arm on that day and the day after. On Saturday 1/23/2021, she had a fever of 100.5 F (11AM), nausea, light headache and chills. The temperature went down after she took ibuprofen. Patient's husband enrolled her to V-Safe to report all the adverse effects she experienced. On Sunday 1/24/2021, her temperature was 98.3F. She still had nausea and no appetite. She and her husband watched a football game in their bedroom upstairs. Husband noticed that his wife was pacing around the room many times. At 7Pm, Husband went downstairs for dinner but she refused to come down to eat. He went upstairs around 8pm, TV was still on. He turned off TV and went down stairs again thinking his wife felt as sleep while watching TV. He went back upstairs for bed around 10:30 PM. Husband said his wife had a deviated septum so she would snore very loudly when asleep. He didn?t hear her snoring so he went to check on her and found her not responsive. Husband called		No prior vaccinations for this event.

emergency services. Paramedic came at 10:45 and said patient was passed. Husband sent many texts to V-safe after that to report the incident. No response was received from V-safe. Patient?s doctor told her husband that she died due to cardiac arrest.

	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
covid shot 2/2; feel bad 2/5; covid positive diagnosis - 2/8 s/s cough, fever, shortness of breath , hypertension, afib (in er) - admitted went into DIC per intensivist 2/11 patient died		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
2/10: Fever, fatigue, tylenol 2/11 @ 1300: pt made DNR, hospice consulted 2/11 @ 1800 decreased LOC, increased RR, fever, chills - 1/5L NS bolus IV, rectal tylenol. Refusing to eat/drink, PO morphine 2/12 @ 16:30, deceased at facility **resident was not doing well prior to vaccination		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Two days later passed away; difficulty breathing, shortness of breath; difficulty breathing, gurgling; Not feeling well; Achiness; Severe fever; Chills; A spontaneous report was received from a physician concerning a 56-year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed fever, chills, achiness, shortness of breath, gurgling and unresponsive. The patient's medical history was not provided. Concomitant product use was not provided. On 19 Jan 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Lot 042L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. After receiving the vaccine on 19 Jan 2021, the patient experienced fever, chills, shortness of breath, gurgling and achiness. On 21 Jan 2021, the patient was found unresponsive. Emergency medical services were called to perform life saving measures however, they were		No prior vaccinations for this event.

unsuccessful. No further treatment information was provided. The patient died on 21 Jan 2021. The cause of death was reported as unknown. An autopsy was planned.; Reporter's Comments: This case concerns a 56-year-old, female, who experienced a serious event of death, with many other events after receiving second dose of mRNA-1273 (Lot# 042L20A). Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

PYREXIA

COVID19 (COVID19 (MODERNA)) (1201)

Fever by the next day, difficulty breathing, pneumonia, and then DEATH within a few days. (Died 02/01/2021)

No prior vaccinations for this event.

PYREXIA

COVID19 (COVID19 (MODERNA)) (1201)

She had pain in the injection site Tuesday night and then during Tuesday she got worse with nausea and some fever. By Wednesday she was complaining that she could not pee even though she was drinking a lot of fluids. She continued to complain it was the worst she ever felt and then at 0600 Thursday morning she woke us up and said she needed to go to the hospital. We arrived at the hospital just before 0700 and she immediately threw up in the trash can. We went into a treatment room and they took blood and started fluids as she became incoherent. She said she had taken Tylenol so they started a drug to counter that but her liver function was all wrong and they started to look for a hospital that could transplant a liver. She was air evade about 0930 to Medical center and just over 30 hours latter she was dead. There is a pending autopsy. She was a healthy 39 year old mother who got the shots because she worked as a surgical tech and she was the single mother of a 9 year old little girl.

No prior vaccinations for this event.

PYREXIA

COVID19 (COVID19 (MODERNA)) (1201)

Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.		No prior vaccinations for this event.
PYREXIA		**COVID19 (COVID19 (MODERNA)) (1201)**
He developed a fever on 1/8, become unable to swallow and bedbound. He was already end of life and Hospice care at the time of the vaccine.		No prior vaccinations for this event.
PYREXIA		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be		No prior vaccinations for this event.

the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.		
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
According to patient's caregiver, patient presented with symptoms of fever (101.6 F) and purple blotches all over the body within an hour. Since patient was in hospice , caregiver called Hospice and a pharmacy and was told to give patient Benadryl and Tylenol. Patient was given both medications and the fever subsided in a few days but the purple blotches never went away. Patient passed away at the facility a week later.		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Individual developed severe body aches, severe shoulder discomfort, high fevers (documented max temp. 103.7 F). Daughter reported that she became non-responsive with high fevers, and when the fevers decreased she was more lucid. Her condition rapidly progressed to nausea vomiting, diarrhea and patient died on 2/9/2021.		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19**

		(MODERNA)) (1201)
He vaccine on 2/5/2021 I went to see my husband the next day he was shaking and his mouth was open shaking, and he had fever of 105, they gave him Tylenol suppositories and he passed away 2 hours later. They should not have given him should not have given him the vaccine that is on hospice, it was not the right decision. I am worried about the elderly and those very sick.	No prior vaccinations for this event.	
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
pt woke up at 0400 with fever, chills, and body aches progressing over 4 hours to the point when she became unresponsive. husband called 911, pt was declared dead at the time of EMS arrival around 1200	No prior vaccinations for this event.	
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
On January 1, 2021, patient was admitted to Medical Center with COVID. Tested positive on January 2, 2021. Spent 10 days in hospital. Once recovered from pneumonia and fever gone, on January 10, 2021, she was transferred to Rehabilitation Center for continued treatment. She spent 16 days there. She developed UTI and CDIF infections and was on/off oxygen. She started physical therapy. She was scheduled to be released to go home on January 27, 2021. On January 26, 2021, the day before going home, Rehabilitation Center gave her the Moderna vaccine. On January 27, the day she went home, she started feeling very weak and couldn't walk. My dad tried lifting her and they both fell to the ground. My dad called 911 and she was taken to Medical Center, with high fever and possible stroke symptoms (which later was negative). Two days later, she had difficulty breathing and was put on a ventilator. She was on a ventilator for about three days. They took it off and she slowly started recovering. The doctors did all kinds of tests (blood clot in lung, heart, etc.) and all was negative. The only thing they could trace it to was an adverse reaction to the vaccine. After spending 11 days at hospital and treating her for various infections, her heart stopped and she passed away suddenly.	No prior vaccinations for this event.	

	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
	High grade MDS; Multiorgan failure; Pancytopenia; shortness of breath; Inflammatory marker increased; Chills; Fever; Fatigue; A spontaneous report was received from a healthcare provider concerning a 71Years-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and who experienced chills, fever, fatigue, pancytopenia, shortness of breath (dyspnoea), multi organ failure, and myelodysplastic syndrome (MDS). The patient's medical history was reported to include Breast Cancer and mastectomy. No relevant concomitant medications were reported. On 16 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch:unkown) intramuscularly for prophylaxis of COVID-19 infection. On 16 Jan 2021, The patient experienced events like chills, fever, and fatigue. On an undisclosed date, the patient was admitted to the hospital for shortness of breath. Laboratory details include Bone Marrow biopsy with abnormal results such as showed high grade MDS with 19% blasts. Blood work done with normal results. Body temperature results came out 103 degrees Fahrenheit. On 30 Jan 2021 the patient experienced worsening shortness of breath and was intubated. Her IL-6 was very high, and she had profound liver failure. She ended up needing pressors and requiring continuous renal replacement therapy. Treatment included steroids. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Feb 2021. The cause of death was reported as high grade MDS. An autopsy was planned.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death	No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
	Fever, chills, fatigue, muscle aches, nausea, death 48 hours after injection	No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
	loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt	No prior vaccinations

subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.	for this event.
PYREXIA		**COVID19 (COVID19**

	(MODERNA)) (1201)
Day after second dose decedent had fever and tremors, subsided on day three (less than 72 hours) after dose with exterem wekness followed by death less than 72 hours after second dose	No prior vaccinations for this event.
PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
My grandpa got his second covid vaccine on Thursday. Saturday he complained of stiff neck. Sunday he had low grade fever, nausea and vomiting, chills, and mild headache. He was feeling bad enough to call squad at 3 pm. The paramedics did evaluation and thought he was just experiencing normal side effects from vaccine and felt no need to transport to hospital so my grandpa decided to stay home and just rest. At 2 am that same night he went into cardiac arrest and was not able to be brought back	No prior vaccinations for this event.
PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
approximately 24 hours post vaccine Patient developed a low grade fever of 99.5 and had increased fatigue. 48 hours later she had decreased neurological functioning. 02/23 she had difficulty swallowing. 02/23 She was admitted to hospice services. 02/26 she passed just before 10 am.	No prior vaccinations for this event.
PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
The day after the administration of the vaccine, the fever began, the patient claim that he had no blood pressure problems. He was given acetaminophen every 4 hrs. and vitamin C and D. On February 11, he was stabilized, he had his regular meals without any problem but in the afternoon his temperature rose again and they put him to bed. The patient died that same afternoon around 4:00 pm	No prior vaccinations for this event.

	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Beginning in the evening 2/19/21, fever/chills/fatigue; worsening of symptoms 2/20/21 with lethargy/lack of appetite/weakness; unable to arouse on 2/21/21 then breathing stopped, patient's spouse called 911 performed CPR, EMS continued for 15 min then while in ambulance to hospital where he was pronounced dead. Official time of death 2:20pm		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
sepsis; respiratory failure; Fever; Unresponsive; A spontaneous report was received from Pfizer concerning a 56-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced respiratory failure, sepsis, fever and sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 04 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient began to have a fever. She was sent to the emergency room for evaluation. That evening, she died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 11 Jan 2021. The cause of death was reported as respiratory failure and sepsis. Plans for an autopsy were unknown/not provided.; Reporter's Comments: This is a case of 56-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sepsis, fever, respiratory failure and sudden death. Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Respirtory Failure; Sepsis		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered		No prior vaccinations for

mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse

this event.

PYREXIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Within 24 hours of receiving the vaccine, fever and respiratory distress, and anxiety developed requiring oxygen, morphine and ativan. My Mom passed away on the evening of 12/26/2020.

No prior vaccinations for this event.

PYREXIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Fever, Malaise No prior vaccinations for this event.

PYREXIA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Fever, shortness of breath and chest pain that resulted in a heart attack a few hours after vaccination

No prior vaccinations for this event.

	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/7-21 - Received second dose of pfizer covid-19 vaccine 1/8/21 - Fever, dizziness, headache 1/10/21 0250 was found not breathing. EMS performed CPR and patient deceased		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
COVID-19; COVID-19; Pneumonia; respiratory failure; This is a spontaneous report from a contactable consumer. An 80-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 02Jan2021 for COVID-19 immunization. Medical history included Alzheimer's and others. No known allergies. Concomitant medications included unspecified medications. The reporter's mother in law was tested for COVID-19 at a nursing facility on 25Dec2020 and she was negative. On 02Jan2021, she received the first dose of Pfizer vaccine. On 04Jan2020, she developed a high fever, needed oxygen and was positive for COVID-19. Date of death was 04Jan2021. The cause of her death was listed as pneumonia, respiratory failure and COVID-19. No autopsy performed. No treatment received. No one knew if the vaccination contributed to her death. It was hard to know if her death was due to the administration of the vaccine or it exacerbated the COVID19 symptoms which led to her death. Since this was unknown, it could have been a possibility. The reporter wanted to give us this information because we might want to consider having high risk population, patients with underlying conditions, older population tested for COVID-19 prior to the vaccination, as this is not currently a recommendation or a requirement. All is very new and they are all learning so the reporter wanted to share this information with us. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There are medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. The outcome of the events was fatal. Information about Lot/Batch has been requested.; Sender's Comments: The association between the fatal event lack of effect (pneumonia, respiratory failure and		No prior vaccinations for this event.

COVID-19) with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19

	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.		Influenza Virus Vaccines - Unknown date/type or brand

	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
died two days after receiving the vaccine; Fever; This is a spontaneous report from a contactable consumer (patient's stepchild). A 66-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 07Jan2021 (at the age of 66-years-old) as a single dose for COVID-19 immunization. The patient's medical history was not reported. Concomitant medications included an unspecified statin. The patient experienced fever on		No prior vaccinations for this event.

08Jan2021. The patient died two days after receiving the vaccine on 09Jan2021, which was reported as fatal. The clinical course was reported as follows: The patient had a fever the day after getting the vaccine and then he just died in the middle of night. It was reported that it was not clear what exactly happened, but they are looking into this. The clinical outcome of fever was unknown and of died two days after receiving the vaccine was fatal. The patient died on 09Jan2021. The cause of death was not reported. An autopsy was not performed (was reported to be taking place soon). The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: died two days after receiving the vaccine		
	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/11/21 at 8:57 Resident with fever and at 11 am saturation down to 83 O2 to 10 liters. Resident		No prior vaccinations for this event.

continued to decline until CTB on 1/14/2021 at 1325

	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away		No prior vaccinations for this event.

	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG		No prior vaccinations for this event.

changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."

	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient developed 104.4 temp approximately 48 hours after being given the vaccine. I treated him with antibiotics, IV fluids, cooling methods. CXR does show a new right perihilar infiltrate. However, his fever came down within the next 24-48 hours. Unfortunately, he suffered a cardiac arrest on 1/21/21 in the early morning and expired.		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness; respiratory distress Narrative: Patient tolerated his 1st dose of the COVID-19 vaccine well, on 12/16/2020, and received his 2nd dose on 1/6/2021. Patient had some mild clinical decline the past few days prior to 2nd vaccination, with a decreased appetite and some increased fatigue per nursing report, but no significant changes. He experienced nausea on the evening of 1/6/21, which was effectively managed, but by early morning he spiked a fever of 102.9 with a sat of 86.1%. He continued to deteriorate from that point on and died 1/7/21 @13:20. Clinically, the presentation was most consistent with an aspiration pneumonia.		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Symptoms of fever (Tmax 102.9), diarrhea, and altered mental status started ~ 24 hours after vaccination. No evidence of septicemia with negative blood cultures Minimal improvement over 3 days, transferred to tertiary care center for MRI brain after which LP was recommended. However family declined as intubation would have been required and was not consistent with patient's goals of care.		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
respiratory distress; fever; anxiety developed requiring oxygen; Passed away; This is a spontaneous report via a Pfizer-sponsored program from a non-contactable consumer. A 63-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot and expiry not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. Medical history included anaphylactic reaction (broad), neuroleptic malignant syndrome (broad), anticholinergic syndrome (broad), acute central respiratory depression (broad), hypersensitivity (broad), respiratory failure (narrow), drug reaction with eosinophilia and systemic symptoms (broad), hypoglycaemia (broad), COVID-19 (broad) and chronic obstructive pulmonary disease (COPD); all from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine sodium and lorazepam (ATIVAN). Within 24 hours of receiving the vaccine, the patient experienced fever, respiratory distress, and anxiety developed requiring oxygen, morphine and lorazepam (ATIVAN). The patient passed away on the evening of 26Dec2020. The patient underwent lab tests and procedures which included SARS-COV-2 antibody test: negative on an unspecified date. The outcome of the event death was fatal, while of the other events was unknown. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Passed a		No prior vaccinations for this event.
	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient developed fever to 102 within 24 hours with decreased mentation. Stopped eating/drinking despite aggressively treating fever. Was DNR B status. Family agreed to a trial of IV fluids on 1/21 but was not successfully started until 1/22 after several attempts. Family wanted only comfort measures with no transfer to hospital. Patient continued to have fevers to 102-103 range. Patient passed on 1/23 . Patient did test positive for COVID in early September without significant illness. She was in usual state of health prior to vaccination.	No prior vaccinations for this event.	
	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."	No prior vaccinations for this event.	
	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
See initial report	No prior vaccinations for this event.	

PYREXIA **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

The next morning after vaccine, patient ran a fever, vomited, and was very tired. Mom laid her down to sleep and when she checked later, patient had passed away.

No prior vaccinations for this event.

PYREXIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021.

No prior vaccinations for this event.

PYREXIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident was weak, fatigued and had a fever of 101. F the following morning after receiving the 2nd dose of vaccine. Later in the day she was feeling better and vital signs were WNL. The next morning, she was found unresponsive and pronounced dead by paramedics.

No prior vaccinations for this event.

PYREXIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient got the injection and quickly developed a fever and felt weak. Family was contacted

No prior vaccinations for this event.

and he was sent to Hospital.

PYREXIA	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar	No prior vaccinations for this event.

opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
24 hours after shot had high fever 101, chills, weakness, became listless, family called 911, client became unresponsive and died in the Emergency room.		No prior vaccinations for this event.

	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/15: Pfizer vaccine dose 1 administered 1/16: Fever, chills 1/22: Sore throat, coughing w/white phlegm, taking Tylenol and Mucinex. Fever and chills from 1/16 subsided. Had telehealth consultation with PA. Per		No prior vaccinations for this event.

her notes, patient said he gets these symptoms annually, requested for an antibiotic. PA referred him for a COVID test. Ordered hydrocodone/chlorphen ER suspension for his cough and an antibiotic. Antibiotic was recommended if symptoms do not subside. 1/23: COVID test administered 1/25: Reported positive for COVID 1/26: Telehealth session w/PA: she informed patient of his positive test, advised to quarantine and seek medical help at hospital if symptoms worsen. Patient reported that his sore throat mostly subsided but is still coughing at night. Said that the pharmacy didn't receive the prescription order for the antibiotic, so this was re-ordered. 1/31: Partner found him dead at 8:18AM on his bed. Death certificate issued by state says cause of death: COVID. Autopsy was not performed. Buried on 2/9/21.

	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident had slight/slow decline in health prior to vaccine but continued to be able to walk around with walker at community. The day of the vaccine she had a fever. 2 days after vaccine resident did not get out of bed all day and refused to eat. She had small amounts of orange juice as her blood sugar level was low due to not eating. Resident was diagnosed with a UTI and began an oral antibiotic. 3 days after and on day 5 after vaccine resident began feeling weak and had a fall on each day. The following day again resident spent the day in bed. The next day she was quite restless, was on the edge of her bed attempting to self transfer often throughout the day. Resident continued to be restless on the 10th of Feb, had further decline on the 11th of Feb. Resident passed away early the AM of Feb. 12th.		No prior vaccinations for this event.

	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was not seen at our facilities prior to or after COVID-19 vaccination. Patient received first dose on 1/23/2021 and as reported by the family member, patient expired on 2/5/21. Symptoms were reported to		No prior vaccinations for this event.

have stared on 2/1/2021, 9 days after receiving the first dose with a drop in oxygen levels and fever. He was reported to also have a history of chronic lung disease. Patient's family member to be contacted if necessary.

	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature	No prior vaccinations for this event.

was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his

cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

PYREXIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient had sore arm on the day of vaccination. Per patient's nephew , the next morning patient experienced body pains, aches, headache . Onn Tuesday patient had fever. Patient's condition progressively got worse. He had difficulty breathing by Wednesday night. He had low oxygen levels at 80 per pulse ox reading. Patient was coughing up blood. Family took him to hospital on Thursday morning due to breathing difficulty and patient died 2.18.21 at 10 am

No prior vaccinations for this event.

PYREXIA

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.	No prior vaccinations for this event.
PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was hospitalized 15 days after receiving vaccine. Admission was not due to vaccine and was admitted for acute ascites and patient had reported fever and hypoxia. Patients admission resulted in death 7 days after being admitted to hospital.	No prior vaccinations for this event.
PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/21 - Resident complained of SOB. SPO2 66% on RA, vs 105/66-96-20 T98.2 O2 administered Pox 97% Binax test revealed (+) COVID results. Resident transferred to COVID wing. Family (HCP) updated and declined transfer to hospital Resident continued with fever, hypoxia and lethargy. Family elected CMO and Hospice notified. Resident died on 1/16/2021 @ 930AM.	No prior vaccinations for this event.
PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
1. Fatigue ? day 1 - Tuesday 2. Loss of appetite ? day 1 Tuesday 3. Fever 102.0 ? day 2 - Wednesday 4. Chills ? day 2 - - Wednesday 5. Weak ? day 2 - - Wednesday 6. Non-ambulatory (unusual) ? day 2 - - Wednesday 7. Two emergency service ambulance assessment ? day 2 - - Wednesday 8. Symptoms improved ? day 3 - Thursday 9. Ambulatory - day 3 - Thursday 10. Symptoms worsened ? day 4 - Friday 11. Chills ? day 4 - Friday 12. Non-ambulatory again ? day 4 - Friday 13. Fever 102.0 ? day 4 - Friday 14. Left side flank pain ? day 4 - Friday 15. CPR and declared decease at home by paramedics - day 5 - Saturday morning @ 1:32am	No prior vaccinations for this event.
PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers	No prior vaccinations for this event.

turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away

	PYREXIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion; On 21Feb he went to the ER after vomiting and passing out; On 21Feb he went to the ER after vomiting and passing out; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; fever; headache; stomach upset; This is a spontaneous report from a contactable consumer reporting for the father: A 75-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EL3428) at single dose at left arm on 03Feb2021 for Covid-19 immunisation. Medical history included type 2 diabetes mellitus. No known allergies. The patient had not experienced Covid-19 prior vaccination. Concomitant medication in 2 weeks included amitriptyline hydrochloride (manufacturer unknown) 10 mg, atorvastatin (manufacturer unknown) 20 mg, dutasteride (manufacturer unknown) 0.5 mg, linaclotide (LINZESS) 290 mcg, gabapentin (manufacturer unknown) 300 mg, montelukast (manufacturer unknown) 10 mg, ramipril (manufacturer unknown) 5 mg, insulin degludec (TRESIBA) 100 unit/ml, liraglutide (VICTOZA) 18 mg/3ml solution. No other vaccine in 4 weeks. The patient experienced cardiac arrest due to pericardial		No prior vaccinations for this event.

effusion on 21Feb2021 14:15, fever on 13Feb2021, headache on 13Feb2021, stomach upset on 13Feb2021, on 19feb, he began to feel ill again with a fever, he felt worse on 20feb on 19Feb2021, on 21feb he went to the ER after vomiting and passing out on 21Feb2021. Events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of cardiac arrest due to pericardial effusion. Course of events: In Feb2021, 10 days after his 1st injection, the patient developed fever, headache, and stomach upset. He went for a rapid Covid-19 test (nasal swab) and it was negative on 11Feb2021. The doctor told him he might be having a delayed reaction to the vaccination. After a couple of days, he improved. On 19Feb2021, he began to feel ill again with a fever. He felt worse on 20Feb2021. On 21Feb2021 he went to the ER after vomiting and passing out and received treatment: IV fluids, diagnostic testing at ER. Rapid Covid test (nasal swab) at ER came back negative again on 21Feb2021. His heart arrested suddenly and he could not be resuscitated. CT scan results, that came back after death, showed Covid like pneumonia and pericardial effusion. The patient died on 21Feb2021 14:15. Cause of death was cardiac arrest due to pericardial effusion. An autopsy was not performed. The outcome of cardiac arrest due to pericardial effusion was fatal, of fever, headache, stomach upset was recovering, of he began to feel ill again with a fever, he felt worse was not recovered, of he went to the ER after vomiting and passing out was unknown.; Reported Cause(s) of Death: cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion

PYREXIA

COVID19 (COVID19 (UNKNOWN)) (1202)

Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2 diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated) then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and was intubated. Transported to hospital. SARS CoV-2 and influenza negative.

No prior vaccinations for this event.

	RADIAL PULSE ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.		No prior vaccinations for this event.
	RADIOTHERAPY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin,		No prior vaccinations for this event.

LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on

imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

RALES

COVID19 (COVID19 (MODERNA)) (1201)

2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.

No prior vaccinations for this event.

RALES

COVID19 (COVID19

	(MODERNA)) (1201)
1-25-2021- Phone call: pt had cold and cough prior to vaccine. cough worsened 1-28-2021 Phone call: pt requesting provider visit, cough is same and taking tessalon pearls 1-29-2021 Provider in office visit: pt complain of cough and SOB for 6 days. Getting worse. Temp 101.2, pulse ox 87%, BP 128/70. level of distress- leaning forward to breath. appeared ill. diffuse rales throughout both lung fields, more at bases. Diagnosis Pneumonia due to COVID 19 virus. Sent to ER	No prior vaccinations for this event.
RALES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was	No prior vaccinations for this event.

made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

	RALES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
At approximately 12:15 pm the resident had a brief unresponsive episode that resolved quickly. Her Vital signs were stable and her mentation was at baseline. Later that evening approximately 10 pm she had labored respirations, shortness of breath, lethargy with bilateral crackles, Oxygen desaturated to 76% on room air, tachycardia and hypotension. She expired at 6:30 a.m. the following day.		No prior vaccinations for this event.
	RALES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client tested positive for COVID-19 by rapid test on 1/8/21. On 1/9/21 at 1405 his oxygen saturation dropped to 86% and oxygen was initiated at 2L per nasal cannula. A non-productive cough was noted on 1/10/21 and oxygen was increased to 3L. On 1/12/21 Client became non-responsive with 30 second periods of apnea. Dexamethasone was initiated on 1/13/21. Lung sounds were noted with crackles on 1/15/21 at 1158 and at 2120 Client was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.		No prior vaccinations for this event.
	RALES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.	
RALES		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Early in the shift on January 31 resident was noticed to be more tired than usual and was not eating well. Lung sounds were crackly and resident was found to be hypotensive. He was evaluated in emergency department. He was diagnosed with pneumonia. Received a loading dose of antibiotic and returned to facility.	No prior vaccinations for this event.	
RASH		**COVID19 (COVID19 (MODERNA)) (1201)**
The patient had severe shortness of breath resulting in cardiac arrest on the 5th day after the vaccine. Shortness of breath started 12 hours after injection. On the 5th day, the patient was discovered to also have a rash throughout his body, but it is unknown when this rash started.	No prior vaccinations for this event.	
RASH		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine given on 12/29/20 by Pharmacy. On 1/1/21, resident became lethargic and sluggish and developed a rash on forearms. He was a Hospice recipient and doctor and Hospice ordered no treatment, just to continue to monitor. When no improvement of codition reported, doctor and Hospice ordered comfort meds (Morphine, Ativan, Levsin). Resident expired on 1/4/2021	No prior vaccinations for this event.	
RASH		**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
At approximately 10:30pm on 1/14/2021, resident was noted to have a rash on her face, hands, arms, and chest. VS:100.2, 113, 20,108/59, 84% room air. applied nasal cannula at 4-L, telephoned Physician orders 6mg Decadron one time order, a second set of Vitals , reads 99.3, 110, 20, 106/60, 90% on 4-L N/C. On coming shift advised. At approximately 2:00am on 1/15/2021, resident congested and coughing. BP 151/70, pulse 124, temp 98.1 forehead, resp 20 and pulse oc 79% on 3L. At approximately 2:30am PRN cough syrup and breathing tx. Resident's condition began to worsen with breathing tx. This LPN updated at 0248 doctor on resident's condition. Doctor gave permission for resident to go to hospital. At 4:19am the Er called to say resident passed away.	No prior vaccinations for this event.
RASH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/29/21 patient began not feeling well and saw her provider. The doctor gave her fluids and tramadol for pain. They noticed increased confusion, but thought that could have been due to the tramadol. They also increased her gabapentin as she was experiencing nerve pain. Patient also developed a rash and was diagnosed with shingles on 2/1/21. Patient died on 2/3/21	No prior vaccinations for this event.
RASH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Presented from clinic with 3-4 days of extensive rash. There were multiple areas of skin sloughing on bilateral upper extremities and abdominal wall.	No prior vaccinations for this event.
RASH	**COVID19 (COVID19 (PFIZER-**

		BIONTECH)) (1200)
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
	RASH	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Day After - severe headache, 2 days after headache continues, itchy scalp, day 3 rash visible at hair line headache continues, more confusion than normal, day 4 on site nurses check rash and think it is dermatitis, day 5 continues to get work nurse practitioner was to visit next day, day 6 NP thinks that she has UTI and sends her to hospital (2/11/21). Hospital determines - Rash is Shingles, UTI present, - MRSA is now present in shingles which is on right back of head and right neck and face. Next Sepsis is diagnosed. Since 2/11/21 patient was not conscious. 2/20/21 famiy is notified that she should be moved to Hospice. Moved to hospice on 2/20/21. The patient, my mother, died on 2/23/21 official cause of death is UTI.		No prior vaccinations for this event.
	RASH MACULAR	**COVID19 (COVID19 (MODERNA)) (1201)**
According to patient's caregiver, patient presented with symptoms of fever (101.6 F) and purple blotches all over the body within an hour. Since patient was in hospice , caregiver called Hospice and a pharmacy and was told to give patient Benadryl and Tylenol. Patient was given both medications and the fever subsided in a few days but the purple blotches never went away. Patient passed away at the facility a week later.		No prior vaccinations for this event.

RECTAL HAEMORRHAGE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM		No prior vaccinations for this event.
RED BLOOD CELL ANALYSIS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
RED BLOOD CELL BURR CELLS PRESENT		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to		No prior vaccinations for this event.

death of patient prior to lab company arrival.

RED BLOOD CELL COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
RED BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.	No prior vaccinations for this event.
RED BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level.	No prior vaccinations for this event.

Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.

RED BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
RED BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	No prior vaccinations for this event.
RED BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious,	No prior vaccinations for this event.

but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

	RED BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.		No prior vaccinations for this event.

	RED BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite.		No prior vaccinations for this event.

	RED BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute		No prior vaccinations for this

MD visit-basilar crackles right and coughing. Increased confusion.

event.

RED BLOOD CELL COUNT DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar

No prior vaccinations for this event.

opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

	RED BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM		No prior vaccinations for this event.
	RED BLOOD CELL COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
RED BLOOD CELL COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	No prior vaccinations for this event.
RED BLOOD CELL MICROCYTES	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
RED BLOOD CELL NUCLEATED MORPHOLOGY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of	No prior vaccinations for

chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	this event.
RED BLOOD CELL NUCLEATED MORPHOLOGY PRESENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.
RED BLOOD CELL SCHISTOCYTES	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Pt received dose #1 of COVID-19 vaccine (Pfizer-BioNTech) on 12/18/20 and dose #2 (Pfizer-BioNTech) on 1/8/21. On 1/30, patient was evaluated at urgent care due to back pain. No bloodwork done; metronidazole prescribed for 7 days. On 2/8, patient was admitted to outside hospital due to ongoing symptom progression. At time of admission, hgb 5 g/dL and plt 9k. Per Dr. (hematology/oncology), pt with schistocytes, LDH 1500, and elevated reticulocyte count consistent with thrombotic thrombocytopenic purpura (TTP). SCr >2 mg/dL. Patient immediately treated with plasma exchange and steroids, however continued to decline. Patient expired on 2/14/21.

No prior vaccinations for this event.

RED BLOOD CELL SEDIMENTATION RATE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note,

No prior vaccinations for this event.

PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard

of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

RED BLOOD CELL SEDIMENTATION RATE NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation

No prior vaccinations for this event.

RED BLOOD CELL SEDIMENTATION RATE NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right

No prior vaccinations for this event.

middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

RED BLOOD CELLS URINE

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep

No prior vaccinations for this event.

his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

RED BLOOD CELLS URINE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the

No prior vaccinations for this event.

emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

RED BLOOD CELLS URINE POSITIVE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.

RED CELL DISTRIBUTION WIDTH	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid	No prior vaccinations for this event.

retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.

RED CELL DISTRIBUTION WIDTH INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Resident was seen by MD on 1/11/2021 due to increasing in edema and shortness of breath. Lasix 40 mg STAT given. New orders to get a STAT CBC, CMP, and BNP. Resident has been dependent on Oxygen since his diagnosis of COVID-19 on 11/23/2020. Labs were abnormal. Continued on the lasix 40 mgs. Resident remained short of breath with exertion and on oxygen. He was assisted to the toilet on 1/15/2021 in the morning where he subsequently passed away.

No prior vaccinations for this event.

RED CELL DISTRIBUTION WIDTH INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained.

No prior vaccinations for this event.

He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

RED CELL DISTRIBUTION WIDTH NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
RED CELL DISTRIBUTION WIDTH NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	No prior vaccinations for this event.
RED CELL DISTRIBUTION WIDTH NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.

RED CELL DISTRIBUTION WIDTH NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."		No prior vaccinations for this event.

RED CELL DISTRIBUTION WIDTH NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.		No prior vaccinations for this event.

REFUSAL OF TREATMENT BY PATIENT		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt was hospitalized Jan 18, 2021 after he had fallen outside overnight and lay there approximately 12 hours until he was found. Hypothermic & rhabdomyolis diagnosis. Gradually improved w/ strength & mental status - was in swing bed @ hospital. He got his first Covid 19 shot on 2-8-21. Was fine @ 0300 on 2-9-21 and @ 0430 he was found unresponsive. Dx: probable arrythmia & pronounced dead @ 0454. Noted on pain scale @ 2/8/21 @ 21:11, clients pain was a 7/10 They offered pain med & he refused They repositioned & distracted him @ 2047 on 2/8/21 Pain had decreased to 3/10 and nothing given. Then @ 0300 check he was sleeping and @ 0430 unresponsive.		No prior vaccinations for this event.
REFUSAL OF TREATMENT BY PATIENT		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient with failure to thrive symptoms prior to 2nd dose, not eating, not taking medications.		No prior vaccinations for this event.
REFUSAL OF TREATMENT BY PATIENT		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.		
REGURGITATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient did not display any obvious signs or symptoms; the vaccination was administered at approximately 10:00 AM and the patient continued throughout her day without any complaints or signs of adverse reaction. Patient was helped to bed by the nursing assistant estimated at around 9:00 PM. The facility received notification from the lab around 11:00 PM that the patient's COVID-19 specimen collection from Sunday,		No prior vaccinations for this event.

1/3/21, detected COVID-19. When the nursing staff went to the room to check on the resident and prepare her to move to a COVID-19 care area the patient was found unresponsive, no movement, no chest rises, noted regurgitated small amount of food to mouth left side, lying on left side. Pupils non reactive.

	RENAL FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**
He had not been feeling well after his second Covid vaccination (on 01/23/2021) and was found unresponsive in his room at the nursing home (late evening on 02/02/2021). He was taken to a hospital where they did tests and he had pneumonia and kidney failure, but he was being transferred to a larger hospital when he arrested and died (02/03/2021)		No prior vaccinations for this event.

	RENAL FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**
Death; kidney failure (unable to urinate); shortness of breath; required oxygen; A spontaneous report was received from consumer concerning an 87-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced shortness of breath, kidney failure and death. The patient's medical history included advanced kidney and heart disease. No relevant concomitant medications were reported. On 06 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 17 Jan 2021, the husband reported that the patient experienced adverse events. Symptoms included shortness of breath and kidney failure (unable to urinate). The patient was admitted to the hospital and discharged to hospice. Oxygen was administrated for shortness of breath. Action taken with mRNA-1273 in response to the events was not applicable. On 20 Jan 2021, the patient died. The cause of death was unknown. Autopsy details were unknown.; Reporter's Comments: This case concerns a 87-year-old, female patient with the medical history of advanced kidney and heart disease, who experienced fatal unexpected event of dyspnea, renal failure and death. The events of dyspnea and renal failure occurred 12 days and the event of death occurred 15 days after the first dose of mRNA-1273		No prior vaccinations for this event.

(Lot: unknown). The patient was admitted to the hospital and discharged to hospice. Oxygen was administrated for shortness of breath. The cause of death was unknown. Autopsy details were unknown. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, the history of advanced kidney and heart disease may remain as confounder. Additional information has been requested.; Reported Cause(s) of Death: Unknown cause of death

RENAL FAILURE		**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"	No prior vaccinations for this event.	

RENAL FAILURE		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident had severe CAD, DM type 2, and hx of RBKA and left 5 digits on foot amputation. Hx of osteomyelitis post surgical. After last surgery, resident did not have a good appetite, more restless, increased confusion with dementia. Significant other passed away on 12/30/20, resident began refusing meals, decreased eating. Vaccinated on 1/13/21. On 1/25/21 Resident labs showed kidney failure. Dr. spoke with family and transitioned to Comfort care, on 2/5/21 went hospice. Patient passed away on 2/13/2021.	No prior vaccinations for this event.	

RENAL FAILURE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Legs started swelling and shortness of breath Thursday January 21 2021 Was rushed to hospital with kidney failure and fluid build up around lungs and entire body Blood pressure dropped and had multiple organ failure

No prior vaccinations for this event.

RENAL FAILURE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 2/5/2021 resident noted to be azotemic. Creatinine up to 3.8 and BUN in 80's. He was started on NS hydration. On 2/7/2021 he was noted without VS, per MD notes, possible VF arrest, renal failure; death unclear exact cause.

No prior vaccinations for this event.

RENAL FAILURE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Unresponsive, Increase BP and H. Hospital Dx Renal Failure No prior vaccinations for this event.

RENAL FAILURE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.

No prior vaccinations for this event.

RENAL FAILURE

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
My dad received the Pfizer vaccination on 2/5/21. He was admitted into the hospital the next day for C-Diff bacterial infection. He had been on dialysis treatments for kidney failure treatment since 2017 and had recently been diagnosed with stage 3 colon cancer in June 2020. He had completed his final treatment of chemotherapy on 2/4/21 and several weeks prior had been determined cancer free. On Tuesday 2/9/21 he was released from the hospital and went home. Early Thursday morning 2/11/21 @ approximately 1:30 am CST his eyes rolled back in head and he stopped breathing and was non responsive. My mother called 911 and attempted CPR. Paramedics arrived and were able to successfully get a pulse then transferred him to the hospital. He was put on a ventilator @ the hospital and then transferred to a different hospital a few hours later. He lost pulse/heartbeat several times @ the 2nd hospital he was transferred to. We were not allowed to travel with him or see him b/c of all of the COVID restrictions. We were communicating with the ICU doctor by phone who ultimately communicated to us that there was nothing further that could be done to save his life. He subsequently passed away @ approximately 8:55 am CST on 2/11/21.	No prior vaccinations for this event.
RENAL REPLACEMENT THERAPY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021.	No prior vaccinations for this event.
RENAL TUBULAR NECROSIS	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	No prior vaccinations for this event.
RESPIRATION ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.	No prior vaccinations for this event.
RESPIRATION ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
"On 1/15/2021 at 1800, resident noted to be lethargic and shaking, stating ""I don't care."" repeatedly. C/O head and neck pain. T100.6. Given Tylenol with no relief of pain. Order received for Aleve and administered.. Assisted to bed as usual in evening. Monitored during night shift and noted to be resting comfortably/sleeping.. Noted agonal breathing at 4:10 AM 1/16/2021 , T 99.4, Absence of vital signs at 4:15AM 1/16/21 and death pronounced at 4:40AM 1/16/21."	No prior vaccinations for this event.
RESPIRATION ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Two days later passed away; difficulty breathing, shortness of breath; difficulty breathing, gurgling; Not feeling well; Achiness; Severe fever; Chills; A spontaneous report was received from a physician concerning a 56-	No prior vaccinations

year-old female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed fever, chills, achiness, shortness of breath, gurgling and unresponsive. The patient's medical history was not provided. Concomitant product use was not provided. On 19 Jan 2021, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Lot 042L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. After receiving the vaccine on 19 Jan 2021, the patient experienced fever, chills, shortness of breath, gurgling and achiness. On 21 Jan 2021, the patient was found unresponsive. Emergency medical services were called to perform life saving measures however, they were unsuccessful. No further treatment information was provided. The patient died on 21 Jan 2021. The cause of death was reported as unknown. An autopsy was planned.; Reporter's Comments: This case concerns a 56-year-old, female, who experienced a serious event of death, with many other events after receiving second dose of mRNA-1273 (Lot# 042L20A). Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death		for this event.
	RESPIRATION ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.		No prior vaccinations for this event.
	RESPIRATION ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.	No prior vaccinations for this event.

RESPIRATION ABNORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
Hx dementia, CVA, CAD. 2-3 year history of only consuming 25% of 1-2 meals daily. All meds d/c early 2020 because of refusing to eat or drink anything. Suddenly began drinking april/may, gained weight back. Vaccinated on 1/7/21 & 2/4/21. On 2/22/21 had significant changes in respiratory status. Passed away 2/23/21.		No prior vaccinations for this event.
RESPIRATION ABNORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
All residents had been in isolation due to multiple cases of COVID in the facility. Resident voiced no health related complaints. He continued to visit with staff and required moderate assist with toileting. Resident had fall 0130 on 1-15-2021, which resulted in laceration with surgical repair. Resident was noted to change in mental status and respirations on morning of 1-16-2021 during morning blood sugar check. Resident had O2 @1.5l/m via n/c and respirations of 10 with periods of apnea and unresponsive to verbal stimuli. Blood sugar was 583. Resident deceased upon re-check after calling PCP to report status change.		No prior vaccinations for this event.
RESPIRATION ABNORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
73-year-old man s/p first dose of Pfizer at 10:20 AM Ambulated comfortably to exit after 20 minutes in observation but 10:45 collapsed while exiting the building 10:47 CPR initiated 10:49 medical team/EMS found no pulse, agonal respirations, ventricular fibrillation Paramedics and team performed ACLS; of note patient was intubated 7.5 ETT with bilateral breath sounds on ventilation; paramedic reported easy intubation with no apparent throat swelling; 11:02 transported to Emergency Department 11:30 Pronounced		No prior vaccinations for this event.

dead at Emergency Department

RESPIRATORY ACIDOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (	No prior vaccinations for this event.
RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
on 12/24/2020 the resident was sleepy and stayed in bed most of the shift. He stated he was doing okay but requested pain medication for his legs at 250PM. At 255AM on 12/25/2020 the resident was observed in bed lying still, pale, eyes half open and foam coming from mouth and unresponsive. He was not breathing and with no pulse	No prior vaccinations for this event.
RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**

Resident had lunch on 01/14/21 and after lunch around 2:00pm, he vomited and stopped breathing. We coded the resident and 911 paramedics came. They pronounced him dead at 2:18pm.	No prior vaccinations for this event.	
RESPIRATORY ARREST		**COVID19 (COVID19 (MODERNA)) (1201)**
"Pt. woke up the next morning after vaccination and ""didn't feel well"", described by wife as fatigue, no energy. At approximately 2 PM, he vomited. His wife checked on him at 4:20 PM and he wasn't breathing sitting in his chair. EMS squad was called but when they arrived he was asystole and mottling present. Did not start CPR since he was already gone too long. Pronounced by coroner on scene."	No prior vaccinations for this event.	
RESPIRATORY ARREST		**COVID19 (COVID19 (MODERNA)) (1201)**
UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless and breathless and was pronounced. Autopsy currently pending.	No prior vaccinations for this event.	
RESPIRATORY ARREST		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident passed away at 8:15 am on 1/28/21-found to be without pulse/respirations/DNR order in place.	No prior vaccinations for this event.	

RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**	
Patient was seen at 0710 he was sleeping but at normal cognitive behavior Patient was again assessed at 0720 where he was noted to be unresponsive, BP 180/100s, HR 230s, he was a DNR therefore not CPR was administered. EMS arrived at facility patient was noted to be in full cardiac and respiratory arrest. Time of death 0735		No prior vaccinations for this event.
RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**	
We don't know what happened. 25 hours after the shot, he started gagging and stopped breathing. He was pronounced at OSF at 8:07pm after we took him off life support.		No prior vaccinations for this event.
RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**	
Notes of the checks/events with resident: 18:36 2/2/21 Resident had no complaint of pain, swelling, redness or warmth to vaccine site. No signs and symptoms of fever, chills, tiredness or headache. T 97.2 02:50 2/3/2021 Resident received 2nd COVID vaccine. No complaint of pain, swelling, redness or warmth to vaccine site. No signs and symptoms of fever, chills, tiredness or headache. T 98.1 07:15 2/3/2021 Resident was observed not breathing. 911 was contacted along with the doctor. Resident was confirmed having passed away.		No prior vaccinations for this event.
RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**	
DISCOVERED UNRESPONSIVE WITHOUT PULSE, RESPIRATIONS, HEART BEAT ON 2/7/21 AT		No prior vaccinations for this

0435 A.M. RESIDENT WAS DNR STATUS. event.

RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.	No prior vaccinations for this event.
RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
2/7/2021 at 0630, resident found in recliner without pulse or respirations. Resident had not been found to have any adverse reactions to the vaccine between the time of the vaccine on 2/4 until found deceased on 2/7.	No prior vaccinations for this event.
RESPIRATORY ARREST	**COVID19 (COVID19 (MODERNA)) (1201)**
Admitted to hospital with sob upon exertion that started prior to vaccine. Hx COPD, HTN, CKD, hyperlipidemia, bladder cancer in remission. Stated he has been taking Eliquis and Xarelto between renal doctor and cardiologist Dr. Anticipating going home 2/5/21 but then turned blue and stopped breathing under a DNR. COVID test negative. Labs show acute on chronic renal failure with an elevated troponin likely from demand ischemia.	No prior vaccinations for this event.

RESPIRATORY ARREST

COVID19 (COVID19 (MODERNA)) (1201)

Given First Moderna covid vacc 1/19/2021. Doing well on multiple contacts from health care providers, then 2/5/2021 was driving, pulled over to the side of the road into a yard, got out of the car and told an observer that he could not breathe, collapsed face down in the snow, EMS called, unable to revive him.

No prior vaccinations for this event.

RESPIRATORY ARREST

COVID19 (COVID19 (MODERNA)) (1201)

Patient was found unconscious without a pulse. Patient remained in asystole without pulse or respirations despite CPR.

No prior vaccinations for this event.

RESPIRATORY ARREST

COVID19 (COVID19 (MODERNA)) (1201)

Found lying face down without respiration or pulse, believed to be within 5 minutes of event. ACLS procedures unsuccessful. Unable to get autopsy. Believed to be heart attack secondary to COVID infection, but unconfirmed. Relative contribution of recent vaccination unknown.

No prior vaccinations for this event.

RESPIRATORY ARREST

COVID19 (COVID19 (MODERNA)) (1201)

Patient received Covid Vaccine Moderna at 1145, multiple syncopal episodes at pharmacy, sent to ER. Outcome Death

No prior vaccinations for this event.

RESPIRATORY ARREST

COVID19 (COVID19 (MODERNA)) (1201)

2-24-21 patient with development of cough, fatigue, increasing on chronic disability worsening debility and falls. scheduled for office visit 2-25.21 0900 call from spouse 0210 am patient was not breathing and lvad alarming low flow alarm on arrival of ems confirm asystolic not breathing and dead		No prior vaccinations for this event.
RESPIRATORY ARREST		**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation		No prior vaccinations for this event.
RESPIRATORY ARREST		**COVID19 (COVID19 (MODERNA)) (1201)**
Beginning in the evening 2/19/21, fever/chills/fatigue; worsening of symptoms 2/20/21 with lethargy/lack of appetite/weakness; unable to arouse on 2/21/21 then breathing stopped, patient's spouse called 911 performed CPR, EMS continued for 15 min then while in ambulance to hospital where he was pronounced dead. Official time of death 2:20pm		No prior vaccinations for this event.
RESPIRATORY ARREST		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident found unresponsive without pulse, respirations at 04:30 CPR performed, expired		No prior vaccinations for this event.

at 04:52 by Rescue

RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident became SOB, congested and hypoxic requiring oxygen, respiratory treatments and suctioning. Stabilized after treatment and for the next 72 hours with oxygen saturations in the 90s. On 1/3/2021 was found without pulse and respirations. Resident was a DNR on Hospice.	No prior vaccinations for this event.
RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"The resident received is vaccine around 11:00 am and tolerated it without any difficulty or immediate adverse effects. He was at therapy from 12:36 pm until 1:22 pm when he stated he was too tired and could not do anymore. The therapist took him back to his room at that time and he got into bed himself but stated his legs felt heavy. At 1:50 pm the CNA answered his call light and found he had taken himself to the bathroom. She stated that when he went to get back into the bed it was ""abnormal"" how he was getting into it so she assisted him. At that time he quit breathing and she called a RN into the room immediately. He was found without a pulse, respirations, or blood pressure at 1:54 pm. He was a DNR."	No prior vaccinations for this event.
RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient did not display any obvious signs or symptoms; the vaccination was administered at approximately 10:00 AM and the patient continued throughout her day without any complaints or signs of adverse reaction. Patient was helped to bed by the nursing assistant estimated at around 9:00 PM. The facility received notification from the lab around 11:00 PM that the patient's COVID-19 specimen collection from	No prior vaccinations for this event.

Sunday, 1/3/21, detected COVID-19. When the nursing staff went to the room to check on the resident and prepare her to move to a COVID-19 care area the patient was found unresponsive, no movement, no chest rises, noted regurgitated small amount of food to mouth left side, lying on left side. Pupils non reactive.

	RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt last seen at 1200 by nurse for ID band check. No visible signs of distress noted. Pt states ""I just want to be left alone"". 1230 nurse was called to pt room. Pt was noted unresponsive, no pulse and respiration noted. CPR started immediately, at 1239 first shock given. 1245 EMT took over, at 1319 EMT called time of death"		No prior vaccinations for this event.

	RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/7-21 - Received second dose of pfizer covid-19 vaccine 1/8/21 - Fever, dizziness, headache 1/10/21 0250 was found not breathing. EMS performed CPR and patient deceased		No prior vaccinations for this event.

	RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Cardiac Arrest; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; This is a spontaneous report from a contactable other healthcare professional (HCP). A 66-year-old female patient (pregnant at the time of vaccination: no) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284) via intramuscular at left arm on 11Jan2021 12:15 PM at single dose for COVID-19 immunization. Medical history included diastolic CHF, spinal stenosis, morbid		No prior vaccinations for this event.

obesity, epilepsy, pulmonary hypertension and COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19). The patient received medication within 2 weeks of vaccination included amiodarone, melatonin, venlafaxine hydrochloride (EFFEXOR), ibuprofen, aripiprazole (ABILIFY), lisinopril, cranberry capsules, diltiazem, paracetamol (TYLENOL), famotidine, furosemide (LASIX [FUROSEMIDE]), ipratropium bromide, salbutamol sulfate (IPRATROPIUM/ALBUTEROL), buspirone, senna alexandrina leaf (SENNA [SENNA ALEXANDRINA LEAF]), polyethylene glycol 3350 and morphine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient used took Penicillin, propranolol, quetiapine, topiramate, Lamictal and had allergy to them. Patient used took the first dose of BNT162B2 (lot number: EJ1685) via intramuscular at right arm on 21Dec2020 12:00 PM at single dose for COVID-19 immunization. Since the vaccination, the patient been tested for COVID-19 (Sars-cov-2 PCR) via nasal swab on 06Jan2021, covid test result was negative. Patient was found pulseless and breathless 20 minutes following the vaccine administration (11Jan2021 12:30 AM). MD found no signs of anaphylaxis. Patient died on 11Jan2021 12:30 AM because of cardiac arrest. No treatment received for the events. Outcome of pulseless and breathless was unknown. the autopsy was performed, and autopsy remarks was unknown. Autopsy-determined cause of death was unknown. It was reported as non-serious, not results in death, Life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.; Sender's Comments: Based on the available information this patient had multiple underlying medical conditions including morbid obesity, diastolic CHF, epilepsy, pulmonary hypertension and COVID-19 diagnosed prior to vaccination. All these conditions more likely contributed to patients cardiac arrest resulting in death. However, based on a close temporal association (""Patient was found pulseless and breathless 20 minutes following the second dose of BNT162B2 vaccine administration, contributory role of BNT162B2 vaccine to the onset of reported events cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Cardiac arrest; Autopsy-determined Cause(s) of Death: autopsy remarks was unknown. Autopsy-determined cause

of death was unknown"

	RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"83yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, the patient reportedly got up in the middle of the night with c/o feeling ""blah"", restlessness, and nausea. VS normal, no other s/sx. At 4:15am, the patient was asked to go back to bed, assisted by a nurse and GNA. At 6am, GNA was going to do morning VS and found the patient unresponsive, no pulse, no respirations. GNA notified the nurse. At 6:03am, CPR started and EMS called. At 6:15am, EMS arrived and took over. At or around 6:30am, EMT called time of death"		No prior vaccinations for this event.

	RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/11/21 at 8:57 Resident with fever and at 11 am saturation down to 83 O2 to 10 liters. Resident continued to decline until CTB on 1/14/2021 at 1325		No prior vaccinations for this event.

	RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
tired; legs felt heavy; stopped breathing; This is a spontaneous report from a Pfizer-sponsored program a non-contactable consumer. A 93-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 04Jan2021 11:00 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Patient received vaccine around 11:00 a.m. About two hours later, he said he was tired and couldn't continue with the physical therapy he was doing. He was taken back to his room, where he said his legs felt heavy. Soon		No prior vaccinations for this event.

after, he stopped breathing. A nurse declared a do-not-resuscitate order. The patient died on 04Jan2021. It was not reported if an autopsy was performed. Outcome of stopped breathing was fatal. Outcome of tired and legs felt heavy was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: stopped breathing

	RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.		No prior vaccinations for this event.
	RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient passed su hospital on 23Jan2021 stopped breathing; complained of not feeling well; had an inflamed gall bladder; This is a spontaneous report from a contactable consumer. A 98-year-old female patient received bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL8982 and expiry date unknown), via an unspecified route of administration on 16Jan2021 at single dose for covid-19 immunisation. The patient medical history was not reported. The patient concomitant medication reported as has received other medications (unspecified) within 2 weeks. The patient passed in hospital on 23Jan2021 with stopped breathing. Day after vaccine on 17Jan2021, the patient complained of not feeling		No prior vaccinations for this event.

well, went to hospital where was told she had an inflamed gall bladder. The events caused patient hospitalization for 4 days. The cause of death reported as stopped breathing. It was unknown if autopsy done. Prior to vaccination, the patient not diagnosed with COVID-19. The outcome of the event breathing arrested was fatal, outcome of the other events was unknown.; Reported Cause(s) of Death: Stopped breathing		
	RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
family states seemed short of breath since after the covid vaccine. Staff said beginning on 1/22/21 the patient seemed sluggish, more tired, and nausea noted. She stayed in her room more after the vaccine because worried about giving/getting COVID to others. was talking on the phone at 11:30 PM on 1/26/21 to staff person about temperature of room. at 12:15 AM on 1/27/21 staff noted not breathing, started CPR and called EMS. When EMS arrived they stopped the code because she was too long deceased.		No prior vaccinations for this event.
	RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or		No prior vaccinations for this event.

lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board

for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt suffered Cardiac Arrest and respiratory arrest on 2/9/21 and passed away at a local hospital. He had multiple health conditions likely contributing to this. he arrested at home and CPR was attempted and unsuccessful. Pt received his Covid vaccine #1 on 1/27/21. No issues were noted after vaccine and was due for his 2nd dose next week. However, we were notified he passed away on 2/9/21. Very likely death not at all related to vaccine but wanted to document as patient was in the middle of the covid vaccine series.	No prior vaccinations for this event.
RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful	No prior vaccinations for this event.

ventilation and acls protocol. Code was stopped.

	RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My dad received the Pfizer vaccination on 2/5/21. He was admitted into the hospital the next day for C-Diff bacterial infection. He had been on dialysis treatments for kidney failure treatment since 2017 and had recently been diagnosed with stage 3 colon cancer in June 2020. He had completed his final treatment of chemotherapy on 2/4/21 and several weeks prior had been determined cancer free. On Tuesday 2/9/21 he was released from the hospital and went home. Early Thursday morning 2/11/21 @ approximately 1:30 am CST his eyes rolled back in head and he stopped breathing and was non responsive. My mother called 911 and attempted CPR. Paramedics arrived and were able to successfully get a pulse then transferred him to the hospital. He was put on a ventilator @ the hospital and then transferred to a different hospital a few hours later. He lost pulse/heartbeat several times @ the 2nd hospital he was transferred to. We were not allowed to travel with him or see him b/c of all of the COVID restrictions. We were communicating with the ICU doctor by phone who ultimately communicated to us that there was nothing further that could be done to save his life. He subsequently passed away @ approximately 8:55 am CST on 2/11/21.		No prior vaccinations for this event.

	RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative.		No prior vaccinations for this event.

2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

RESPIRATORY ARREST

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

02/07/21 through 2/13/21 slightly fatiqued, took all his prescribed medications, ate breakfast, lunch and dinner was drinking eight 10 oz bottles of water. On 02/14/21 was very tired had a difficult time breathing after taking the normal meds. He took a breathing treatment with his prescribed Ipratropium Bromide and Albuterol Sulfate via home nebulizer. This did not improve his breathing. He was very weak and breathing was labored. 911 was called by wife. 911EMTchecked pulse and breathing. Informed him they would give him a breathing treatment.He started to go limp. EMT's got him to Ambulance and to Medical Center to the ER. Heroics done. He died. Pulmonary and Cardiac Arrest

No prior vaccinations for this event.

RESPIRATORY ARREST

COVID19 (COVID19

		(PFIZER-BIONTECH)) (1200)
Unable to breathe and died. Doctors unable to save her upon arrival No prior vaccinations for this event.		
RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
The recipient was feeling well immediately after the vaccination, all day on 2.8 and in the morning of 2.9. His daughter in law text him at 0930 and he did not respond to the text (atypical) and then he missed a morning meeting. His wife was downstairs in a meeting herself and after the meeting was over she called to him and he did not respond. She found him with no pulse and was not breathing. She called 911 and attempted CPR. They did not complete an autopsy, they stated that they believe the cause of death was either an embolism, Heart attack or aneurism. The wife stated that she does not believe the death was due to the vaccination; however, there were no tests completed to prove or disprove.		No prior vaccinations for this event.
RESPIRATORY ARREST		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Minor arm pain on 2nd day of each vaccine Diarrhea 3 days after 2nd vaccine Massive heart attack (left ventricle) 8 days (2/24/21) after vaccine Home hospice 3:30pm 2/24/21 Stopped breathing 5:45 am, pronounced dead at 8:22 am on 2/25/21		No prior vaccinations for this event.
RESPIRATORY ARREST		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt received 2nd Pfizer BioNTech Covid 19 EUA vaccine @1:50 pm; Pt released from Observation @2:09 pm. Approximately 2:18 pm RN called to parking lot and observed pt having difficulties. Called for EMS &		No prior vaccinations for

crash cart. Vitals taken 2:20 BP 83/55, no respirations noted, pt unresponsive. AED attached. EMS arrived 2:22 and took over care of pt. and transported @2:40 pm to Hospital. Per wife, pt has history of PE in Oct. 2020, HTN, diabetes with insulin pump, obesity, gastroparesis, home oxygen and uses motorized scooter. Wife also said pt had allergy to iodine not previously reported, and MD had stopped Zarelto subsequent to 1st Pfizer vaccine 2/8/21 ""due to breathing difficulty"". Patient was unable to be resuscitated. Time of death 14:59."	this event.
RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2	No prior vaccinations for this event.

high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good

recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

RESPIRATORY ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Expired within 30days of vaccination. Received vaccine 1/22/21 did not have any complaints, during a bed check she was found on the floor with no apparent injury, no pulse or respirations.	No prior vaccinations for this event.
RESPIRATORY DEPRESSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Fever, RespDepression & COVID positive REMDESIVIR (EUA) 200 mg x1 then 100 mg daily	No prior vaccinations for this event.
RESPIRATORY DEPRESSION	**COVID19 (COVID19 (MODERNA)) (1201)**
Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021and felt poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM	No prior vaccinations for this event.

CHLORIDE 1000 MG ONCE

	RESPIRATORY DEPRESSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of the COVID-19 Moderna vaccine on 1/19/2021 at an outside facility (no lot #, route, or site available to me in electronic charting). Pt began having hypoxia, SOB, and a dusky appearance of extremities on 1/29/2021 and was brought by EMS to our hospital. PT is a DNR and family had been looking into a hospice sign up due to dementia and general decline in the weeks prior to hospitalization. Pt tested positive on admission for COVID-19 via PCR test on 1/29/2021. Pt continued to have respiratory decline, was put on comfort care per wishes of family/advanced directives, and he passed away the evening of 1/30.		No prior vaccinations for this event.
	RESPIRATORY DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
began itching within 24 hours, within 5 days couldn't move on her own, by 6th day was having respiratory issues, by day 7 unresponsive, by day 8 dead		No prior vaccinations for this event.
	RESPIRATORY DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt developed COVID-19 infection, symptoms starting 7 days after first dose was given. Patient was admitted to hospital on 1/21 after falling (secondary to weakness) and striking head on toilet. Patient expired due to respiratory complications of COVID on 1/25.		No prior vaccinations for this event.
	RESPIRATORY DISTRESS	**COVID19 (COVID19**

	(MODERNA)) (1201)
36 hours after vaccination, the patient had increased respiratory distress. He was placed on high flow nasal cannula oxygen with mild improvement. He then continued to be hypotensive requiring IV fluids and subsequently IV vasopressors. Patient's BP was stabilized with vasopresor, however he continued to deteriorate clinically with altered mental status and lethargy, concerned for bowel peroration based on physical exam by MD. He was then emergency intubated and placed on mechanical ventilation. He was then transferred to acute care hospital near by.	No prior vaccinations for this event.
RESPIRATORY DISTRESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29	No prior vaccinations for this event.
RESPIRATORY DISTRESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the Moderna COVID vaccine 1/28/21. He was tested for COVID 19 on 1/29/31. Results were received 1/30/21, at which time he was evaluated and found to be hypoxic with tachycardia. He was sent to the local ER and returned this same day. On 2/2/21, he was evaluated by the provider, who sent him to the emergency room with acute respiratory distress and poor O2 sats	No prior vaccinations for this event.
RESPIRATORY DISTRESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR	No prior vaccinations

status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	for this event.
RESPIRATORY DISTRESS	**COVID19 (COVID19 (MODERNA)) (1201)**
This is a hospice patient under the care of Hospice at an affiliated nursing home. Pt received the vaccination around noon on 2-16-21 by a representative from Pharmacy. The following afternoon 2-17-21 at 14:45 the pt started to experience severe SOB resp rate 36, audible wheezing and use of respiratory accessory muscles. BP180/80, 113 pulse temp 98. Pt was given morphine and ativan. The respiratory distress was eased however pt never returned to baseline and died 2-22-21 around 4am.	No prior vaccinations for this event.
RESPIRATORY DISTRESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received dose 1 of Moderna Vaccine on 1/14/21 administered by pharmacy. Patient was hospitalized on 1/31/21 due to shortness of breath and diminished O2 sats down to 88%. Patient was in atrial fibrillation. Patient discharged from hospital on 2/25/21 to home. Patient received dose 2 of Moderna Vaccine on 2/25/21 prior to discharge from hospital. Last hospital note stated that patient was pleasant and cooperative with good motivation. Patient passed away after discharge from the hospital on 2/26/21. Patient's son called the hospital to report his passing.	No prior vaccinations for this event.
RESPIRATORY DISTRESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Within 24 hours of receiving the vaccine, fever and respiratory distress, and anxiety developed requiring oxygen, morphine and ativan. My Mom passed away on the evening of 12/26/2020.	No prior vaccinations for this event.

	RESPIRATORY DISTRESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness; respiratory distress Narrative: Patient tolerated his 1st dose of the COVID-19 vaccine well, on 12/16/2020, and received his 2nd dose on 1/6/2021. Patient had some mild clinical decline the past few days prior to 2nd vaccination, with a decreased appetite and some increased fatigue per nursing report, but no significant changes. He experienced nausea on the evening of 1/6/21, which was effectively managed, but by early morning he spiked a fever of 102.9 with a sat of 86.1%. He continued to deteriorate from that point on and died 1/7/21 @13:20. Clinically, the presentation was most consistent with an aspiration pneumonia.		No prior vaccinations for this event.
	RESPIRATORY DISTRESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
respiratory distress; fever; anxiety developed requiring oxygen; Passed away; This is a spontaneous report via a Pfizer-sponsored program from a non-contactable consumer. A 63-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot and expiry not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. Medical history included anaphylactic reaction (broad), neuroleptic malignant syndrome (broad), anticholinergic syndrome (broad), acute central respiratory depression (broad), hypersensitivity (broad), respiratory failure (narrow), drug reaction with eosinophilia and systemic symptoms (broad), hypoglycaemia (broad), COVID-19 (broad) and chronic obstructive pulmonary disease (COPD); all from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine sodium and lorazepam (ATIVAN). Within 24 hours of receiving the vaccine, the patient experienced fever, respiratory distress, and anxiety developed requiring oxygen, morphine and lorazepam (ATIVAN). The patient passed away on the evening of 26Dec2020. The patient underwent lab tests and procedures which included SARS-COV-2 antibody test: negative on an unspecified date. The outcome of the event death was fatal, while of the other events was unknown. It was		No prior vaccinations for this event.

not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Passed a

RESPIRATORY DISTRESS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient noted with respiratory distress on 1/10/2021, transferred to hospital via 911.

No prior vaccinations for this event.

RESPIRATORY DISTRESS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Note Text: Resident oxygen was going down to 74% during change of shift 3-11, oxygen initiated 3liters via nasal canula per standing order want up to 84-86% NP notified, ordered Prednisone 20mg stat, Rocephin 1gram IM stat administered, Per NP statement if pt's condition worsening sent him to ER, continue monitoring pt and his oxygen going to 82% increasing distress. Notified Nurses supervisor, 911 was called pt left building at 1819 to Hospital alert oriented. Vs bp. 165/60, temp. 98.3,m pulse 109, res 22, 02. 82%. Resident father notified.

No prior vaccinations for this event.

RESPIRATORY DISTRESS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

No adverse reactions noted. Resident is on hospice for end of life care for terminal diagnosis cerebral atherosclerosis. Experiencing respiratory distress 2/10/2021 r/t to hospice prognosis.

No prior vaccinations for this event.

RESPIRATORY DISTRESS

COVID19 (COVID19 (PFIZER-

BIONTECH)) (1200)

DEATH Narrative: Presented to ED via EMS c/o increasing shortness of breath, O2 sat mid to high 80s on 4L. When EMS arrived , pt was in distress, intubated by EMS and transported to ED. Pt had a PEA arrest en route but resuscitated w/ return of spontaneous circulation after receiving a dose of epinephrine and chest compressions. Pt was hypotensive on arrival to ED. He was started on sepsis protocol , volume resuscitation and empiric antibiotics. Once stabilized, he was admitted to icu at hospital. Removed from respirator 2/22/21

No prior vaccinations for this event.

RESPIRATORY FAILURE

COVID19 (COVID19 (MODERNA)) (1201)

Patient vaccinated on 12/28. Approximately one day later, develops cough and on azithromycin x 1 week. On 1/3, patient develops left-sided weakness and aphasia. Taken to the hospital, tested COVID+, required intubation -- acute hypoxic respiratory failure secondary to COVID - on H&P. Patient died on 1/4/21 at 7:20am.

No prior vaccinations for this event.

RESPIRATORY FAILURE

COVID19 (COVID19 (MODERNA)) (1201)

Worsening respiratory failure 1/20/2021 death 1/27/2021 No prior vaccinations for this event.

RESPIRATORY FAILURE **COVID19 (COVID19 (MODERNA)) (1201)**

Resident passed away unexpectedly on 01/19/21 after developing acute hypoxic respiratory failure on morning of 01/19/21. She was transferred to hospital via EMS where she was intubated, coded, and ultimately expired with uncertain underlying cause, potentially ACS.

No prior vaccinations for this event.

RESPIRATORY FAILURE

COVID19 (COVID19

	(MODERNA)) (1201)
ON 02/08/2021 AROUND 0600 RESIDENTCOMPLAINED OF MOUTH PAIN AND RECEIVED OXYCODONE. DURING THE COURSE OF THE MORNING, RESIDENT EXHIBITED A FEW EPISODES OF LABORED/SHALLOW BREATHING AND SOB AT RESTING. 0XYGEN SATURATION RATE WAS 93-98% ON ROOM AIR, LUNG SOUNDS CLEAR IN ALL LOBES AND PULSE AND TEMPERATURE WITHIN NORMAL RANGE. AS THE DAY PROGRESSED, VITAL SIGNS REMAINED STABLE BUT RESIDENT CONTINUED TO HAVE PERIODS OF SOB/LABORED BREATHING.FAMILY AND NURSE PRACTIONER UPDATED AND THE ORDER WAS RECEIVED TO SEND PATIENT TO MEDICAL CENTER ER FOR EVALUATION PER AMBULANCE. RESIDENT TRANSPORTED AT 1425. RESIDENT RETURNED FROM THE ER AT 1830 ON HOSPICE CARE WITH THE DIAGNOSIS OF: ACURE RESPIRATORY FAILURE WITH HYPOXIA AND END OF LIFE DECISION MAKING. RESIDENT WAS MADE COMFORTABLE AND MONITORED DURING THE NIGHT AND EXPIRED AT 0630 ON 02/09/2021.	No prior vaccinations for this event.
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was vaccinated on 1/14/2021. On 1/22/2021, patient tested positive for COVID-19 and admitted to the hospital for acute hypoxemic respiratory failure, COVID-19 pneumonia, and severe ARDS. Patient was intubated on 1/23/2021 and later died on 2/10/2021 after being extubated and placed on comfort measures.	No prior vaccinations for this event.
RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with	No prior vaccinations for this event.

improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡ enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

RESPIRATORY FAILURE

COVID19 (COVID19 (MODERNA)) (1201)

death; hemiparesis; respiratory failure; Aphasia; SARS-COV-2 test positive; cough; A spontaneous report was received from other health care professional concerning a 32- year -female patient who received Modena's COVID-19 vaccine (mRNA-1273) and experienced aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive. The patient's medical history was not provided. No relevant concomitant medications were reported. On 28-Dec-2020, the patient received their first of two planned doses of mRNA-1273 (lot/batch 039k20A) intramuscularly on left arm for prophylaxis of COVID-19 infection. Approximately, one day later, patient developed cough and on treatment with azithromycin for one week. On 03-jan-2021, she experienced left sided weakness and aphasia and was shifted to hospital. Patient was confirmed COVID-19 positive which required intubation for acute hypoxic

No prior vaccinations for this event.

respiratory failure secondary to COVID-19. No laboratory data was provided. Action taken with mRNA-1273 in response to the events aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive not applicable. On an unknown date, the outcome of the events aphasia, cough, death, endotracheal intubation, hemiparesis, respiratory failure and SARS-COV-2 tested positive was fatal. On 04 Jan 2021, the patient passed away due to the unknown cause. Autopsy results were unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the event of COVID-19 is assessed as unlikely related. The cause of death was not reported. Autopsy results were unknown.; Reported Cause(s) of Death: Unknown cause of death

RESPIRATORY FAILURE

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen

No prior vaccinations for this event.

levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

RESPIRATORY FAILURE	**COVID19 (COVID19 (MODERNA)) (1201)**
sepsis; respiratory failure; Fever; Unresponsive; A spontaneous report was received from Pfizer concerning a 56-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced respiratory failure, sepsis, fever and sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 04 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient began to have a fever. She was sent to the emergency room for evaluation. That evening, she died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 11 Jan 2021. The cause of death was reported as respiratory failure and sepsis. Plans for an autopsy were unknown/not provided.; Reporter's Comments: This is a case of 56-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sepsis, fever, respiratory failure and sudden death. Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Respirtory Failure;	No prior vaccinations for this event.

Sepsis

RESPIRATORY FAILURE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
COVID-19; COVID-19; Pneumonia; respiratory failure; This is a spontaneous report from a contactable consumer. An 80-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 02Jan2021 for COVID-19 immunization. Medical history included Alzheimer's and others. No known allergies. Concomitant medications included unspecified medications. The reporter's mother in law was tested for COVID-19 at a nursing facility on 25Dec2020 and she was negative. On 02Jan2021, she received the first dose of Pfizer vaccine. On 04Jan2020, she developed a high fever, needed oxygen and was positive for COVID-19. Date of death was 04Jan2021. The cause of her death was listed as pneumonia, respiratory failure and COVID-19. No autopsy performed. No treatment received. No one knew if the vaccination contributed to her death. It was hard to know if her death was due to the administration of the vaccine or it exacerbated the COVID19 symptoms which led to her death. Since this was unknown, it could have been a possibility. The reporter wanted to give us this information because we might want to consider having high risk population, patients with underlying conditions, older population tested for COVID-19 prior to the vaccination, as this is not currently a recommendation or a requirement. All is very new and they are all learning so the reporter wanted to share this information with us. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There are medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. The outcome of the events was fatal. Information about Lot/Batch has been requested.; Sender's Comments: The association between the fatal event lack of effect (pneumonia, respiratory failure and COVID-19) with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well	No prior vaccinations for this event.

as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19

RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Admitted to hospital after vaccination with Acute hypoxemic respiratory failure, Septic shock; Aneurysm of arteriovenous dialysis fistula; expired 1/16/2021	No prior vaccinations for this event.
RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (	No prior vaccinations for this event.
RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced

No prior vaccinations for this event.

pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued.

Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

	RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."		No prior vaccinations for this event.

	RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
According to medical report, Pt presented to the ED on 1/14/21 w/ cc of SOB for 1 day. She received her COVID-19 vaccine on 1/9/21. Pt stated that she developed a dry hacking cough 2 days prior to the vaccine on 1/7/21. Over the last few days prior to admission, she developed generalized weakness, SOB, loss of sense of taste and smell w/ associated decreased appetite and nausea ultimately SOB in the24 hours prior to admission. Final Diagnosis- acute hypoxic respiratory failure secondary to COVID-19 pneumonia. Pt died on 2/3/21. See Medical report for more information.		No prior vaccinations for this event.

RESPIRATORY FAILURE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"		No prior vaccinations for this event.
RESPIRATORY FAILURE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."	No prior vaccinations for this event.
RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer 1/22/2021. RNA+ 2/4/2021. S/S SOB, cough, confusion. COVID assoc. resp. failure, stage 4 lung cancer, COPD, HTN, former smoker. patient in hospice and died 2/10/2021.	No prior vaccinations for this event.
RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.	No prior vaccinations for this event.
RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed/died on 09Feb2021 from respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed/died on 09Feb2021 from respiratory failure from COVID19; This is a spontaneous report from a contactable physician. An 89-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in 10Jan2021 at 12:00 at a	No prior vaccinations for this event.

single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had no COVID prior to vaccination. The patient received one dose of Pfizer vaccine on 10Jan2021. The patient was presented to the ER with COVID symptoms and was diagnosed on 27Jan2021. Patient subsequently died on 09Feb2021 from respiratory failure from COVID19. It was unknown if autopsy was done. The patient was tested for COVID post vaccination via nasal swab: covid-19 virus test positive on 27Jan2021. The events resulted in emergency room/department or urgent care, hospitalization, and patient died. No follow-up attempts are possible, information about batch number cannot be obtained. No further information is expected.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported COVID post vaccination and respiratory failure with fatal outcome, and the administration of COVID 19 vaccine, BNT162B2, based on the reasonable temporal association. More information on the underlying medical condition in this 89-year-old male patient is required for the Company to make a more meaningful causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: presented to the ER with COVID symptoms and was diagnosed on 27Jan. Patient subsequently died on 09Feb from respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed on 27Jan. Patient subsequently died on 09Feb from

RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at	No prior vaccinations for this event.

5:54AM

RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
RESPIRATORY FAILURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
RESPIRATORY FAILURE Narrative: PT PASSED AWAY WHILE IN THE HOSPITAL	No prior vaccinations for this event.
RESPIRATORY RATE DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.	No prior vaccinations for this event.
RESPIRATORY RATE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital	No prior vaccinations

signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics	for this event.

RESPIRATORY RATE INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face,	No prior vaccinations for this event.

increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

RESPIRATORY RATE INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

2/10: Fever, fatigue, tylenol 2/11 @ 1300: pt made DNR, hospice consulted 2/11 @ 1800 decreased LOC, increased RR, fever, chills - 1/5L NS bolus IV, rectal tylenol. Refusing to eat/drink, PO morphine 2/12 @ 16:30, deceased at facility **resident was not doing well prior to vaccination

No prior vaccinations for this event.

RESPIRATORY RATE INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 1/9/2021 observed with elevated respirations of 38-42 per minute, BP manually 72/50. pulse is jumping

No prior vaccinations for

rapidly between 110-16 bpm. oxygen sat 76% RA, resident refusing oxygen at first attempt, allowed oxygen to be placed, is now 84% on 4L. resident shaking head yes that he is hurting, and yes that he would take medication for pain. Dr. notified, branch block. Received order for morphine 2mg per hr as needed for elevated respirations and pain. Dr. also gave orders to D/C Tamsulosin and finasteride. Resident continue with decreased O2 sats and elevated respirations. Absence of vital signs on 1/10/21 at 826PM.		this event.
	RESPIRATORY RATE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
emesis bright yellow in color, liquid BM, increased respirations No prior vaccinations for this event.		
	RESPIRATORY SYMPTOM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Heard through a family member had some feeling badly and some respiratory symptoms. We do not have any real information. This is a coroners case.		No prior vaccinations for this event.
	RESPIRATORY SYNCYTIAL VIRUS TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
CARDIAC ARREST THAT LEAD TO DEATH - IT WAS REPORTED BY EMS THAT THE PT HAD RECEIVED THE VACCINE ABOUT 30 MINS PRIOR. HE ARRIVED HOME, BECAME SHORT OF BREATH & COLLAPSED. 911 WAS CALLED AND HE WAS TRANSPORTED VIA EMS TO HOSPITAL (16:17) WHERE HE LATER EXPIRED (23:01).		No prior vaccinations for this event.
	RESPIRATORY SYNCYTIAL VIRUS TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.	No prior vaccinations for this event.
RESPIRATORY TRACT CONGESTION	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.	No prior vaccinations for this event.
RESPIRATORY TRACT CONGESTION	**COVID19 (COVID19 (MODERNA)) (1201)**
Congestion, Hypoxia, SOB, Tachycardia, Weakness. Started on O2 @ 3L, HOB elevated, Tylenol supp	No prior vaccinations for this event.
RESPIRATORY TRACT CONGESTION	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident getting rehab therapy in the facility and has a long history of Parkinson's Disease. On 01/29/21,	No prior vaccinations for

he received the COVID vaccine on left deltoid, resident was recently hospitalized due to Pneumonia and was on antibiotic IV and was recently placed on GT feeding due to severe dysphagia from his Parkinson's disease. On 01/31/21, started having increased congestion. On 02/02/21, started having increased temperature and WBC went up >20,000 on 02/03/21, started on Vancomycin IV on 02/04/21 but was transferred to the hospital. Facility was notified today (02/18/21) that resident expired in the hospital.	this event.	
RESPIRATORY TRACT CONGESTION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident became SOB, congested and hypoxic requiring oxygen, respiratory treatments and suctioning. Stabilized after treatment and for the next 72 hours with oxygen saturations in the 90s. On 1/3/2021 was found without pulse and respirations. Resident was a DNR on Hospice.	No prior vaccinations for this event.	
RESPIRATORY TRACT CONGESTION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
At approximately 10:30pm on 1/14/2021, resident was noted to have a rash on her face, hands, arms, and chest. VS:100.2, 113, 20,108/59, 84% room air. applied nasal cannula at 4-L, telephoned Physician orders 6mg Decadron one time order, a second set of Vitals , reads 99.3, 110, 20, 106/60, 90% on 4-L N/C. On coming shift advised. At approximately 2:00am on 1/15/2021, resident congested and coughing. BP 151/70, pulse 124, temp 98.1 forehead, resp 20 and pulse oc 79% on 3L. At approximately 2:30am PRN cough syrup and breathing tx. Resident's condition began to worsen with breathing tx. This LPN updated at 0248 doctor on resident's condition. Doctor gave permission for resident to go to hospital. At 4:19am the Er called to say resident passed away.	No prior vaccinations for this event.	
RESPIRATORY TRACT CONGESTION		**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Resident on Hospice. 1/18 Hand Shaky. 1/19- Covid +19. 1/20 Desat 85% on RA, provided 2L O2 supplement= 97% 1/20 congestive cough, 1/28- RR-28;1/29- Hypoglycemia 1/30-NPO. 1/30-resident passed away.	No prior vaccinations for this event.
RESPIRATORY TRACT CONGESTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
(02/15/2021): vaccine (02/16/2021) : severe body aches and weakness, increased congestion and mucous production. (02/16-17/2021) : death possibly during the night	No prior vaccinations for this event.
RESPIRATORY TRACT CONGESTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident is a Hospice patient. On 1-23-2021 am shift resident was observed by nursing have chest congestion and had a emesis times 1 with SOB, Zofran 4 mg was given. HOB (02 sats 88%) was elevated resident on 02 via nasal canula with 02 sat now @ 90% . no respiratory distress noted. MD was called with response pending for orders. @ 1400 resident with no signs of life. vs 90%-24-97/71-97.6. Hospice on site and time of death 1436	No prior vaccinations for this event.
RESPIRATORY VIRAL PANEL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient	No prior vaccinations for this event.

had recently received vaccine. ME updated with that information today as soon as discovered.

	RESTLESSNESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident had severe CAD, DM type 2, and hx of RBKA and left 5 digits on foot amputation. Hx of osteomyelitis post surgical. After last surgery, resident did not have a good appetite, more restless, increased confusion with dementia. Significant other passed away on 12/30/20, resident began refusing meals, decreased eating. Vaccinated on 1/13/21. On 1/25/21 Resident labs showed kidney failure. Dr. spoke with family and transitioned to Comfort care, on 2/5/21 went hospice. Patient passed away on 2/13/2021.		No prior vaccinations for this event.

	RESTLESSNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021,		No prior vaccinations for this event.

after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was okay, but he was very agitated; reported as not like this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away

RESTLESSNESS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"83yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, the patient reportedly got up in the middle of the night with c/o feeling ""blah"", restlessness, and nausea. VS normal, no other s/sx. At 4:15am, the patient was asked to go back to bed, assisted by a nurse and GNA. At 6am, GNA was going to do morning VS and found the patient unresponsive, no pulse, no respirations. GNA notified the nurse. At 6:03am, CPR started and EMS called. At 6:15am, EMS arrived and took over. At or

No prior vaccinations for this event.

around 6:30am, EMT called time of death"

	RESTLESSNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated	No prior vaccinations for this event.	

ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

RESTLESSNESS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident had slight/slow decline in health prior to vaccine but continued to be able to walk around with walker at community. The day of the vaccine she had a fever. 2 days after vaccine resident did not get out of bed all day and refused to eat. She had small amounts of orange juice as her blood sugar level was low due to not eating. Resident was diagnosed with a UTI and began an oral antibiotic. 3 days after and on day 5 after vaccine resident began feeling weak and had a fall on each day. The following day again resident

No prior vaccinations for this event.

spent the day in bed. The next day she was quite restless, was on the edge of her bed attempting to self transfer often throughout the day. Resident continued to be restless on the 10th of Feb, had further decline on the 11th of Feb. Resident passed away early the AM of Feb. 12th.

RESTLESSNESS	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.	No prior vaccinations for this event.

	RESTLESSNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per Patients Wife - Same day - Flu like symptoms, Nausea, Headache. Restless that night. Next day - Weak, shortness of breath. Wife called squad to get him out of his wheelchair but patient refused hospital as it gets him agitated. Patient passed away around 11 AM the day after vaccination.		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
syncopal episode - arrested - CPR - death No prior vaccinations for this event.		
RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**	
No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had been diagnosed with COVID-19 on Dec. 11th, 2020. Symptoms were thought to have started on 12/5/2020. Received Moderna vaccine on 12/23. Unexpected death on 1/8/2021. Resuscitation attempts unsuccessful		No prior vaccinations for this event.

RESUSCITATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Staff reported that patient was found Friday morning (Jan 8) sitting at a table with his head tilted forward and unresponsive to verbal or physical stimuli. Staff lowered patient to floor and started CPR. EMS was called and continued CPR at scene, however they were not able to revive patient. Patient was pronounced dead at the scene. Staff written statements following the death of patient show that he had a fall about 1 hr. prior. It is unknown if this fall contributed to patient's death. An autopsy has been requested.		No prior vaccinations for this event.
RESUSCITATION		**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient was found ""acting abnormal"" on 1/9/2021 at 1215. VS HR 20-30's. EMS activated. EMS arrived and patient was found pulseless in PEA/ asystole, CPR and ACLS initiated and then transported to the MC. Unsuccessful resuscitation and expired on 1/09/2021 at 1348. Clinical impression Cardiopulmonary arrest."		No prior vaccinations for this event.
RESUSCITATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Around 00:50am on 01/15/21, C.N.A. reported that the resident looked different and not responding. Initiated Code Blue and started CPR. 911 arrived and pronounced resident dead at 1:01 am.		No prior vaccinations for this event.
RESUSCITATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient woke apx 0200 complaining of nausea to group home staff. Vitals were checked at that time and WNL. Patient went back to bed. When staff went to wake patient apx 0530, he was unresponsive and had no pulse. Chest compressions were started and EMS called.		No prior vaccinations for this event.

RESUSCITATION		**COVID19 (COVID19 (MODERNA)) (1201)**
My dad got the Moderna Vaccine on Tuesday, January 12, 2021 in his left arm at the Mall injection site for the Health Department. He was told that the side effects could mean his arm hurting, tiredness, headache, and even a low grade fever. Additionally, the site informed us both (as I was with him to get the injection) that this was all normal and not to seek medical attention unless these symptoms last longer than 72 hours. That evening, my dad was experiencing all of those symptoms, and went to bed at 7pm. A little after 10am on Wednesday, January 13, 2021, when he awoke, my dad went to the bathroom vomiting. This was where he collapsed and went into cardiac arrest. Fire/Rescue was dispatched about 10:30am after my mom started CPR. County Fire Rescue EMTs and Paramedics continued CPR and other attempts at reviving him all the way to Hospital Emergency Department. He was pronounced dead at 12:14pm on Wednesday, January 13, 2021. We have no doubt my dad, following the instructions of the injection facility, thought he was just experiencing the side effects of the vaccine. He had no chance. Had this injection been done in the RIGHT arm, perhaps he could have recognized the arm numbness being that of an impending heart attack. We really miss Dad. He served this country with distinction for over 50 years, and we believe his country failed him.		No prior vaccinations for this event.
RESUSCITATION		**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient was tested positive for Covid-19 on 12/9/20. Patient received Covid Vaccine on 1/21/21. Patient was observing for 15 minutes in treatment room by Nursing staff. Patient denied any signs/symptoms adverse effect: headache, dizziness & weakness, difficulty breathing, muscle pain, chills, nausea and vomiting, and fever . Patient seated on treatment table appeared to be relaxed, respiration even and unlabored. Health teaching provided. Patient educated to report any changes in condition to staff immediately. Patient verbalized understanding and able to verbalize signs and symptoms and adverse effects to be aware of related vaccine. On 1/22/21: patient was seen by medical provider for ""altered behavior"". Per medical provider's documentation: ""Patient was fallen on 1/2/21 and was sent out to outside hospital on 1/4/21. CT head: no		No prior vaccinations for this event.

intracranial abnormality, age-related changes. Patient had labs (B12, RPR, folate) were within normal limit"". We did MMSE today: 22/30 score ""mild dementia"" On 1/23/20: ""Patient was inside his cell. He was walking towards cell door to obtain his breakfast, when custody witnessed him collapse and activated the alarm. Nursing staff arrived at cell front at 06:34 am and found the patient pulseless and unresponsive, and CPR was immediately initiated. AED was attached at 06:35 am and no shock advised. AMR then arrived and patient did not have ROSC, and was pronounced dead at 06:54 am."""

RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
about 20+ hours after vaccination resident was having hard time breathing, 911 was called. Resident coded multiple times at the facility after CPR she was taken to ICU. She coded again and was placed on life support. Due to her choice to not be on life support she passed on 11/26/2021.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless and breathless and was pronounced. Autopsy currently pending.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**

Pt presented to ER via EMS at 1556 3 days after receiving vaccine. pt was breathing approximately 50 times a minutes and o2 sats in the 70's upon arrival. NP decided to intubate, Rocuronium and Versed given. Pt became bradycardic and 1 amp of Atropine was given without improvement. No pulse felt, CPR started per ACLS protocol. 7 Epi's given. Time of death- 1632. After TOD pt was swabbed for COVID-19 and the results were positive.	No prior vaccinations for this event.	
RESUSCITATION		**COVID19 (COVID19 (MODERNA)) (1201)**
The patient went home around 11 am on 1-31-21 after her vaccine and 15 minute observation period. She was eating breakfast after at home and complained to a neighbor that her teeth hurt and she was nauseated after eating. In the afternoon, she felt dizzy and had diarrhea accompanied with blood. Close to 9 PM, her son went to check on her. The patient was found on the floor--she was unresponsive and had purple lips. Her son called an ambulance and started chest compressions. The patient passed away at the hospital. The doctor has ordered an autopsy, and the results are pending.	No prior vaccinations for this event.	
RESUSCITATION		**COVID19 (COVID19 (MODERNA)) (1201)**
PATIENT WAS IN CLINIC FOR 1ST CLINIC. WAS DISCHARGED BEFORE OUR 2ND CLINIC. HE CAME BACK TO OBTAIN HIS 2ND SHOT. WE WENT OUT TO THE CAR GAVE SHOT. THE NEXT DAY TO MY KNOWLEDGE, HE STARTED CODING AT HOME. AMBULANCE WAS CALLED AND HE CONTINUED TO CODE. THE AMBULANCE CREW TRIED CPR FOR 30 MINS WITH NO LUCK. PATIENT PASSED 2-3-21.	No prior vaccinations for this event.	
RESUSCITATION		**COVID19 (COVID19 (MODERNA)) (1201)**
CARDIAC ARREST, DEATH Narrative: The patient presents to the emergency department in cardiopulmonary arrest. CPR was continued upon arrival. The Combi tube was removed and an endotracheal	No prior vaccinations	

tube was placed without complications. ROSC was obtained multiple times but the patient continued to go into PEA. The patient was seen in the emergency department by both critical care and Cardiology. EKG shows ST elevations, but the patient was unstable to go to catheterization. The patient had 1 episode of asystole. Despite best efforts and multiple attempts we were unable to resuscitate the patient. Time of death 1253 on 1/24/21.		for this event.
	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Received Covid vaccine in am. Last seen by family at 17:30 pm and observed to be well. About an hour later he collapsed, unresponsive. A 911 call was initiated at 18:29. Paramedics arrived to find the patient in cardiac arrest. CPR/ACLS was initiated, but resuscitation was unsuccessful. Pt. was transported to MC where he was pronounced dead at 19:32. There was no sing of an injection site reaction, nor of allergic reaction..		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Cardiac arrest resulting in death on the third day post vaccine administration, 0224. Reported syncopal event post toileting. Rescue measures attempted but not successful. Time of death 0358, 02/06/2021.		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received his second dose of Moderna COVID vaccine on 2/6 at 12:40PM. Patient was observed for 15 minutes post-vaccination with no adverse events. On the evening of 2/6 (time unknown) the patient began to develop dry cough and fatigue. He was checked by a physician at that time (who was a family member). Patient continued to feel unwell into Sunday. His lungs were clear when checked Sunday afternoon (time unknown). At approximately 5:30pm on 2/7 the patient began experiencing sudden onset shortness of breath. A pulse ox was conducted at that time and it was 92%, and again shortly thereafter and it was 90% (as		No prior vaccinations for this event.

reported by family member). 9-1-1 was contacted at this time. CPR was initiated when he arrived at the emergency department, pulse ox was 60% (as reported by family member). The patient passed away shortly thereafter on 2/8/2021.

RESUSCITATION

COVID19 (COVID19 (MODERNA)) (1201)

Patient found down at home with agonal respirations and per EMS asystole, received 2 rounds of epi at her house with return of spontaneous pulses, lost pulse again in route to ER and another round of epi was given, CPR in progress when arrived at hospital. Prior to this patient's husband states he heard her fall in the bathroom but did not immediately check on her as he states that this has happened before. He checked on her 10 min later and that's when he found her unconscious. Daughter called 911 and she began CPR. No previous complaints of headache, chest pain, back pain, fever or chills. Husband states patient was drinking that evening which is not unusual for her. Patient died at hospital.

No prior vaccinations for this event.

RESUSCITATION

COVID19 (COVID19 (MODERNA)) (1201)

Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.

No prior vaccinations for this event.

RESUSCITATION

COVID19 (COVID19 (MODERNA)) (1201)

"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Received first 1/15/2021 with no adverse reaction. Received 2nd dose 2/9 @ 0846 with no adverse reaction or report of feeling ill. Traveled to store and arrived approx. 2 hours after receiving vaccine. Daughter stated patient felt well and had to go to the restroom to have BM. Collapsed in bathroom. Transported by ambulance to Hospital @ 1439 in cardiac arrest. Was in PEA and went in v fib back to PEA. Resuscitation efforts initiated and patient expired with time noted at hospital records at 15:11.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
My dad received his first COVID vaccine on January 14, 2021. On January 16, 2021 he ate breakfast around 7:00 am and went back to his room. When the staff checked on him around 8:00 am they found my dad unresponsive. His blood pressure was over 220 and his pulse was 43. They began manual CPR until the paramedics arrived, but my dad died.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient had COVID vaccination on 2/3 with no adverse s/s before leaving unit. Upon coming to treatment Friday 2/5 he reported to the RN that he had fallen on thursday 2/4 due to ""getting up fast"" did not hit head or hurt anything per RN discussion. Began treatment without difficulty. About 3/4 way through treatment was	No prior vaccinations for this event.

talking with staff and became unresponsive - code was called and pt expired after 30 minute resuscitation efforts."

RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine given in clinic per protocol - patient monitored for 15 minutes, no adverse reactions noted at the time. Patient stated he felt fine following 15 minute monitoring time. Patient left facility- it was later reported that pt had a fall at home. Upon review of pt's medical record - Pt's wife had to initiate CPR and call EMS for transportation and life saving measures enroute to the Emergency Room. Pt was intubated as pt was in asystole upon arrival to the ER, ACLS was continued, pt was noted to have a traumatic brain injury from his fall at home, and pt was pronounced dead at 1620.	No prior vaccinations for this event.

RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Short version The patient has long-standing health issues. The patient received the first dose of Moderna COVID-19 vaccine on 1/16/2021 (unknown location). The patient suffered an event in his home on 1/24/2021. CPR and treatment was begun and he was transported to the ED. He was pronounced dead in the ED at 0846. Long version 70-year-old male with past medical history of CAD with pacemaker, A. fib, COPD, hypertension/hyperlipidemia presenting in cardiac arrest. 911 call at 0724. Per EMS, patient was witnessed by family to have seizure-like activity and then collapsed and became unresponsive. Patient was noted by family to be pulseless and CPR was started right away. Patient received two doses of epi by police were on scene first (AED defibrillation x2) and six doses of epi (plus 6 more AED shocks) by EMS when they arrived. Patient had CPR performed for 45 minutes prior to arriving at the hospital. On route, patient had episodes of paced rhythm and V. fib. Patient received one amp of bicarb and one amp of calcium en route. Patient also received 300 mg of amiodarone en route. Arrived in ED at 0810 Patient received ongoing compressions, shocks and additional medications (epinephrine x6, lidocaine IV, sodium bicarbonate) until time of death called at 0846 in	No prior vaccinations for this event.

the ED.

	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.		No prior vaccinations for this event.

	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive MI, PE or ruptured AAA"". Death certificate notes indicate ""signficant conditions contributing to death after cardiac arrest; ASCVD""."		No prior vaccinations for this event.

	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was at a gym watching his daughter. He slumped over unconscious. EMS was called. He was found to be in fine ventricular fibrillation and resuscitation efforts failed. He was brought to Hospital ED where he was pronounced dead. He had underlying cardiac disease but his family requested I report this event as possibly		No prior vaccinations for this event.

related to the recent COVID vaccination.

RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Per EMS/Hospital report patient had difficulty breathing and cardiac arrest with prolonged CPR (greater than 45 mins in the ER) who was resuscitated. Family subsequently arrived including son and daughter and all family members were in the ER room are in agreement that patient would not want further aggressive cares given her extremely poor prognosis in light of chronic debilitation with numerous medical issues and now a very long period of CPR. Hospital Course After updating family they stated patient would not want further aggressive cares given her grim prognosis and chronic severe and debilitating medical issues. She continued to have myoclonic jerking. She was extubated to comfort cares in the ER and did not pass immediately therefore brought to a room. She received comfort cares and passed away at 0450 with family present.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
"The patient came to the Emergency Room at approx 3:30 am on 02/03/2021 with pain in right arm (same arm the COVID vaccine had been administered in approx 12 hours earlier) and feeling generally unwell. Patient was concerned about possibility of gout flare or that something was wrong with her arm. Elevated blood pressure was noted; this was attributed to anxiety. She was evaluated, given 500 mg Tylenol, and discharged since the pain was decreasing and blood pressure was stabilized. Patient instructed to follow-up with physician. The next day, on 02/04/2021, the patient arrived at the Emergency Room by ambulance; cardiac arrest was the chief complaint. The patient's daughter stated the patient had been ""feeling generally poor and then suddenly collapsed."" Daughter described ""gurgling respirations"" and being unresponsive. 911 was called, police arrived within 5 minutes and initiated CPR. Epinephrine, atropine, lidocaine and bicarb administered after arrival to Emergency Room. Shockable rhythm never demonstrated. Patient never recovered spontaneous respiration or movement. The death was called at 23:04. Coronary artery disease with	No prior vaccinations for this event.

cardiac arrest is the cause from the ER records; the coroner is putting COVID-19 vaccination in Part 1 of the death certificate."

	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.		No prior vaccinations for this event.

	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient previously had dizzy spills, but about a week after receiving the vaccine her dizzy spills began to get worse. The whole prior she kept saying I am just not right. On the 2/7/21 she a COVID test done, a nurse came to her house and preformed. On the morning of the 8th patient was on the phone with someone else and patient asked this person to call me and go check on her. Within 5 minutes I was over at her house, and I found her on the floor, she on her belly facedown. It looked like she was on the toilet, and it looked like she fall getting her off, she was still wet, she still felt warm. I called the ambulance and immediately began CPR. When EMS arrived they took over the CPR and transported her to the Hospital. The EMS was there for about 40 minutes and used an machine to preform the compressions. She was pronounced deceased at the hospital. No autopsy was done.		No prior vaccinations for this event.

RESUSCITATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was found unconscious without a pulse. Patient remained in asystole without pulse or respirations despite CPR.		No prior vaccinations for this event.
RESUSCITATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127		No prior vaccinations for this event.
RESUSCITATION		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient passed away Saturday at 14:04pm. Patient's wife reports his death was sudden, he passed away sitting in his chair his heart just stopped she said. They tried to perform CPR, 911 was called and paramedics arrived at the scene and he was given medication but never had any return of vital signs and so his death was called at the scene. Wife reports he was not ill, did not have any symptoms prior to the event. They are not going to be doing a autopsy. She wanted us to know based on timing that there may be some possible correlation with his COVID19 vaccine. He obtained the vaccine on 02/09/2021 - wife reports he had no symptoms, not even arm soreness after the vaccine. Had no fever, shortness of breath. Did not complain of chest pain. We can update chart to reflect the patient is deceased and lets make a card for the family.		No prior vaccinations for this event.
RESUSCITATION		**COVID19 (COVID19**

	(MODERNA)) (1201)
Since I was not with my husband I can only tell you what was told to me. He walked out of the store toward our car. Someone watched him, concerned, because he was walking very slowly (normally has a slow gait because of leg braces and toe amputations so I don't know if it was unusually slow). The woman saw him fall and she ran to help-administered CPR immediately-and told me he died instantly. Medics tried to resuscitate and failed to bring a pulse. (My husband left our home around 11:15 to drop a package off at store. The store is one mile from our home. At around 12:30 a deputy came to my door and when I saw him my knees buckled. I knew something horrible happened.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
While at counseling appointment on February 17 patient had witnessed sudden cardiac arrest and was not able to be resuscitated. She was pronounced dead at 12:09. At the time of death her glucose was about 500.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient discovered unresponsive in cell, blue coloration to skin, vital signs, undetectable. CPR initiated, Ambulance summoned. Following EMS arrival with additional unsuccessful attempts to revive patient, patient was determined to have expired.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Hypoxia, Decreased responsiveness, Narrative: 86yo male with PMHx HTN, Afib not on AC after head trauma, CVA, and colon cancer who was brought to the ED by his family on 2/17. Per documentation the pt	No prior vaccinations

was in his usual state of health until 2/16. Received Moderna covid vaccine #2 on 2/16/21 at 0900, and was monitored for 15 minutes following immunization no noted issues. Later that night, had myalgias and took Tylenol. Per the family he slipped on the ice and fell on his butt. Overnight, had several dark stools and vomitus. was brought to the ED by his family because he was being less responsive. Pt arrived to the emergency department in extremis. No pulse identified. CPR immediately initiated for several rounds lasting about 25-30 minutes. ROSC unable to be achieved. Patient expired on 2/17 at 1941. Of note, per previous documentation had waxing and waning mental status at baseline. No symptoms noted with 1st dose of Moderna vaccine, which was administered on 1/16/21.	for this event.

RESUSCITATION

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506	No prior vaccinations for this event.

	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
2nd dose of Moderna at 9:00am. No side effect (except pinch at injection site) throughout the day and evening. At ~9:45pm, my wife suddenly fell unconscious. Immediate CPR & with Paramedic were not able to revive her. SHE PASSED AWAY at home. We believe it may be triggered by the vaccine. Did not have a chance to go to hospital or emergency room - it was too sudden. A sad day for us.		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Beginning in the evening 2/19/21, fever/chills/fatigue; worsening of symptoms 2/20/21 with lethargy/lack of appetite/weakness; unable to arouse on 2/21/21 then breathing stopped, patient's spouse called 911 performed CPR, EMS continued for 15 min then while in ambulance to hospital where he was pronounced dead. Official time of death 2:20pm		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Unwitnessed Cardiac arrest. ACLS protocols were performed. Cessation of resuscitation was called in the field by Dr.		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident found unresponsive without pulse, respirations at 04:30 CPR performed, expired at 04:52 by Rescue		No prior vaccinations for this event.

	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt last seen at 1200 by nurse for ID band check. No visible signs of distress noted. Pt states ""I just want to be left alone"". 1230 nurse was called to pt room. Pt was noted unresponsive, no pulse and respiration noted. CPR started immediately, at 1239 first shock given. 1245 EMT took over, at 1319 EMT called time of death"		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/7-21 - Received second dose of pfizer covid-19 vaccine 1/8/21 - Fever, dizziness, headache 1/10/21 0250 was found not breathing. EMS performed CPR and patient deceased		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Patient went to bed around 11pm on Saturday PM and sometime between then and 1:30am on Sunday morning got up and went into the living room without waking up her husband (which is normal). At 1:30am, the husband got up to use the restroom and she was out of bed then, but the husband did not know if she was having any problems at this time. When he got up at 7:45am, she was in the recliner and did not move or anything, which is normal for her. At 8:45am, the husband went back into the living room and tried to wake his wife and that is when he noticed there was no pulse and he called 9-1-1 at this time. EMS got on scene and did CPR for 30 mins and she was pronounced dead at 9:21am.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
54 y/o M with PMH of HTN, HLD, Alcoholic Cirrhosis, Aortic Valve Stenosis, and angina BIBA as a Medical Alert for cardiac arrest noted PTA. Per EMS, the patient called because he was having constant, diffuse abdominal pain x 1 day that radiated to his chest. On scene, the patient had a witnessed arrest with EMS starting CPR. He was given 3 rounds of epi without ROSC. Pt had no associated shockable rhythm. Of note, pt's wife, had noted pt had received covid vaccine the prior day.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
71yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, VS taken at 10am, B/P 99/60, O2 sats, 95% (trach w/O2). At 11:30am, Patient showed no s/sx of distress, A&Ox3. At 11:50am, a nurse went to perform a COVID test and assessment (the facility is experiencing an outbreak), and found the patient unresponsive on the bathroom floor. CPR was immediately started; no shock advised	No prior vaccinations for this event.

per AED; 12:15pm EMS arrived and took over. At 12:38pm, EMT called time of death.

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"83yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, the patient reportedly got up in the middle of the night with c/o feeling ""blah"", restlessness, and nausea. VS normal, no other s/sx. At 4:15am, the patient was asked to go back to bed, assisted by a nurse and GNA. At 6am, GNA was going to do morning VS and found the patient unresponsive, no pulse, no respirations. GNA notified the nurse. At 6:03am, CPR started and EMS called. At 6:15am, EMS arrived and took over. At or around 6:30am, EMT called time of death"	No prior vaccinations for this event.

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and	No prior vaccinations for

a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."	this event.
RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
This is a 94-year-old male who is brought in by ambulance after being found on the floor with unknown downtime. He was in asystole upon EMS arrival. He remains in asystole. No advanced airway is in place. The patient is getting compressions from Lucas device upon arrival. It was reported that he was last talked to by family at 2 PM. The patient got his SARS-CoV-2 vaccination this morning. The patient is evaluated emergently. CPR was ongoing with 3 rounds of epinephrine given. The patient remains in asystole. He has rigor mortis. The patient's pupils are fixed and dilated. The patient has compressions paused and ultrasound is used to evaluate for cardiac activity. None is detected. The patient has no electrical activity on	No prior vaccinations for this event.

monitor. The patient's time of death is 2113.

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/13/2021 12:00 PM: Patient received COVID-19 Vaccine. 1/14/2021 21:00: Nurse performed routine rounds and the patient appeared okay. 1/14/2021 22:00: CNA discovered patient unresponsive in bed, began CPR, and called 911. 1/14/2021 23:08: Pronounced deceased.	No prior vaccinations for this event.

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (	No prior vaccinations for this event.

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

"CC:full arrest HPI:HPI and ROS limited due to patient's condition. History is via EMS, medical record, and son. Per Son patient had Covid vaccine on Saturday morning. Slept all day Sunday. Woke up Sunday night a bit ""like coming out of a deep sleep per son, around 10 pm. Shortly after that patient was having a hard time breathing. Emergency called. Arrested around the time EMS arrived. King airway, I/O and CPR initiated. Patient has been in v fib. Was shocked multiple times, given 4 rounds of epi, bicarb and amiodarone. ACLS continued on arrival. Multiple rounds of epi, and attempted defib. Patient given epi, bicarb. Rhythms included fine v fib, asystole, and PEA. Unrecoverable with no cardiac motion. Time of death 11:50 pm."

No prior vaccinations for this event.

RESUSCITATION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.

No prior vaccinations for this event.

RESUSCITATION

COVID19 (COVID19

	(PFIZER-BIONTECH)) (1200)
Patient arrived at ER with complaints of CPR in progress. Per EMS, patient became short of breath while performing yard work on 1/26/2021. At arrival, patient was in fine v fib with a total of 6 shocks delivered along with 300 mg amiodarone followed by 150 mg amiodarone, 1 amp epinephrine and 2 epinephrine drips adminstered en route to ED. CPR initiated at 1755 and EMS reports asystole at 1829. TOD 1909 pronounced by ED DO Dx: Cardiac arrest	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per EMS, the patient was last seen walking and talking to wife 10 minutes prior to EMS arrival. EMS reports via patients wife, that patient was upstairs to change for his doctor appointment then patient's wife found him down. The patient received his COVID-19 vaccine on 1/25/21. EMS states they gave 5 rounds of EPI then patient moved into vfib then was shocked once but returned to asystole. In ED, the patient initially in asystole CPR was started immediately. The patient was given 3 rounds EPI, 1 round bicarb. The patient stayed in PEA throughout. Patient was given tPA. Patient continued to be in asystole and time of death was called at 11:35 am.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Was at work on 1/26/21 and collapsed, no known complaints a the time. CRP was initiated immediately, transported to ER and pronounced dead	No prior vaccinations for this event.

	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
family states seemed short of breath since after the covid vaccine. Staff said beginning on 1/22/21 the patient seemed sluggish, more tired, and nausea noted. She stayed in her room more after the vaccine because worried about giving/getting COVID to others. was talking on the phone at 11:30 PM on 1/26/21 to staff person about temperature of room. at 12:15 AM on 1/27/21 staff noted not breathing, started CPR and called EMS. When EMS arrived they stopped the code because she was too long deceased.		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Heart stopped; Could not swallow; This is a spontaneous report from a contactable nurse (patient's wife). An 85-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 21Jan2021 at a single dose for COVID-19 immunization. Medical history included blood pressure abnormal (verbatim: blood pressure) from an unknown date and unknown if ongoing, neuropathy from an unknown date and unknown if ongoing, weight issue from an unknown date and unknown if ongoing, diabetes from an unknown date and unknown if ongoing, walker user from an unknown date and unknown if ongoing. Concomitant medications included insulin aspart (NOVOLOG) taken for diabetes from an unspecified date to an unspecified date; and he was taking a long acting one as well. The patient previously received the influenza vaccine (MANUFACTURER UNKNOWN) for immunization on unknown dates (""had flu shots before with no reactions and everything, nothing before""). On 24Jan2021, the patient's heart stopped (death, medically significant), and could not swallow (medically significant). The clinical course was reported as follows: The patient's wife stated the patient was taking insulin aspart (NOVOLOG) and he was taking a long acting one as well. The reporter, the patient's wife and a retired registered nurse (RN) stated, her husband (patient) just died and she thought he died from the COVID vaccine (later clarified the reason of death was-heart stopped). The patient had the		No prior vaccinations for this event.

vaccine on 21Jan2021, which was on a Thursday, and he was fine. On the following Sunday around 1:30 (on 24Jan2021), the patient was feeling a little weak, however, the patient's wife thought maybe his blood sugar was low. The patient's wife checked, and the patient's blood sugar was 91. The patient's wife went to get some yogurt to feed him in order to get his blood sugar up a little; ""which was a normal thing for him, it was not that low for him."" Then, suddenly, the patient fell, and the patient's wife could not get a pulse or anything. The patient's wife called an unspecified number and she started compressions; however, he was dead. The patient's wife stated the patient just had his heart test, a three hour long one, and it was ""perfect three weeks ago."" The patient had just gone to the doctor the other day and his blood pressure was ""fine and everything."" The patient's wife stated that other than his diabetes, ""which he had for (sentence incomplete)."" Regarding lab tests, the patient's wife stated, ""No, he had it before but not in the last two weeks. He was going for one because we just went to the doctor last week and he was going to call yesterday to make the appointment request to get his blood work done. Blood work has been good except his A1C was always high, but other than that everything was good"" (as reported). Regarding causality, the patient's wife stated, ""I do, because he was fine until about half an hour before he died. He said to me, I feel a little weak today and then I was talking to him that your upper body strength is really good and then I said, we just have to work on your weight a little more because he did have neuropathy. And then, I went out of the room and all of a sudden I just heard him fall and that is when I just went in to check his blood sugar and it was 91 and I got him yogurt and he started eating that and then that was it, he started spitting it out and he said, I could not swallow and that was it, he just died."" The patient's wife further added, ""I just wanted other people to know that things like this happen and I am sure it was from that because he was healthy as could be. He was walking with his walker, the day before outside and he felt fine."" The clinical outcome of the event, heart stopped, was fatal. The clinical outcome of the event, could not swallow, was unknown. The patient died on 24Jan2021 due to ""heart stopped."" An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: Heart stopped"

RESUSCITATION

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Patient noted to have irregular breathing in bed and unable to arouse. Provided life saving measures in the field x 30 minutes and transferred to hospital. Noted to have heart arrhythmia which suspected to cause cardiac arrest.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
dead; Collapsed; bnt162b2 was given to patient with immunocompromised w/ reportable conditions; bnt162b2 was given to patient with immunocompromised w/ reportable conditions; This is a spontaneous report from a contactable nurse. A 40-year-old male patient receive first dose of bnt162b2 (Lot number: EK9231, Brand: Pfizer), intramuscular in left arm on 21Jan2021 15:15 at single dose for COVID-19 immunization. Medical history included immunocompromised w/ reportable conditions from an unknown date and unknown if ongoing, positive for Covid in September from Sep2020 to an unknown date. The patient's concomitant medications were not reported. The patient experienced dead, collapsed on 26Jan2021. Therapeutic measures were taken as a result of collapsed. The outcome of collapsed was unknown. The patient died on 26Jan2021. It was not reported if an autopsy was performed. Received Covid vaccine here on 21Jan2021, was at work on 26Jan2021 and collapsed, no known complaints at the time, CPR (cardiopulmonary resuscitation) was initiated immediately, transported to ER (Emergency room) and pronounced dead. Unknown if other vaccine in four weeks. The patient had COVID prior vaccination. Unknown If COVID tested post vaccination.; Sender's Comments: Based on the information currently provided, the patient was immunocompromised and had prior COVID infection. The death and syncope more likely are associated with the patient underlying medical conditions. More information such medical history, concomitant medications, treatment indication and event term details especially death cause and autopsy results are needed for fully medical assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and	No prior vaccinations for this event.

analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Dead		
	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Myocardial infarction Narrative: PMH significant for aortic valve stenosis, mitral valve stenosis, CKD, CHF, DM, HTN, obesity, hypothyroidism and dyslipidemia. Per report from primary care - the patients wife reports that the patient went on Saturday (1/30/21 - about 1050) morning to receive his COVID vaccine. He returned home and told her about the experience and denied any side effects. He then proceeded to sit in his easy chair for a while and around 1:30, she asked him if he wanted any lunch. The patient's wife reports he ""grumbled"" at her, and then got up to go to the bathroom. She then heard a loud crash and found him lying on the floor of the bathroom, with his head knocking hole in the wall as he fell. She could not detect a pulse. She called 911 and began compressions. First responders to the scene likewise tried to revive him but were not successful in her efforts. Per primary care documentation - Uncertain if related to Pfizer vaccine; vaccine administered on 1/30/21 and approximately 3 hours later suffered fatal MI at home."		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient expired. Per Emergency MD note: ""This is a 72-year-old male with what sounds like diabetes, atrial fibrillation, and hypertension who presents via EMS in cardiac arrest. It sounds like he received his Covid vaccine last week. Initially he had some mild effects from it. However over the last day or so he has felt very unwell. He apparently called his wife today and told her that he was not feeling well and so she returned home. Shortly thereafter he attempted to get up from his chair. He then collapsed and fell forward		No prior vaccinations for this event.

onto his face. Sounds like his wife had some difficulty rolling him over to perform CPR. When EMS arrived they found him in PEA. He received a total of 5 rounds of epinephrine. At some point they did have return of spontaneous circulation. However just prior to arriving in the emergency department they lost pulses again. The patient was intubated with an 8 oh endotracheal tube prior to arrival."""

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19**

	(PFIZER-BIONTECH)) (1200)
73-year-old man s/p first dose of Pfizer at 10:20 AM Ambulated comfortably to exit after 20 minutes in observation but 10:45 collapsed while exiting the building 10:47 CPR initiated 10:49 medical team/EMS found no pulse, agonal respirations, ventricular fibrillation Paramedics and team performed ACLS; of note patient was intubated 7.5 ETT with bilateral breath sounds on ventilation; paramedic reported easy intubation with no apparent throat swelling; 11:02 transported to Emergency Department 11:30 Pronounced dead at Emergency Department	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom only had site soreness after her covid vaccine on 1/21 which resolved within a couple days. However, she died in the early morning hours of 1/25, she was fine the day before, no sign of injury. We found her collapsed on the ground and although we tried cpr she was already dead. She had gone to the hospital on 12/28 for shortness of breath, angina and symptomatic anemia, her ekg was unchanged and blood work normal except for anemia. The cardiologist did not think a cardiac cath was needed. Her shortness of breath improved with a blood transfusion and a dose of lasix (no heart failure).	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into	No prior vaccinations for this event.

full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of

pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and ACLS guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and ACLS guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19**

(PFIZER-BIONTECH))
(1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off

No prior vaccinations for this event.

to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

RESUSCITATION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

For the two days prior to presentation the patient had been complaining of chest pain, his breathing seemed to be labored Monday. He and the family thought the pain was due to shingles as he carried this diagnosis from a month ago. Patient had also received the COVID vaccine 2 days prior to presentation and assumed he was feeling unwell due to the vaccine. Family wanted to take him to the hospital yesterday and earlier today but he refused. She left him in his home earlier this afternoon prior to presentation and returned to check on him finding him unresponsive and apneic at which time EMS was activated. #cardiac arrest -- suspect primary cardiac given collateral from family at home, consider hypoxemia which was corrected with advanced airway and 100% FiO2, patient clinically euvolemic and with soft brown stool in diaper not

No prior vaccinations for this event.

suggestive of GI hemorrhage, attempt to address acidosis with CPR and bicarbonate, not hypoglycemia, on bedside ultrasound FAST neg and no pericardial effusion suggestive of tamponade and +lung sliding bil not spontaneous pneumothorax Assessment/Diagnosis: -cardiac arrest, cause unspecified

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt suffered Cardiac Arrest and respiratory arrest on 2/9/21 and passed away at a local hospital. He had multiple health conditions likely contributing to this. he arrested at home and CPR was attempted and unsuccessful. Pt received his Covid vaccine #1 on 1/27/21. No issues were noted after vaccine and was due for his 2nd dose next week. However, we were notified he passed away on 2/9/21. Very likely death not at all related to vaccine but wanted to document as patient was in the middle of the covid vaccine series.	No prior vaccinations for this event.

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.	No prior vaccinations for this event.

	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
At 10:33 am Patient pushed her pendant for staff, staff arrived to her apartment and Patient was found unresponsive in her bathroom. Patient received her second COVID-19 Pfizer vaccine about 75 minuets prior to this, she had no adverse reaction's within the first hour of receiving the second dose. CPR was started until paramedics arrived, they took over and tried to resuscitate. Patient was pronounced dead at 11:33 am at scene.		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Few minutes post vaccination, after moving to observation area via wheelchair, the patient complained of dizziness. She took glucose tabs she had brought with her. Staff wheeled her to Triage # 1. Her eyes rolled back in her head and she lost consciousness. Staff (paramedics on site) transferred her to gurney and started compressions. AED placed, V- Fib was rhythm, Shock # 1 given, CPR resumed. Shocked again. Fire truck and additional EMT arrived on site and took over care. Epinephrine was given 3 times via intra-osseous route, Amiodarone given intra-osseous route. Additional defibrillation with on site AED for a total of 6-7 times. Patient had good chest rise with ambu-bag, no airway obstruction or peri-oral edema noted. Code called at 12:40 PM.		No prior vaccinations for this event.
	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Swollen leg/pain- taken to urgent care- became unresponsive - CPR initiated-		No prior vaccinations for this event.

expired

	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia		No prior vaccinations for this event.

	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/4/21, at around 3:00pm he began feeling very tired and he began burping in the evening. The following morning, he woke up early and was still burping and not feeling well. At around 5:00am, he collapsed. My mother called 9-1-1 and began giving CPR. The parademics arrived and tried to revive him, and transported him to the hospital but at 6:11am, he was pronounced dead of a heart attack. He was healthy.		No prior vaccinations for this event.

	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient and her husband are elderly, but healthy and live independently. Patient took blood pressure medicine 'off and on' according to family. She was 5'2"", 120 pounds and slim and healthy and active, so was her husband, though he had pulmonary fibrosis so they had been staying home and not attending church etc, and masking when they did go out to protect against covid disease. They were both vaccinated		No prior vaccinations for this event.

with covid Pfizer vaccine (dose #1) on Thursday Feb 11. (02/11/2021) Thursday night as they went to bed they checked in with each other on how they each felt. Patient said she felt totally fine, and her husband said his arm was a bit sore. Patient woke before her husband on Friday Feb 12, went downstairs and, from what the family can tell, fixed herself a snack, then sat on the sofa. Patient's husband found her deceased on the sofa. He called 911 and they asked him to do CPR until the paramedics arrived. Because of proximity to covid vaccine, the ME wanted to examine the body in the home and also ordered an autopsy. Autopsy was completed on the same day as death, Feb 12, 2021"

	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My dad received the Pfizer vaccination on 2/5/21. He was admitted into the hospital the next day for C-Diff bacterial infection. He had been on dialysis treatments for kidney failure treatment since 2017 and had recently been diagnosed with stage 3 colon cancer in June 2020. He had completed his final treatment of chemotherapy on 2/4/21 and several weeks prior had been determined cancer free. On Tuesday 2/9/21 he was released from the hospital and went home. Early Thursday morning 2/11/21 @ approximately 1:30 am CST his eyes rolled back in head and he stopped breathing and was non responsive. My mother called 911 and attempted CPR. Paramedics arrived and were able to successfully get a pulse then transferred him to the hospital. He was put on a ventilator @ the hospital and then transferred to a different hospital a few hours later. He lost pulse/heartbeat several times @ the 2nd hospital he was transferred to. We were not allowed to travel with him or see him b/c of all of the COVID restrictions. We were communicating with the ICU doctor by phone who ultimately communicated to us that there was nothing further that could be done to save his life. He subsequently passed away @ approximately 8:55 am CST on 2/11/21.		No prior vaccinations for this event.

	RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.	No prior vaccinations for this event.

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident found unresponsive in his room. CPR performed and patient expired. No prior vaccinations for this event.

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident found unresponsive, CPR initiated and EMS called. EMS called time of death after arrival.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1. Fatigue ? day 1 - Tuesday 2. Loss of appetite ? day 1 Tuesday 3. Fever 102.0 ? day 2 - Wednesday 4. Chills ? day 2 - - Wednesday 5. Weak ? day 2 - - Wednesday 6. Non-ambulatory (unusual) ? day 2 - - Wednesday 7. Two emergency service ambulance assessment ? day 2 - - Wednesday 8. Symptoms improved ? day 3 - Thursday 9. Ambulatory - day 3 - Thursday 10. Symptoms worsened ? day 4 - Friday 11. Chills ? day 4 - Friday 12. Non-ambulatory again ? day 4 - Friday 13. Fever 102.0 ? day 4 - Friday 14. Left side flank pain ? day 4 - Friday 15. CPR and declared decease at home by paramedics - day 5 - Saturday morning @ 1:32am	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt received 2nd Pfizer BioNTech Covid 19 EUA vaccine @1:50 pm; Pt released from Observation @2:09 pm. Approximately 2:18 pm RN called to parking lot and observed pt having difficulties. Called for EMS & crash cart. Vitals taken 2:20 BP 83/55, no respirations noted, pt unresponsive. AED attached. EMS arrived 2:22 and took over care of pt. and transported @2:40 pm to Hospital. Per wife, pt has history of PE in Oct. 2020, HTN, diabetes with insulin pump, obesity, gastroparesis, home oxygen and uses motorized scooter. Wife also said pt had allergy to iodine not previously reported, and MD had stopped Zarelto subsequent to 1st Pfizer vaccine 2/8/21 ""due to breathing difficulty"". Patient was unable to be resuscitated. Time of death 14:59."	No prior vaccinations for this event.

RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had an unwitnessed cardiac arrest while outside walking his dog. AED in the field initially advised shock and was shocked 3 times without effect. At the time EMS ALS arrived, patient was in PEA arrest. He was transferred to Hospital with CPR in progress. Time of death called at 1857.	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Presented to ED via EMS c/o increasing shortness of breath, O2 sat mid to high 80s on 4L. When EMS arrived , pt was in distress, intubated by EMS and transported to ED. Pt had a PEA arrest en route but resuscitated w/ return of spontaneous circulation after receiving a dose of epinephrine and chest compressions. Pt was hypotensive on arrival to ED. He was started on sepsis protocol , volume resuscitation and empiric antibiotics. Once stabilized, he was admitted to icu at hospital. Removed from respirator 2/22/21	No prior vaccinations for this event.
RESUSCITATION	**COVID19 (COVID19 (UNKNOWN)) (1202)**
Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2 diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated) then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and was intubated. Transported to hospital. SARS CoV-2 and influenza negative.	No prior vaccinations for this event.

RESUSCITATION

COVID19 (COVID19 (UNKNOWN)) (1202)

Received first SARS-CoV2 vaccination yesterday at local store Experienced new symptoms of chills, nausea as well as worsening from baseline dyspnea at night. Wife states he had rough morning breathing and had sudden loss of consciousness and unresponsiveness and failed to respond to bystander CPR. He expired at his home.

No prior vaccinations for this event.

RETCHING

COVID19 (COVID19 (MODERNA)) (1201)

We don't know what happened. 25 hours after the shot, he started gagging and stopped breathing. He was pronounced at OSF at 8:07pm after we took him off life support.

No prior vaccinations for this event.

RETCHING

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

RETCHING

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/22/2021 10:09 pm resident reported 1 episode of being nauseous and having dry heaves, no temperature, MD notified and nurse was told to continue to monitor, no new orders, daughter made aware. Vital signs being done every 4 hours. 2/23/2021 3:04am resident complains of nausea, scant BM amount x 2, MD notified and no new orders, continue to monitor and encourage fluids, vital signs continue every 4

No prior vaccinations for this event.

hours.

	RETICULOCYTE COUNT INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received dose #1 of COVID-19 vaccine (Pfizer-BioNTech) on 12/18/20 and dose #2 (Pfizer-BioNTech) on 1/8/21. On 1/30, patient was evaluated at urgent care due to back pain. No bloodwork done; metronidazole prescribed for 7 days. On 2/8, patient was admitted to outside hospital due to ongoing symptom progression. At time of admission, hgb 5 g/dL and plt 9k. Per Dr. (hematology/oncology), pt with schistocytes, LDH 1500, and elevated reticulocyte count consistent with thrombotic thrombocytopenic purpura (TTP). SCr >2 mg/dL. Patient immediately treated with plasma exchange and steroids, however continued to decline. Patient expired on 2/14/21.		No prior vaccinations for this event.
	RHABDOMYOLYSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt was hospitalized Jan 18, 2021 after he had fallen outside overnight and lay there approximately 12 hours until he was found. Hypothermic & rhabdomyolis diagnosis. Gradually improved w/ strength & mental status - was in swing bed @ hospital. He got his first Covid 19 shot on 2-8-21. Was fine @ 0300 on 2-9-21 and @ 0430 he was found unresponsive. Dx: probable arrythmia & pronounced dead @ 0454. Noted on pain scale @ 2/8/21 @ 21:11, clients pain was a 7/10 They offered pain med & he refused They repositioned & distracted him @ 2047 on 2/8/21 Pain had decreased to 3/10 and nothing given. Then @ 0300 check he was sleeping and @ 0430 unresponsive.		No prior vaccinations for this event.
	RHABDOMYOLYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021.	No prior vaccinations for this event.

RHEUMATOID ARTHRITIS	**COVID19 (COVID19 (MODERNA)) (1201)**
I helped facilitate scheduling for his COVID vaccine and received notification from his wife that he passed away unexpectedly this morning. She reported he had been experiencing a rheumatoid arthritis flare and was on steroids. His diabetes was not well controlled as a result. He did not have any reactions in the days immediately after the vaccine.	No prior vaccinations for this event.

RHEUMATOID ARTHRITIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
COVID 19 symptoms and a positive test was confirmed on 1/6, employee noted previous exposure to positive family members Narrative: Employee noted exposure to COVID prior to presenting for 1st dose of vaccine on 1/5/21. On 1/6/21 employee reported the onset of symptoms and was tested and was confirmed COVID positive that day. Positive result was reported to employee health on 1/8/21. Employee Health continued to track employees progress and was informed of the need for hospitalization on 1/14/21. Course of hospitalization noted the need for intubation and significant issue with comorbid condition (rheumatoid arthritis). Employee died on 2/9/2021. Unable to confirm a direct connection to Vaccine vs. COVID infection, but felt it should be reported.	No prior vaccinations for this event.

RHINORRHOEA		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident expired on 2/5/21 at 03:35pm, about 25 hours after second dose of vaccine. At breakfast, resident was spitting a lot of secretions, coughing up liquids from nose and phlegm, facial swelling, which were all symptoms that he was struggling with prior to both doses of COVID vaccine, but had increased more than prior incidences on 2/5/21. Gurgling noted in upper airways, hyscolamine given, bath given to loosen secretions, morphine given. Family notified and came into facility for compassionate care visit around 1300. 1400 HR was 3 and RR was 2, but increased back to 60 and 12 within 20 minutes. Then resident expired at 1535.	No prior vaccinations for this event.	
RHONCHI		**COVID19 (COVID19 (MODERNA)) (1201)**
2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.	No prior vaccinations for this event.	
RIB FRACTURE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac	No prior vaccinations for this event.	

arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex.

There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

ROAD TRAFFIC ACCIDENT	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene when EMS arrived. Autopsy showed a left temporal subdural hematoma.	No prior vaccinations for this event.
ROAD TRAFFIC ACCIDENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
She started having breathing problems/heart attack appearance. on 1/22/21 and went to the ER. Upon admittance was told it was an anaphylactic shock from the Covid shot. They kept her in ICU and released her 1/23/21. At 12:45 am on 1/24/21 she passed out and we called the ambulance. Hospital admitted her and worked through multiple organ failure issues and thought her numbers were under control. She was released on 1/27/21 and was driving on 1/28/21 around 4:15 pm and appears to have had heart failure and had a wreck. She passed away that day.	No prior vaccinations for this event.
RUPTURED CEREBRAL ANEURYSM	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."	No prior vaccinations for this event.
SALIVARY HYPERSECRETION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient has been under Hospice services for almost a year. She began to demonstrate a large amount of	No prior vaccinations for

oral secretions on 1/10/21 at 2130. She was suctioned and a Rapid COVID-19 test was performed, which was negative. The COVID-19 Rapid test was repeated on 1/11/21 and was positive. Oxygen saturation was noted to be 78% on 1/12/21, and oxygen was initiated at 1133 at 3L per nasal cannula. Oxygen was increased to 4L at 1635 d/t shortness of breath. On 1/15/21 @ 0645 patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.		this event.
	SARS-COV-2 ANTIBODY TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion; On 21Feb he went to the ER after vomiting and passing out; On 21Feb he went to the ER after vomiting and passing out; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; fever; headache; stomach upset; This is a spontaneous report from a contactable consumer reporting for the father: A 75-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EL3428) at single dose at left arm on 03Feb2021 for Covid-19 immunisation. Medical history included type 2 diabetes mellitus. No known allergies. The patient had not experienced Covid-19 prior vaccination. Concomitant medication in 2 weeks included amitriptyline hydrochloride (manufacturer unknown) 10 mg, atorvastatin (manufacturer unknown) 20 mg, dutasteride (manufacturer unknown) 0.5 mg, linaclotide (LINZESS) 290 mcg, gabapentin (manufacturer unknown) 300 mg, montelukast (manufacturer unknown) 10 mg, ramipril (manufacturer unknown) 5 mg, insulin degludec (TRESIBA) 100 unit/ml, liraglutide (VICTOZA) 18 mg/3ml solution. No other vaccine in 4 weeks. The patient experienced cardiac arrest due to pericardial effusion on 21Feb2021 14:15, fever on 13Feb2021, headache on 13Feb2021, stomach upset on 13Feb2021, on 19feb, he began to feel ill again with a fever, he felt worse on 20feb on 19Feb2021, on 21feb he went to the ER after vomiting and passing out on 21Feb2021. Events resulted in Emergency room/department or urgent care. Therapeutic measures were taken as a result of cardiac arrest due to pericardial effusion. Course of events: In Feb2021, 10 days after his 1st injection, the patient developed fever, headache, and stomach upset. He went for a rapid Covid-19 test (nasal swab) and it was negative on 11Feb2021. The doctor told him		No prior vaccinations for this event.

he might be having a delayed reaction to the vaccination. After a couple of days, he improved. On 19Feb2021, he began to feel ill again with a fever. He felt worse on 20Feb2021. On 21Feb2021 he went to the ER after vomiting and passing out and received treatment: IV fluids, diagnostic testing at ER. Rapid Covid test (nasal swab) at ER came back negative again on 21Feb2021. His heart arrested suddenly and he could not be resuscitated. CT scan results, that came back after death, showed Covid like pneumonia and pericardial effusion. The patient died on 21Feb2021 14:15. Cause of death was cardiac arrest due to pericardial effusion. An autopsy was not performed. The outcome of cardiac arrest due to pericardial effusion was fatal, of fever, headache, stomach upset was recovering, of he began to feel ill again with a fever, he felt worse was not recovered, of he went to the ER after vomiting and passing out was unknown.; Reported Cause(s) of Death: cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion

SARS-COV-2 ANTIBODY TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Pt developed COVID-19 infection, symptoms starting 7 days after first dose was given. Patient was admitted to hospital on 1/21 after falling (secondary to weakness) and striking head on toilet. Patient expired due to respiratory complications of COVID on 1/25.

No prior vaccinations for this event.

SARS-COV-2 ANTIBODY TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

respiratory distress; fever; anxiety developed requiring oxygen; Passed away; This is a spontaneous report via a Pfizer-sponsored program from a non-contactable consumer. A 63-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot and expiry not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. Medical history included anaphylactic reaction (broad), neuroleptic malignant syndrome (broad), anticholinergic syndrome (broad), acute central respiratory depression (broad), hypersensitivity (broad), respiratory failure (narrow),

No prior vaccinations for this event.

drug reaction with eosinophilia and systemic symptoms (broad), hypoglycaemia (broad), COVID-19 (broad) and chronic obstructive pulmonary disease (COPD); all from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine sodium and lorazepam (ATIVAN). Within 24 hours of receiving the vaccine, the patient experienced fever, respiratory distress, and anxiety developed requiring oxygen, morphine and lorazepam (ATIVAN). The patient passed away on the evening of 26Dec2020. The patient underwent lab tests and procedures which included SARS-COV-2 antibody test: negative on an unspecified date. The outcome of the event death was fatal, while of the other events was unknown. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Passed a

SARS-COV-2 ANTIBODY TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"	No prior vaccinations for this event.
SARS-COV-2 TEST	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient diagnosed with COVID on January 9, 2021 after being exposed to family member that was under quarantine in the same household. Admitted to the hospital and was discharged on January 14, 2021 with home hospice. Patient passed away on January 18, 2021	No prior vaccinations for this event.
SARS-COV-2 TEST	**COVID19 (COVID19 (MODERNA)) (1201)**
cough congestive heart failure death No prior vaccinations for this event.	

SARS-COV-2 TEST **COVID19 (COVID19 (MODERNA)) (1201)**

Patient passed away (Dead on Arrival on presentation to ER) on 02/03/2021 No prior vaccinations for this event.

SARS-COV-2 TEST **COVID19 (COVID19 (MODERNA)) (1201)**

Passed away; tired; nonresponsive; cold; difficulty breathing; swelling; sore arm; feeling weird and funny; A spontaneous report (United States) was received from a consumer concerning a 63 year old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and the patient experienced limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal and the patient passed away . Medical history included treatment for tuberculosis and dialysis. Concomitant medication included calcium acetate, Renvela, glipizide, omeprazole, aspirin, vitamin D, losartan, furosemide, rifampin, and Sensipar. On 14 Jan 2021, the patient received the first of their first planned doses of mRNA-1273 (lot number 030L20A) for prophylaxis of COVID-19 infection. On 13 Jan2021, the patient tested negative for COVID-19). On 16 Jan 2021, the patient experienced a sore arm, and feeling weird/funny. On 17Jan2021, the patient experienced difficulty breathing and swelling. On 18 Jan 2021, the patient declined dialysis, was tired and wanted to lay down. At 8 am, the patient was found nonresponsive and cold and is believed to have passed away around 4 am. The coroner tested the deceased for COVID-19 and the test was positive. No autopsy was reported. No death certificate was issued at the time of the report but the reporter believes it will list cause of death as COVID complications. Action taken with the mRNA-1273 was not applicable. The outcome of the events of limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal, was fatal. On 18 Jan 2021, the patient was died. Cause of death was COVID-19. Autopsy details were not provided.; Reporter's Comments: The events developed on four days after first dose of mRNA-1372. Dyspnea, unresponsive to stimuli, and death were consistent with infection in pandemic set up confounded by age of patient and refusal of dialysis Cause of death was reported as COVID-19. Autopsy details were not provided. Based on reporter's causality the events are assessed as unlikely related to mRNA-1273.; Reported Cause(s) of Death: COVID-19

No prior vaccinations for this event.

SARS-COV-2 TEST		**COVID19 (COVID19 (MODERNA)) (1201)**
Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127		No prior vaccinations for this event.
SARS-COV-2 TEST		**COVID19 (COVID19 (MODERNA)) (1201)**
"""Feeling Hot"" without fever and nausea 10 hours post vaccine and resolved within 1 hour. Seizure, Hypotension, Unresponsive followed shortly by cardiac arrest and pulseless electrical activity 21 hours post vaccine. Pronounced dead 22 hours post vaccine"		No prior vaccinations for this event.
SARS-COV-2 TEST		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21		No prior vaccinations for this event.

	SARS-COV-2 TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."		No prior vaccinations for this event.
	SARS-COV-2 TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Stroke; This is a spontaneous report from a contactable consumer. A 94-year-old female patient received		No prior vaccinations for

the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 16Jan2021, at single dose, for COVID-19 immunisation. Medical history included ongoing hypertension (took medication). Patient did not have COVID-19 prior to vaccination. Concomitant included unspecified medication for hypertension. The patient experienced stroke on 31Jan2021. The patient was brought to the emergency room and hospitalized due to the event on 31Jan2021. No therapeutic measures were taken as a result of the event. The patient underwent lab tests and procedures which included COVID-19 virus test: negative in Feb2021 (a week before report); investigation: brain bleed and discovered she had a stroke (on unknown date in 2021). The patient died on 03Feb2021 due to stroke and old age. An autopsy was not performed. Patient's family did not attribute her death to the vaccine at all. The information on the Lot/Batch number has been requested.; Reported Cause(s) of Death: stroke; Old age		this event.
	SARS-COV-2 TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed/died on 09Feb2021 from respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed/died on 09Feb2021 from respiratory failure from COVID19; This is a spontaneous report from a contactable physician. An 89-year-old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in 10Jan2021 at 12:00 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had no COVID prior to vaccination. The patient received one dose of Pfizer vaccine on 10Jan2021. The patient was presented to the ER with COVID symptoms and was diagnosed on 27Jan2021. Patient subsequently died on 09Feb2021 from respiratory failure from COVID19. It was unknown if autopsy was done. The patient was tested for COVID post vaccination via nasal swab: covid-19 virus test positive on 27Jan2021. The events resulted in emergency room/department or urgent care, hospitalization, and patient died. No follow-up attempts are possible, information about batch number		No prior vaccinations for this event.

cannot be obtained. No further information is expected.; Sender's Comments: The Company cannot completely exclude the possible causality between the reported COVID post vaccination and respiratory failure with fatal outcome, and the administration of COVID 19 vaccine, BNT162B2, based on the reasonable temporal association. More information on the underlying medical condition in this 89-year-old male patient is required for the Company to make a more meaningful causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: presented to the ER with COVID symptoms and was diagnosed on 27Jan. Patient subsequently died on 09Feb from respiratory failure from COVID19; presented to the ER with COVID symptoms and was diagnosed on 27Jan. Patient subsequently died on 09Feb from

SARS-COV-2 TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Is patient deceased: Yes; Low pulse; This is a spontaneous report from two contactable nurses reporting for a patient. A 70-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EL0140 expiration date Mar2021) intramuscular on 22Dec2020 at 10:30 at single dose in right arm for COVID-19 immunisation. The patient was vaccinated at Nursing Home. Patient age at time of vaccination was 70 years. Patient's Medical History included ongoing Type 2 Diabetes Mellitus Without Complication onset date: admission 22Oct2020, ongoing morbid obesity due to excess calories onset date: admission 22Oct2020, cardiac disorder, essential hypertension, hypertension, schizophrenia, hyperlipidemia, benign prostatic hyperplasia (BPH), Gastrooesophageal reflux disease (GERD), depression, hypothyroid, epilepsy, pain, dry eyes, anxiety, restlessness, 17Jan2020 Slid out of chair to floor, no injury, on 27Jan2020, 28Jan2020, 29Jan2020 diarrhea noted. Concomitant medications included acetylsalicylic acid (ASPIRIN EC) for Cardiac Health, atenolol (ATENOLOL) for Essential Hypertension, atorvastatin	No prior vaccinations for this event.

calcium (ATORVASTATIN CALCIUM) for hyperlipidemia, finasteride (FINASTERIDE) for benign prostatic hyperplasia, tamsulosin hydrochloride (FLOMAX) benign prostatic hyperplasia, insulin glargine (LANTUS) for diabetes mellitus, lithium carbonate (LITHIUM CARBONATE) for Schizophrenia, losartan potassium (LOSARTAN POTASSIUM) for hypertension, lurasidone hydrochloride (LURASIDONE HYDROCHLORIDE) for Schizophrenia, omeprazole (OMEPRAZOLE) for gastrooesophageal reflux disease, sertraline hcl (SERTRALINE HCL) for depression, levothyroxine sodium (SYNTHROID) for hypothyroid, ergocalciferol (VIT D) for supplement, haloperidol (HALOPERIDOL) for Schizophrenia, levetiracetam (KEPPRA) for epilepsy, paracetamol (TYLENOL EXTRA-STRENGTH) for pain, propylene glycol (ARTIFICIAL TEARS) for dry eyes, lorazepam (ATIVAN) for a anxiety or restlessness. As antipyretic use was reported Tylenol ES (500 mg) Tab, 2 Tabs by Mouth Routine use three times a day given at time of vaccination and after. It was reported the patient was Covid+. He was tested on 21Dec2020 and was not admitted to hospital. Event Onset Date was reported as 24Dec2020 (clarification pending). On 30Dec2020 the patient was started on O2 at 2L for low pulse. O2 was increased over time to eventually O2 at 8L on 03Jan2021. Morphine Sulfate was started on 03Jan2021 at 5 mg sl/by mouth every 2 hours as needed for pain or airhunger. The patient deceased on 03Jan2021. The cause of death was unknown. It was not reported if an autopsy was performed. The AEs did not require a visit to Emergency Room or Physician Office. Outcome of Low pulse was unknown.; Sender's Comments: Based on the information available the events Death (unknown cause) and Heart rate decreased are attributed to patient's multiple underlying medical conditions including Type 2 Diabetes Mellitus, morbid obesity, cardiac disorder, hypertension, epilepsy etc. However, based solely on a vaccine-event chronological association, contributory role of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the above mentioned events cannot be completely excluded. The case will be reevaluated should additional information, including the cause of death, become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Is patient deceased: Yes

SARS-COV-2 TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"death was from natural causes; collapsed; This is a spontaneous report from a contactable consumer. A 73-year-old female patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 05Feb2021 at 73-years-old at a single dose for COVID-19 immunization. The patient's medical history included chronic obstructive pulmonary disease (COPD) from an unknown date and unknown if ongoing (on oxygen as needed, but not every day), oxygen therapy from an unknown date and unknown if ongoing. Concomitant medications were not reported. The patient previously received the influenza vaccine (MANUFACTURER UNKNOWN) for immunization on unknown dates (Gets flu shot every year around October). On 06Feb2021, the patient collapsed (medically significant) and experienced death was from natural causes (death, medically significant). The clinical course was reported as follows: The reporter stated that his grandmother received the first dose of the Pfizer COVID-19 vaccine on 05Feb2021 and passed away on the morning of 06Feb2021. The patient went to bed and woke up in the middle of the night around 03:00 to use the bathroom and collapsed and died within 10-15 minutes of collapsing. The patient was pronounced dead at the scene. The reporter asked: ""What do you know about the news in the media about reports of death in nursing home elderly patients?"" The reporter wanted to know the ingredients of the Pfizer COVID-19 vaccine. The reporter wanted to know about the use of the Pfizer COVID-19 vaccine in patients with underlying conditions. The patient had COPD and was on oxygen as needed, but not every day. The Medical examiner said the death was from natural causes and the family was not doing an autopsy. The patient had been tested for COVID and was negative. The patient underwent lab tests and procedures which COVID test: negative on an unspecified date. The clinical outcome of the event, death was from natural causes, was fatal. The clinical outcome of the event, collapsed, was unknown. The patient died on 06Feb2021 due to death was from natural causes. An autopsy was not performed. The batch/lot numbers for the vaccine, bnt162b2, were not provided and will be requested during follow up.; Reported Cause(s) of Death: death was from natural causes"	No prior vaccinations for this event.

SARS-COV-2 TEST	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
chest x-ray shows numerous bilateral patchy opacities; catastrophic brain bleed; Brainstem reflexes were lost; Patient died; shortness of breath; nausea; diarrhea; worsening shortness of breath/numerous bilateral patchy opacities; immunosuppressed status; This is a spontaneous report from a contactable pharmacist and a contactable other health professional. A 61-year-old female patient (not pregnant) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9261), intramuscular at arm right on 28Jan2021 (at the age of 61 years) at single dose for COVID-19 immunization. The patient medical history included bilateral lung transplant on 23Jun2017, lymphangioleiomyomatosis, hepatocellular carcinoma, antibody mediated rejection of lung transplant , bronchiolitis obliterans syndrome, grade 0P, major depressive disorder, RLS (restless legs syndrome), chronic insomnia, long term current use of systemic steroids OSA (obstructive sleep apnea), iron deficiency anemia, bilateral sciatica, hoarseness of voice, memory change, laryngeal stridor, pure hypercholesterolemia senile nuclear cataract, bilateral myopia of both eyes, osteoporosis without current pathological fracture, alopecia, immunosuppressed status, all from an unknown date and unknown if ongoing. Concomitant medication included acyclovir (formulation: capsule, strength: 200 mg) oral at 200 mg twice daily, salbutamol (ALBUTEROL HFA) as needed (MCG/ACT inhaler take 2 puffs by inhalation every 4 hours as needed) for wheezing (shortness of breath), atorvastatin (LIPITOR, formulation: tablet) oral at 80 mg once a day, azithromycin (ZITHROMAX, formulation: tablet)oral at 250 mg (every Monday, Wednesday, Friday), bupropion hydrochloride (WELLBUTRIN XL, formulation: tablet, strength: 150 mg) oral at 150 mg once a day, calcium citrate/cholecalciferol (CALCIUM + VITAMIN D, formulation: tablet) oral at 2 dose form once a day (every morning), everolimus (ZORTRESS, formulation: tablet, strength: 1 mg) oral at 2 mg twice a day, fluticasone propionate/salmeterol xinafoate (ADVAIR, strength: 500 ug/ 20 ug) twice daily (1 puff by inhalation), gabapentin (NEURONTIN, formulation: capsule, strength:100 mg) oral at 300 mg daily (by mouth nightly), loratadine (CLARITIN, formulation: tablet, strength: 10 mg) oral at 10 mg as needed, metoprolol tartrate (LOPRESSOR, formulation: tablet, strength: 25 mg)oral at 50 mg twice daily, minoxidil (ROGAN, strength: 5%) topical apply 1 cap full every other day to affected	No prior vaccinations for this event.

area on scalp for alopecia, ondansetron (ZOFRAN, formulation: tablet, strength: 4 mg) oral at 4 mg as needed for nausea, pantoprazole sodium sesquihydrate (PROTONIX, formulation: tablet, strength: 40 mg) oral at 40 mg once a day, prednisone (DELTASONE, formulation: tablet, strength: 5 mg) oral at 5 mg daily (every morning), sertraline hydrochloride (ZOLOFT, formulation: tablet, strength: 100 mg) oral at 100 mg twice a day (every morning), sulfamethoxazole/trimethoprim (BACTRIM) 400-80 mg per tablet (1 tablet by mouth every Monday, Wednesday, Friday), tacrolimus (formulation: capsule) at 3 mg daily (2 mg every morning and 1 mg at night), salbutamol sulfate (PROVENTIL HFA) as needed for wheezing (shortness of breath), salbutamol sulfate (VENTOLIN HFA) as needed for wheezing (shortness of breath) , salbutamol sulfate (PROAIR HFA) as needed for wheezing (shortness of breath), ascorbic acid/ferrous fumarate/folic acid/ retinol (PRENATAL, formulation: tablet) oral daily. The patient previously took NSAIDs and voriconazole and experienced drug allergies. It was reported that the patient presented to emergency department (ED) on 04Feb2021 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine. Full viral panel including COVID-19 was not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 08Feb2021 and then VV ECMO cannulation on 13Feb2021. Acute pupil exam changes in the early am hours of 15Feb2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. The events were all serious. The patient outcome of the events was fatal. The patient died on 15Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported events due to temporal relationship. However, the reported event may possibly represent intercurrent medical conditions in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for

safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Chest x-ray shows numerous bilateral patchy opacities; Catastrophic brain bleed; Brainstem reflexes were lost; shortness of breath; nausea; Diarrhea; Worsening shortness of breath/numerous bilateral patchy opacities

	SARS-COV-2 TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"never woke up after arrival; Suffered with vascular dementia; Death cause: Covid/Tested positive to Covid 31Jan, tested due to increased lethargy; This is a spontaneous report from a contactable consumer. An 85-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Jan2021 at single dose for COVID-19 immunization. The patient received the vaccine at nursing home/senior living facility. Medical history included dementia, hypertension, past strokes. The patient was exposed to asymptotic staff member on or prior to 25Jan2021. The patient had no known allergy. No COVID prior vaccination. Concomitant medication included lisinopril. No other vaccine was received in four weeks. The patient was tested positive to COVID on 31Jan2021, tested due to increased lethargy started from 26Jan2021. The patient suffered with vascular dementia. She was ambulatory up to 31Jan2021. The patient was sent to hospice that evening on 31Jan2021 to quarantine, never woke up after arrival. Palliative Care started 02Feb2021, the patient expired 12Feb2021. Cause of death was COVID. The patient did not receive treatment for events. The autopsy was not performed. The outcome of events ""never woke up, vascular dementia"" was unknown. Information on Lot /Batch Number has been requested.; Reported Cause(s) of Death: Death cause: Covid"		No prior vaccinations for this event.
	SARS-COV-2 TEST	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

pulmonary edema; Low heart rate; chest pain; This is a spontaneous report from a contactable pharmacist. An 80-years-old male patient received his second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular in left arm on 28Jan2021 at single dose for COVID-19 Immunisation. Medical history included dementia, high blood pressure, COVID prior vaccination. He had no known allergies. Concomitant medication included diltiazem hydrochloride (CARDIZEM), anastrozole (ARIMIDEX), simvastatin and lorazepam. Historical Vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 07Jan2021 (at the age of 80-years-old) at single dose for COVID-19 Immunization. There was no other vaccine received in four weeks. The patient experienced pulmonary edema, low heart rate and chest pain on 26Feb2021. The events resulted in hospitalization and patient died. The patient was hospitalized from 26Feb2021 for 1 day. Treatment received for the events included Epinephrine, morphine, nitroglycerine. The patient underwent lab tests and procedures which included Covid test Nasal Swab post vaccination on 26Feb2021 indicated Negative. The patient died on 26Feb2021. An autopsy was not performed. information on the lot/batch number has been requested.; Sender's Comments: Pulmonary edema, low heart rate, and chest pain, all reported as fatal, are deemed unrelated to BNT162B2 vaccine, being rather accidental occurrences, likely favored by the patient's age and by the mentioned high blood pressure, known risk factor for cardiovascular diseases. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Low heart rate; pulmonary edema; chest pain

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds

No prior vaccinations for this event.

upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

"Narrative: Patient with severe aphasia and only able to say ""hey, hey, hey"" or ""uh huh"" or shake his head no as a way to communicate. Patient previously able to ambulate with significant limp and hyperextension of right knee, but mostly wheelchair bound over last several years as he had had a slow and steady decline in overall health and mobility. Patient developed aggressive behavior of shouting ""hey"" and grabbing of groin in 2016. This was worked up with CT scans, labs, referral to urology, neurology, and referrals to psychiatry. The exact etiology of this action was never able to be affirmed, but thought to be more psychiatrically related. It improved significantly with addition of antipsychotics, worsened when antipsychotics were reduced, and improved again with addition of injectable antipsychotic on 12-10-2020.Patient suffered from falls on occasion given his significantly impaired physical mobility. His last documented fall was 8-31-2019. Patient began utilizing wheelchair most of time following that fall. No significant injuries noted in documentation of the falls. In the last 3 months, patient would often refuse medications. He would sometimes indicate that they would cause dizziness, and other times he would simply refuse. We attempted to hide medications in his food/fluid (with wife's blessing) and when he detected this he would occasionally refuse to eat. Patient previously on DOAC. After pharmacy review in 12/2020 it was recommended to discontinue this as no clear indication to continue use. He was high fall risk and would often refuse this medication as well since 10/2020. Noted to be in NSR on EKGs and decision made to discontinue the DOAC. Patient had no evidence of adverse effects noted after vaccination on December 28th. Patient seen by provider on the morning of his death (1/4/2021) with no noticeable significant change in health condition. Temperature 36.8Con January 4th at 19:45. During routine bedtime cares, patient suddenly collapsed and death was pronounced January 4, 2021 at 20:05. Autopsy was requested from next of kin and no autopsy was granted. Symptoms: & DEATH Treatment:"

No prior vaccinations for this event.

	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received Moderna COVID vaccine on 12/30/2020 at a Pharmacy clinic where he was a resident. Nurses at the facility reported that he was responsive and showed no signs of any adverse effects until 1/2/2021 when he was observed slightly unresponsive and staring at the ceiling and trembling. He had a fever of 101F at this time. The facility ordered labs and a rapid COVID test (all of which came back normal) and started IV antibiotics. A few hours later, patient began bleeding from his eyes, nose, and mouth and was sent to the local ER. The patient refused being admitted to the ICU for possible sepsis/hemorrhage and died the following day on 1/3/2021. All healthcare professionals involved agreed that this was not likely due to the vaccine, but needed to be reported nonetheless.		No prior vaccinations for this event.
	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
CARDIAC ARREST THAT LEAD TO DEATH - IT WAS REPORTED BY EMS THAT THE PT HAD RECEIVED THE VACCINE ABOUT 30 MINS PRIOR. HE ARRIVED HOME, BECAME SHORT OF BREATH & COLLAPSED. 911 WAS CALLED AND HE WAS TRANSPORTED VIA EMS TO HOSPITAL (16:17) WHERE HE LATER EXPIRED (23:01).		No prior vaccinations for this event.
	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient recieved vaccine 1 of covid 19 i 1/19/2021. She felt poorly on 1/20/2021. She felt dizzy and fell at 3 AM on 1/23/2021. She felt poorly and did not know her son's name which was not normal. She went to ER on 1/24. She was assessed as not having fractures. She was going to be transferred to a skilled nursing facility. She was not having respiratory complaints. She was awaiting transfer when her O2 levels started dropping substantially. She declined aggressive intervention and she died within a few hours.		No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless and breathless and was pronounced. Autopsy currently pending.		No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt started complaining of chest heaviness and shortness of breath on the afternoon of 1/21/21. EMS was called to the patients home and she was found to have an O2 sat in the 70's. She was admitted to hospital and found to have a proBNP of 5000. She tested negative for Covid-19. She was determined to be in acute-on-chronic heart failure and was referred for hospice care. She passed away on the evening of 1/24/21.		No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.

	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."		No prior vaccinations for this event.
	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Death Narrative: Patient received the first COVID-19 dose on 12/23. Afterwards, patient complained of localized pain on L deltoid area where the vaccine was administered; his temperature was 98.1 F. On 12/26-27, staff reported that patient appeared more fatigued than usual and was shivering on 12/27, which seized after blanket was given. On 12/28, patient presented with fever (Tmax 100.2 F) and acetaminophen was administered for alleviation of fever. ADR was reported for the fever on 12/29. Patient continued to decline		No prior vaccinations for this event.

and was placed back on hospice care on 12/29; on 12/30. the symptoms reported on nursing note include erythema and pain on whole L arm. Lidocaine was applied. Patient's family and provider mutually agreed not to administer the second dose of vaccine. He continued to decline and was started on end-of-life care around 1/4 and passed on 1/20 1417.

SARS-COV-2 TEST NEGATIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
Lethargy/altered level of consciousness lead to hospital admission. Multiple interventions during hospitalization. Final hospital diagnoses: Acute respiratory failure with hypercapnia, acute pansinusitis.		No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
Unknown. Was informed that the patient went to E/R on 1/25/21 (6 days after receiving vaccine. Died 1/29/21 (10 days after receiving vaccine).		No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29		No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
The patient, who was a pharmacist, developed fatigue and shortness of breath hours after receiving vaccine. Two days later, on 01/28/2021, the patient went to local urgent care for worsening shortness of breath and		No prior vaccinations

was referred to Hospital for worsening dyspnea and hypoxia. The patient was admitted to the hospital We was found to have bilateral pulmonary infiltrates and treated for pneumonia with Rocephin and azithromycin. He was tested for COVID-19 multiple times, but each of the results were negative. Despite the negative results, there was high clinical suspicion for COVID-19 and the patient was started on Remdesivir and Decadron. The patient's oxygen requirements continued to worsen and the patient was transferred to another facility for higher level of care. There his hypoxia worsened and he required mechanical ventilation. Patient then developed hypotension and required vasopressors for blood pressure support. Furthermore, patient developed acute renal failure requiring hemodialysis. Despite mechanical ventilation with FiO2 100%, and for vasopressors, patient clinically deteriorated and family decided to palliatively extubate on 02/05/2021.	for this event.
SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to emergency room on 2/1/2021 with a chief complaint of having a chronic headache and fatigue following receipt of the Moderna vaccine 10 days prior. Following examination by the physician, the patient was diagnosed with an acute subdural hematoma. The patient subsequently underwent decompressive surgery, however demonstrated worsening neurologic status over the next several days and ultimately expired on 2/4/2021.	No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Admitted to hospital with sob upon exertion that started prior to vaccine. Hx COPD, HTN, CKD, hyperlipidemia, bladder cancer in remission. Stated he has been taking Eliquis and Xarelto between renal doctor and cardiologist Dr. Anticipating going home 2/5/21 but then turned blue and stopped breathing under a DNR. COVID test negative. Labs show acute on chronic renal failure with an elevated troponin likely from demand ischemia.	No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Feb 8 states she had a cold. Feb 9 added stomach ache and nausea. Feb 9 visited urgent care facility for exam and Covid-19 test. Rapid test results were negative. Appeared tired but fine. Told to go home and rest. Feb 10 at 9:00 am found dead on the floor in pool of blood and aspirated. Excessive blood in toilet, pooled on floor and hallway rug.

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Resident tested NEGATIVE for COVID-19 last 1/25/2021. She was on monitoring for desaturation and low blood pressure on Jan. 27,2021

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Resident tested NEGATIVE for COVID-19 on 1/25/2021. She was on monitoring for declining in condition on 1/29/2021.

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

On monitoring for declining in condition, loss of appetite and generalized body weakness on2/1/2021. Was confirmed COVID-19 positive 4/23/2020.

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

On monitoring for weight loss . No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE **COVID19 (COVID19 (MODERNA)) (1201)**

ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE **COVID19 (COVID19 (MODERNA)) (1201)**

Pt. received vaccine on 2/3/2021. Coded at home on 2/17/2021. No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE **COVID19 (COVID19 (MODERNA)) (1201)**

"86yo female alert, stable with ankle abrasion eating 100% prior to vaccine in assisted living facility. On 2/1/2021, received Moderna vaccine. Starting thereafter, eating 50% on 2/2/21. Temperature was 98 tympanic. On 2/3, the leg abrasion started having moderate bleeding. On 2/4, the caregiver noted patient ""not looking good, unable to talk, arms moving aimlessly, grasping"". BP 95/41, temperature 98, oxygen on

No prior vaccinations for this event.

room air 92-93%. POA did not want hospital transfer. 2/5 Hospice started, oxygen given, morphine given. 2/5-2/8 comfort care given, patient responsive to tactile stimuli, resting, not taking oral medications or food. 2/8/2021 patient expired."

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Resident getting rehab therapy in the facility and has a long history of Parkinson's Disease. On 01/29/21, he received the COVID vaccine on left deltoid, resident was recently hospitalized due to Pneumonia and was on antibiotic IV and was recently placed on GT feeding due to severe dysphagia from his Parkinson's disease. On 01/31/21, started having increased congestion. On 02/02/21, started having increased temperature and WBC went up >20,000 on 02/03/21, started on Vancomycin IV on 02/04/21 but was transferred to the hospital. Facility was notified today (02/18/21) that resident expired in the hospital.

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Patient previously had dizzy spills, but about a week after receiving the vaccine her dizzy spills began to get worse. The whole prior she kept saying I am just not right. On the 2/7/21 she a COVID test done, a nurse came to her house and preformed. On the morning of the 8th patient was on the phone with someone else and patient asked this person to call me and go check on her. Within 5 minutes I was over at her house, and I found her on the floor, she on her belly facedown. It looked like she was on the toilet, and it looked like she fall getting her off, she was still wet, she still felt warm. I called the ambulance and immediately began CPR. When EMS arrived they took over the CPR and transported her to the Hospital. The EMS was there for about 40 minutes and used an machine to preform the compressions. She was pronounced deceased at the hospital. No autopsy was done.

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19

(MODERNA)) (1201)

Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on

No prior vaccinations for this event.

the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.		
SARS-COV-2 TEST NEGATIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient died on 2/25/21 in the AM after receiving his COVID-19 Moderna vaccine #1 at approximately 2:30P on 2/24/21. I do not have a time of death. I contacted the County Medical Examiner's office who stated that they received his body after he was determined to be deceased at the shelter. No autopsy was performed and his body was released to a funeral home on 2/26. The ME's office said that ""permit for burial/cremation is pending"" and no other information on COD was available. Per staff, he was also tested for COVID as part of shelter protocol on 2/24 and PCR was negative. He arrived to the shelter on 2/19/21."		No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Within 24 hours of receiving the vaccine, fever and respiratory distress, and anxiety developed requiring oxygen, morphine and ativan. My Mom passed away on the evening of 12/26/2020.		No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was		No prior vaccinations for

called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."	this event.
SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mother was given Pfizer vaccine on Thursday and she died 3 days later yesterday on Sunday!!!	No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.	No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH))**

"Cardiac Arrest; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; Patient was found pulseless and breathless 20 minutes following the vaccine administration.; This is a spontaneous report from a contactable other healthcare professional (HCP). A 66-year-old female patient (pregnant at the time of vaccination: no) received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL1284) via intramuscular at left arm on 11Jan2021 12:15 PM at single dose for COVID-19 immunization. Medical history included diastolic CHF, spinal stenosis, morbid obesity, epilepsy, pulmonary hypertension and COVID-19 (Prior to vaccination, the patient was diagnosed with COVID-19). The patient received medication within 2 weeks of vaccination included amiodarone, melatonin, venlafaxine hydrochloride (EFFEXOR), ibuprofen, aripiprazole (ABILIFY), lisinopril, cranberry capsules, diltiazem, paracetamol (TYLENOL), famotidine, furosemide (LASIX [FUROSEMIDE]), ipratropium bromide, salbutamol sulfate (IPRATROPIUM/ALBUTEROL), buspirone, senna alexandrina leaf (SENNA [SENNA ALEXANDRINA LEAF]), polyethylene glycol 3350 and morphine. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. Patient used took Penicillin, propranolol, quetiapine, topiramate, Lamictal and had allergy to them. Patient used took the first dose of BNT162B2 (lot number: EJ1685) via intramuscular at right arm on 21Dec2020 12:00 PM at single dose for COVID-19 immunization. Since the vaccination, the patient been tested for COVID-19 (Sars-cov-2 PCR) via nasal swab on 06Jan2021, covid test result was negative. Patient was found pulseless and breathless 20 minutes following the vaccine administration (11Jan2021 12:30 AM). MD found no signs of anaphylaxis. Patient died on 11Jan2021 12:30 AM because of cardiac arrest. No treatment received for the events. Outcome of pulseless and breathless was unknown. the autopsy was performed, and autopsy remarks was unknown. Autopsy-determined cause of death was unknown. It was reported as non-serious, not results in death, Life threatening, caused/prolonged hospitalization, disabling/Incapacitating nor congenital anomaly/birth defect.; Sender's Comments: Based on the available information this patient had multiple underlying medical conditions including morbid obesity, diastolic CHF, epilepsy, pulmonary hypertension and COVID-19 diagnosed prior to vaccination. All these conditions more likely contributed to patients cardiac arrest resulting in death. However, based on a close temporal association (""Patient was found pulseless and breathless 20

No prior vaccinations for this event.

minutes following the second dose of BNT162B2 vaccine administration, contributory role of BNT162B2 vaccine to the onset of reported events cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Cardiac arrest; Autopsy-determined Cause(s) of Death: autopsy remarks was unknown. Autopsy-determined cause of death was unknown"

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death occurred 3 days after vaccine receipt; attributed to complications of her chronic advanced dementia with aspiration at age 87. No evidence of acute vaccine reaction.

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.

Influenza Virus Vaccines - Unknown date/type or brand

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated hospital bed. Patient committed suicide in home.

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

REPORTING ONLY AS RESIDENT EXPIRED ON 1/17/2021 3 DAYS AFTER. S/S HYPOXIA/CONGESTED LUNG SOUNDS

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

The day following the vaccine, the patient complained of throat issues and anxiety. This was not new... however . That evening he reported difficulty breathing and was placed on oxygen; a COVID test was performed and was negative. On 12/30/2020, patient complained of sternal pressure and was transferred to the hospital. The patient died 12/31/2020 and records obtained from the hospital indicated the patient died from a massive myocardial infarction.

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH))

	(1200)
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.	No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
respiratory distress; fever; anxiety developed requiring oxygen; Passed away; This is a spontaneous report via a Pfizer-sponsored program from a non-contactable consumer. A 63-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot and expiry not reported), via an unspecified route of administration on 23Dec2020 at a single dose for COVID-19 immunization. Medical history included anaphylactic reaction (broad), neuroleptic malignant syndrome (broad), anticholinergic syndrome (broad), acute central respiratory depression (broad), hypersensitivity (broad), respiratory failure (narrow), drug reaction with eosinophilia and systemic symptoms (broad), hypoglycaemia (broad), COVID-19 (broad) and chronic obstructive pulmonary disease (COPD); all from an unknown date and unknown if ongoing. Concomitant medications included levothyroxine sodium and lorazepam (ATIVAN). Within 24 hours of receiving the vaccine, the patient experienced fever, respiratory distress, and anxiety developed requiring oxygen, morphine and lorazepam (ATIVAN). The patient passed away on the evening of 26Dec2020. The patient underwent lab tests and procedures which included SARS-COV-2 antibody test: negative on an unspecified date. The outcome of the event death was fatal, while of the other events was unknown. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch	No prior vaccinations for this event.

number cannot be obtained.; Reported Cause(s) of Death: Passed a

SARS-COV-2 TEST NEGATIVE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20	No prior vaccinations for this event.

without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending

work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
See initial report	No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

All residents had been in isolation due to multiple cases of COVID in the facility. Resident voiced no health related complaints. He continued to visit with staff and required moderate assist with toileting. Resident had fall 0130 on 1-15-2021, which resulted in laceration with surgical repair. Resident was noted to change in mental status and respirations on morning of 1-16-2021 during morning blood sugar check. Resident had O2 @1.5l/m via n/c and respirations of 10 with periods of apnea and unresponsive to verbal stimuli. Blood sugar was 583. Resident deceased upon re-check after calling PCP to report status change.	No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"	No prior vaccinations for this event.

	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
she was hurting at her chest/ Chest pain; on her left arm hurt real bad that's what the clot on her left arm; on her left arm hurt real bad that's what the clot on her left arm; She passed away; heart attack; This is a spontaneous report from a contactable consumer. An 87-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Jan2021 at single dose for COVID-19 immunisation. Medical history included diabetes mellitus, for which she was taking a pill like an hour before she would take her meal. On Monday (Jan2021) the patient experienced was hurting at her chest/ chest pain, her left arm hurt real bad as she had a blockage in her left arm/clot on her left arm, and they wanted to put in a stent and after the surgery it went well and she all go home in two days. The patient was hospitalized in Jan2021 due to the events. She had a heart attack and that the chamber between the dividers had a hole in it and her heart tissue was too thin so much thin she couldn't repair it. The patient passed away on 26Jan2021. The patient was tested negative for COVID-19 on unknown date. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: She passed away		No prior vaccinations for this event.
	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 10 minutes after receiving the COVID- 19 vaccine resident displayed seizure activity, staring straight ahead and strong allover muscle jerking of both the up and lower extremities, color became gray, activity lasted approximately 3 minutes, resident then became relaxed, color returned to normal, BP-140/80, 97.8, 60, 16, sleeping the remainder of the shift,. Resident continued to decline until resident CTB on 1/19/21		No prior vaccinations for this event.
	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19**

	(PFIZER-BIONTECH)) (1200)
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
view 2/5/2021 09:23 e Progress Note Note Text: Patient passed away in the facility this morning. view 2/5/2021 08:39 Orders - Administration Note Note Text: Resident passed. view 2/5/2021 08:33 Nurses Note Note Text: Body released to funeral home at this time. Personal effects sent with resident include: 1 pair of	No prior vaccinations for this event.

glasses, 1 yellow wedding band, 1silver spoon ring, 1 ring with black and clear stones. Resident has own teeth view 2/5/2021 08:32 Nurses Note Note Text: cause of death per CRNP failure to thrive. view 2/5/2021 07:44 Orders - Administration Note Note Text: Take and document temp & PO2 every 4 hours for MONITORING Resident passed. view 2/5/2021 06:49 Nurses Note Note Text: Son returned call and was updated of resident's passing this am view 2/5/2021 06:33 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Unknown Resident expired @ 0604 [linked] view 2/5/2021 06:06 Nurses Note Note Text: Res found without pulse or respirations. Pronounced at 0604. Updated. N/o's for RN to pronounce, release body to funeral home, dispose of medications per facility policy. Daughter updated. Funeral Home called to release body. view 2/5/2021 05:26 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Pulse ox 60% on O2 @ 5L/min via mask. Resps 44 per minute. view 2/5/2021 01:57 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/5/2021 00:52 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Residents resps are 40 per minute, pulse ox 76% on O2 @ 5L/min via mask. Resps are labored, shallow and rapid. view 2/5/2021 00:48 Nurses Note Note Text: Nonresponsive to verbal and tactile stimulation. Appears comfortable. view 2/4/2021 22:01 Nurses Note Note Text: Resident resting comfortably, breathing becoming increasingly shallow, wearing O2 via mask at 5L via mask, no dyspnea noted, feet are mottled, oral and peri care provided Q2H. No s/s of pain or discomfort. view 2/4/2021 21:40 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective [linked] view 2/4/2021 19:32 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger medicated for air hunger, RR 28 to 32/ min view 2/4/2021 19:22 Nurses Note Note Text: Daughter updated on N/O to increase Morphine Sulfate 20mg/mL 0.25mL to Q2H prn from Q6H prn. view 2/4/2021 18:06 Nurses Note Note Text: POA Daughter and daughter aware of residents current condition. view 2/4/2021 11:58 Orders - Administration Note Note Text: Morphine Sulfate

(Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/4/2021 11:13 Nurses Note Note Text: Pt. noted to be lethargic at this time. Does respond to verbal and tactile stimuli by opening her eyes but non verbal currently. Skin warm and dry. No mottling or apnea observed at this time. O2 sat 88% with O2 at 2 LPM via n/c. On increased to 3 LPM via mask as pt. noted to be mouth breathing. Respirations 28. F/U O2 sat 93%. HOB elevated. Pt. medicated with morphine by LPN. Daughter updated on pt.'s condition. Does not want pt. sent out to hospital and would like comfort measures to continue. Daughter also in agreement with delay in d/c d/t pt.'s condition.CRNP updated on pt.'s condition, delay in d/c and daughter's wishes. No n/o's at this time. view 2/4/2021 10:56 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB Resident showing s/s of discomfort. SOB at this time and high respirations. Repositioned, changed for incontinence care and mouth care provided. view 2/4/2021 10:34 Progress Note Note Text: Spoke with RN regarding change in condition. Updated Sr Living regarding change. Recommendation to cancel d/c/transfer for today, see how resident does through the weekend and re-evaluate on Monday. Daughter updated on cancellation of d/c today. view 2/4/2021 10:04 Nurses Note Note Text: Daughter aware that resident's O2 sat was 88% on room air on 3-11 shift and that oxygen was applied via nasal cannula. view 2/4/2021 10:03 Nurses Note Note Text: N/O: Discharge 2/4/21 with scripts to Sr. Living. Daughter aware. view 2/4/2021 09:53 Nurses Note Note Text: Pt. to be d/c'd to another facility this am as per MD order. Pt. alert and responsive. Skin assessment done as per facility policy. No pressure areas noted at this time. No s/sx of pain or discomfort observed at this time. V.S. 97.0 67 20 O2 sat 95% with O2 at 2 LPM via n/c. view 2/4/2021 07:45 Nurses Note Note Text: Resident seen by Dr. for discharge. Orders pending at this time. view 2/4/2021 07:36 Nurses Note Note Text: CRNP and Dr. updated on O2 sat 88% on RA with f/u of 93% with O2 on at 2 LPM as well as rest of VS, 3-11 shift 2/3/21. No n/o's at this time. view 2/3/2021 21:17 Nurses Note Note Text: Resident Sp02 88% on RA. Pulse 124. Respirations 40. PRN morphine given and O2 applied via NC at 2L/min. After recheck pulse ox up to 93%, pulse 100, and respirations 22. Resident appears comfortable at this time. view 2/3/2021 20:05 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective [linked] view 2/3/2021 19:48 Orders - Administration Note Note Text: Morphine Sulfate

(Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN given for SOB after elevation of HOB not effective. view 2/3/2021 11:51 Nurses Note Note Text: CRNP updated rapid COVID test done for d/c tomorrow was negative. No n/o's at this time. view 2/3/2021 11:44 Nurses Note Note Text: Daughter notified of rapid covid swab being negative. view 2/3/2021 09:50 Orders - Administration Note Note Text: Obtain Rapid Covid test on 2/3/2021 for discharge. Please give copy of results to Social Worker every day shift for covid testing for 1 Day Completed and negative. view 2/3/2021 08:45 Skilled Nursing Note Reason for skilled service: Therapy describe skilled service: Nursing, therapy assessment: V.S. 97.8 79 18 138/84 Orientation: Oriented to self only. Oxygen: O2 sat 94% on RA Edema: Trace edema noted BLE. Pedal pulses present. Pain: Denies pain or discomfort at this time. Nursing note: Pt. alert and responsive. Skin warm and dry. Lung sounds diminished. No respiratory distress observed at this time. Abdomen soft. BS+ in all 4 quads. Continent/Incontinent of B&B. 1 assist with ambulation, transfers. 1 assist with ADL's. Working with therapy on gait training, therapeutic exercise, therapeutic activities & neuromuscular reeducation. view 2/2/2021 14:37 Progress Note Note Text: Per health professional at Sr Living, prepared to accept patient to their Memory Care Unit 2/4. Transportation arranged for 11 AM per family request. Daughter (POA) updated on d/c time on 2/4/21. Facility requesting rapid COVID test completed prior to d/c and results sent to them. All other information sent for continuity of care.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in

No prior vaccinations for this event.

bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient got the injection and quickly developed a fever and felt weak. Family was contacted and he was sent to Hospital.	No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient	No prior vaccinations for this event.

coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent

with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia		No prior vaccinations for this event.
	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On December 17, 2020, my husband, received his first BioNTech BNT162b2 COVID-19 vaccination. On Thursday January 7, 2021, he received this second COVID-19 vaccination. The following three days after his second vaccination, he felt fine. The fourth day, on Sunday January 10, my husband felt extremely fatigued. On Monday the 11th and Tuesday the 12th, he worked a full shift but complained of extreme fatigue and extreme chills to the point that his teeth were chattering while on the phone with me. He decided to work through it. When he got home on Monday night, he started vomiting. On Wednesday January 13, he woke up and had swollen eyes. Once again, he felt extremely fatigued, even after a full nights rest. He had the day off but had an early meeting. After his meeting, he was still tired so he went		No prior vaccinations for this event.

back to sleep. I left to get lunch, and drop off our kids, and upon my return, I found him on the walk in closet floor, face up, having passed away. He felt as cold as ice. The rapid test done after they called the paramedics resulted in a negative COVID-19 test for him.		
	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
right arm swelling immediately after injection. followed by bilateral lower leg edema, chills and body aches that continued daily at 2 weeks post immunization admin 2/4/21 treated with dexamethasone 6mg PO x 7 days- this resolved his s/s 2/13/21 patient passed away at facility		No prior vaccinations for this event.
	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.		No prior vaccinations for this event.
	SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full		No prior vaccinations for this event.

viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased	No prior vaccinations for this event.

use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21- N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)

No prior vaccinations for this event.

SARS-COV-2 TEST NEGATIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No known side effects; however, on 1/20 the decedent suffered lethargy. On 2/12/2021, the decedent had a possible seizure and was transported to emergency department where shortly after arrival, he was pronounced dead.	No prior vaccinations for this event.
SARS-COV-2 TEST NEGATIVE	**COVID19 (COVID19 (UNKNOWN)) (1202)**
Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2 diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated) then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and was intubated. Transported to hospital. SARS CoV-2 and influenza negative.	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
After vaccination, patient tested positive for COVID-19. Patient was very ill and had numerous chronic health issues prior to vaccination. Facility had a number of patients who had already tested positive for COVID-19. Vaccination continued in an effort to prevent this patient from contracting the virus or to mitigate his risk. This was unsuccessful and patient died.	No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
At the time of vaccination, there was an outbreak of residents who had already tested positive for COVID 19 at the nursing home where patient was a resident. About a week later, patient tested positive for COVID 19. She had a number of chronic, underlying health conditions. The vaccine did not have enough time to prevent COVID 19. There is no evidence that the vaccination caused patient's death. It simply didn't have time to save her life.		No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
Prior to the administration of the COVID 19 vaccine, the nursing home had an outbreak of COVID-19. Patient was vaccinated and about a week later she tested positive for COVID-19. She had underlying thyroid and diabetes disease. She died as a result of COVID-19 and her underlying health conditions and not as a result of the vaccine.		No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
Fever, RespDepression & COVID positive REMDESIVIR (EUA) 200 mg x1 then 100 mg daily		No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
The resident resides in an independent living facility/apartment. The reporter at the center was informed by his daughter he was not feeling well on 1/1/2021 (specific symptoms could not be ascertained). He reportedly went to be COVID tested on 1/1/2020 and observed to be deceased in his apartment on 1/2/2020. I do not		No prior vaccinations for this event.

have confirmation of his COVID results, although the reporter indicates his daughter reports his test was positive.

	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
The facility had positive cases of COVID when we were able to begin vaccinating residents. Within about a week of vaccination, patient was tested positive for COVID. He was 91 years old and his immune system did not have the time to allow the vaccine to begin working before exposure. His age was a major contributing factor to his death.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
The facility had positive cases for COVID 19 when the vaccine was received and administered to patient. With her advanced age and chronic conditions, she did not have time to build immunity between the time of vaccination and her testing positive.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
The facility had a number of positive COVID 19 cases prior to patients vaccination. Due to her advanced age, chronic condition, and exposure, patient did not have the time to build immunity after exposure before becoming positive.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient vaccinated on 12/28. Approximately one day later, develops cough and on azithromycin x 1 week. On		No prior vaccinations

1/3, patient develops left-sided weakness and aphasia. Taken to the hospital, tested COVID+, required intubation -- acute hypoxic respiratory failure secondary to COVID - on H&P. Patient died on 1/4/21 at 7:20am. for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (MODERNA)) (1201)**

Weakness, Low O2, death. Positive for COVID on 1/12/21, dies on 1/16/21 No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (MODERNA)) (1201)**

mi Narrative: patient with asymptomatic covid 19, covid positive 12/10/2020. No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (MODERNA)) (1201)**

Patient deceased on 01/17/2021 No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE COVID19 (COVID19 (MODERNA)) (1201)

Pt developed COVID-19 infection, symptoms starting 7 days after first dose was given. Patient was admitted to hospital on 1/21 after falling (secondary to weakness) and striking head on toilet. Patient expired due to respiratory complications of COVID on 1/25. No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (MODERNA)) (1201)**

Resident received the first dose of Moderna Vaccine on 01/12/2021 and Tested for COVID-19 on 01/12/2021. Resident tested positive on 01/13/2021. Resident was transferred to acute hospital on 01/19/2021 due to desaturation. Resident expired at Hospital on 01/24/2021. No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt likely presented to vaccine appt with asymptomatic/early infection of COVID-19, as he presented 2 days post-vaccination and tested positive for COVID-19 on rapid and PCR test. He was hospitalized where he eventually died of complications from COVID-19 while in ICU. Date of death was 1/15/2021.	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
weakness and fallsNarrative: 95 yo male w/ a PMH significant for Afib, legal blindness, Hx of CVA, cognitive impairment, GERD, HTN, pseudogout, BPH, chronic knee infection, and DJD who received his first dose of the Moderna COVID-19 vaccine on 01/08/21. The pt's COVID-19 screening questionnaire prior to receiving the vaccine was negative. The pt presented to the ED on 01/13/21 for weakness and m PCR test on ultiple recent falls (since receiving his first dose of the COVID-19 vaccine). The pt's COVID-19 01/13/20 was positive and he was admitted. He was started on treatment with remdesivir + dexamethasone on 1/14. The pt initially required supplemental oxygen via low-flow NC, however his oxygen requirements increased to 100% NRB. On 01/16/21 his MPOA elected for hospice care. The pt passed on 01/17/21. Unclear if the COVID-19 vaccine attributed to the patient's hospitalization and eventual death, or whether these events occurred from COVID-19 itself, however this case is being reported the FDA since this vaccine is under an emergency use authorization (EUA).	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presented to ER via EMS at 1556 3 days after receiving vaccine. pt was breathing approximately 50 times a minutes and o2 sats in the 70's upon arrival. NP decided to intubate, Rocuronium and Versed given. Pt became bradycardic and 1 amp of Atropine was given without improvement. No pulse felt, CPR started per ACLS protocol. 7 Epi's given. Time of death- 1632. After TOD pt was swabbed for COVID-19 and the results	No prior vaccinations for this event.

were positive.

SARS-COV-2 TEST POSITIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
My Mother was given the Covid Vaccine (1st Dose) on 12/28/2020. Later that night we received a call from the nursing facility that my Mother was having uncontrollable seizures and had to be transported to the nearby hospital. The ER doctor confirmed that my Mother had tested positive to Covid. She was treated for Covid and was on life support. A few days later we received a call that my Mother had a major stroke. She passed away on January 4, 2021		No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
Shortness of Breath, decreased oxygen saturation, irregular heart rhythm, hypertension, Positive for COVID, bilateral pneumonia		No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident received the vaccine on 1-22-21 and she was diagnosed with COVID-19 during routine testing on 1-28-21. She didn't have any symptoms except feeling weak and she had a decrease in her appetite. She already had a poor appetite prior. She died on 2-2-21.		No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
Received Moderna covid vaccination 1/14/2021. 1/16/2021 received report of cough and difficulty breathing. Proceeded to hospital and was diagnosed Covid+ on testing. Continued to decline, died		No prior vaccinations for

1/31/2021.		this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient sent to the ED or sudden onset of shortness of breath on 02/02/2021. Per documentation by the MD, the patient had COVID19 ""several weeks ago"" and the nursing facility felt like he had recovered. A rapid test done in the ED was negative. When the patient worsened and seemed to be following the same path as other COVID patients, a send out PCR test was done, which was positive. The patient worsened and passed away that same day (02/05/2021) I was not made aware that the patient had the vaccine on 01/21/2021 until Monday 02/08/2021."		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away; Positive result; A spontaneous report was received from a consumer concerning a female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and developed COVID-19 and passed away. The patient's medical history was not provided. Concomitant product use was not reported. On 05 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 08 Jan 2021, the patient had a positive COVID-19 test. On 18 Jan 2021, the patient passed away. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 18 Jan 2021. The cause of death was not reported.; Reporter's Comments: This spontaneous report concerns a female patient who experienced COVID-19 and passed away. The event of COVID-19 occurred 4 days after the first and only dose of the mRNA-1273 vaccine administered and death occurred 14 days after administration of the mRNA-1273 vaccine. Based on the information provided and the known etiology of COVID-19, it is unlikely to be associated with mRNA-1273 vaccine administration. With no definite information on the clinical details of the death, it is difficult to adequately assess a causal association with mRNA vaccine. Main field defaults to		No prior vaccinations for this event.

æpossibly related'; Reported Cause(s) of Death: unknown cause of death

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (MODERNA)) (1201)**

Patient was vaccinated on 1/14/2021. On 1/22/2021, patient tested positive for COVID-19 and admitted to the hospital for acute hypoxemic respiratory failure, COVID-19 pneumonia, and severe ARDS. Patient was intubated on 1/23/2021 and later died on 2/10/2021 after being extubated and placed on comfort measures. No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (MODERNA)) (1201)**

patient tested positive for covid on 1/29/21. was hospitalized on 2/8/21 for shortness of breath, generalized weakness, nausea. No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (MODERNA)) (1201)**

Patient was given vaccine the following day he died , No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (MODERNA)) (1201)**

Resident tested COVID-19 confirmed positive a few days after covid vaccination. No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (MODERNA)) (1201)**

Patient passed away on 2/2/21 after being admitted on 1/31/21 after receiving COVID19 Moderna Vaccine on 1/26/21. On initial report to the hospital patient reported having a cough for over 2 weeks (starting approx. 1/17/21). He had a postive COVID19 PCR on 1/31/21. Intubated on 1/31/21 and passed away on 2/2/21 No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient described feeling nervous, anxious the next morning (Wednesday) after the vaccine. He later fell in the bathroom after using the restroom, his legs gave out (his words) and consequently was on the ground for 23 hours before being transported to the hospital. That was Thursday afternoon. He was diagnosed with COVID-19 on Saturday night and died the following Friday morning.		No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported feeling weak, fatigue, fever (102), and loss of appetite. Patient subsequently went to the ER 2/6/2021 and tested positive for COVID-19 on 2/7/21 (collection date). See following discharge summary from ED: 82 y.o. female who initially presented to the ED with complaint of generalized weakness, fatigue, fever, and loss of appetite x at least 4 days since receiving Covid 19 vaccine. Her workup in the emergency room was significant for hypoxia with 02 saturation 88% on 2LPM (home nocturnal 02 requirement) with improvement to mid-90s on 4LPM. Blood sugar was 47, Cr 1.61. CXR showed extensive R lung and moderate left lung opacities. She was started on empiric ceftriaxone and azithromycin and admitted to the hospitalist service for further workup and mgmt. During her stay in the hospital, pt did test positive for Covid 19. She developed rapidly progressive respiratory failure, felt to be secondary to ARDS. There was also question of contributing pulmonary edema, however this was refractory to lasix and thus ARDS was felt to be the most significant factor. She had requested DNR/DNI status, thus as her 02 requirement escalated she was transitioned to 15LPM NRB and then to BiPAP support. Unfortunately, she continued to suffer greatly with the BiPAP in place, and therefore made the decision to transition herself to comfort measures only after visitation from her family. Her other medical issues were supported as appropriate during her stay, with dextrose infusion for hypoglycemia and AKI, also hyponatremia felt to be due to IVVF. Unfortunately, am unable to find any documentation regarding how pt was feeling when she received the vaccine compared to her baseline state of health. thus am unable to say whether the severity of her illness represents vaccine¡		No prior vaccinations for this event.

enhanced disease or the much more common cytokine release syndrome leading to ARDS. Regardless, she developed ARDS as result of her Covid 19 illness. Time of death: 1408 on 2/9/21. Cause of death: ARDS due to Covid 19 pneumonia.

	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was admitted to hospital on 2-9-21 for urinary tract infection and tested positive for Covid. Developed pneumonia and expired on 2-12-21.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient rcvd 1st covid 19 vaccine on 1/26/2021. Patient had house guests on 1/30/21. Those house guests tested positive for covid on 2/1/2021. Patient started getting symptoms on 02/2/2021. Patient tested postivie on 2/4/2021. Patient was hospitalized 2/7/2021. Patient passed away on 2/21/21.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Found lying face down without respiration or pulse, believed to be within 5 minutes of event. ACLS procedures unsuccessful. Unable to get autopsy. Believed to be heart attack secondary to COVID infection, but unconfirmed. Relative contribution of recent vaccination unknown.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt tested positive for COVID-19 on 2/10/2021 and died from illness related to COVID-19 on hospice		No prior vaccinations for this

at home on 2/18/2021, per care facility.		event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt tested positive for COVID-19 on 2/10/2021 and was hospitalized on 2/15/2021 and deceased on 2/18/2021 at the hospital of admission, per caregiver.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt tested positive for COVID-19 on 2/10/2021, and was deceased on 2/16/2021 at.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt tested positive for COVID-19 on 2/10/2021, and deceased on 2/12/2021, per caregiver at.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (MODERNA)) (1201)**
1-25-2021- Phone call: pt had cold and cough prior to vaccine. cough worsened 1-28-2021 Phone call: pt requesting provider visit, cough is same and taking tessalon pearls 1-29-2021 Provider in office visit: pt complain of cough and SOB for 6 days. Getting worse. Temp 101.2, pulse ox 87%, BP 128/70. level of distress- leaning forward to breath. appeared ill. diffuse rales throughout both lung fields, more at bases. Diagnosis Pneumonia due to COVID 19 virus. Sent to ER		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Vaccine 12/30/2020 Screening PCR done 12/31/2020 Symptoms 1/1/2021 COVID test result came back positive 1/2/2021 Deceased 1/4/2021	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient did not display any obvious signs or symptoms; the vaccination was administered at approximately 10:00 AM and the patient continued throughout her day without any complaints or signs of adverse reaction. Patient was helped to bed by the nursing assistant estimated at around 9:00 PM. The facility received notification from the lab around 11:00 PM that the patient's COVID-19 specimen collection from Sunday, 1/3/21, detected COVID-19. When the nursing staff went to the room to check on the resident and prepare her to move to a COVID-19 care area the patient was found unresponsive, no movement, no chest rises, noted regurgitated small amount of food to mouth left side, lying on left side. Pupils non reactive.	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
COVID-19; COVID-19; Pneumonia; respiratory failure; This is a spontaneous report from a contactable consumer. An 80-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 02Jan2021 for COVID-19 immunization. Medical history included Alzheimer's and others. No known allergies. Concomitant medications included unspecified medications. The reporter's mother in law was tested for COVID-19 at a nursing facility on 25Dec2020 and she was negative. On 02Jan2021, she received the first dose of Pfizer vaccine. On 04Jan2020, she developed a high fever, needed oxygen and was positive for COVID-19. Date of death was 04Jan2021. The cause of her death was listed as pneumonia, respiratory failure and COVID-19. No autopsy performed. No treatment received. No one knew if the vaccination contributed to her death. It was hard to know if her	No prior vaccinations for this event.

death was due to the administration of the vaccine or it exacerbated the COVID19 symptoms which led to her death. Since this was unknown, it could have been a possibility. The reporter wanted to give us this information because we might want to consider having high risk population, patients with underlying conditions, older population tested for COVID-19 prior to the vaccination, as this is not currently a recommendation or a requirement. All is very new and they are all learning so the reporter wanted to share this information with us. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There are medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. The outcome of the events was fatal. Information about Lot/Batch has been requested.; Sender's Comments: The association between the fatal event lack of effect (pneumonia, respiratory failure and COVID-19) with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19		
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
12/28/2020: generalized weakness and fell twice at home, cough, nausea,1/04/2021: cough, nausea, fever and chronic pain when she fell from being weak. admitted to hospital with Covid pneumonia, shortness of breath, covid postive, 1/09/2021: pt on bipap, 1/15/2021: pt was intubated, on TPN, pt DNR, 1/18/2021: was extubated and put on comfort measures and passed away		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19**

(PFIZER-BIONTECH))
(1200)

"died; tested positive for COVID; tested positive for COVID; This is a spontaneous report from a contactable consumer from a Pfizer-sponsored program, Pfizer First Connect. A 97-year-old male patient received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 30Dec2020 at 97-years-old at a single dose for COVID-19 immunization; administered by the nursing home. Medical history included glaucoma from an unknown date and unknown if ongoing. Concomitant medications included: ""used a sav for skin tears"", and ""eye drops for glaucoma"" from an unknown date to an unknown date. On 07Jan2021, the patient experienced: tested positive for COVID (medically significant). The patient died (death, medically significant) on 17Jan2021. The clinical course was reported as follows: The reporter stated that in regard to the patient's height and weight: ""was probably getting down to about five foot eight. Shrinking."" The reporter stated that If she remembered correctly, they were trying to maintain the patient's weight 135 to 136 pounds. The reporter stated that her father was in a nursing home. The patient received his first dose of the COVID vaccine on 30Dec2020. The patient died on 17Jan2021. The reporter stated that she ""wanted Pfizer to know that the little old people in the nursing might not be strong enough for the vaccine."" The reporter stated that she was ""not calling to complaining."" The reporter stated that there was nothing wrong with her dad. He was elderly with no health issues. ""He was literally on no medications. The only reason he was in the nursing home was because he was afraid to walk."" The reporter stated that she received a call about giving the patient the vaccine and she said yes because she wanted him to have the vaccine. One week after the vaccine, the patient tested positive for COVID ""like all the other people"" (no further details provided). The reporter stated that her dad had no symptoms of COVID. The director of nursing said the patient was doing so well. The patient ate his lunch, he laid down for nap, and at 14:30 he was gone. The patient ""went peacefully in his sleep."" The reporter then again stated that the patient literally had nothing wrong with him. ""They were shocked. They fed him and he took a nap. He was sleeping, but it was eternally."" The reporter stated that, ""it might not have been the Pfizer vaccine, maybe his heart wore out."" In regard to an autopsy: the reporter stated that they would get it done if needed. The patient underwent lab tests and procedures

No prior vaccinations for this event.

which included COVID-19 virus test: positive on 07Jan2021. History of all previous immunization with the Pfizer vaccine considered as suspect: none. It was unknown if there were additional vaccines administered on the same date of the Pfizer suspect, but the reporter doubted it. There were no prior vaccinations within 4 weeks. There were no adverse events following the prior vaccinations. The clinical outcome of the event, died, was fatal. The clinical outcome of the event, tested positive for COVID, was unknown. The patient died on 17Jan2021 due to an unknown cause of death. An autopsy was not performed. The batch/lot numbers for the vaccine, PFIZER-BIONTECH COVID-19 MRNA VACCINE, were not provided and will be requested during follow up.; Reported Cause(s) of Death: died"

SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Cardiac Arrest Narrative: No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient sent to hospital 1/2 and 1/5. Returned both times to nursing home covid unit without a hospital admission. Resident had been diagnosed with COVID later in the day on 12/30, when routine testing PCR results returned to facility, after resident had already had her first covid vaccination on 12/30/20 in the morning. Resident continued decline, was again sent to hospital on 1/24/21, and expired in hospital 1/25/21.

No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient arrived at ER with complaints of CPR in progress. Per EMS, patient became short of breath while performing yard work on 1/26/2021. At arrival, patient was in fine v fib with a total of 6 shocks delivered along with 300 mg amiodarone followed by 150 mg amiodarone, 1 amp epinephrine and 2 epinephrine drips adminstered en route to ED. CPR initiated at 1755 and EMS reports asystole at 1829. TOD 1909 pronounced by ED DO Dx: Cardiac arrest

No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident tested positive for COVID on 1/7/2021. No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

All residents had been in isolation due to multiple cases of COVID in the facility. Resident voiced no health

No prior vaccinations for

related complaints. He continued to visit with staff and required moderate assist with toileting. Resident had fall 0130 on 1-15-2021, which resulted in laceration with surgical repair. Resident was noted to change in mental status and respirations on morning of 1-16-2021 during morning blood sugar check. Resident had O2 @1.5l/m via n/c and respirations of 10 with periods of apnea and unresponsive to verbal stimuli. Blood sugar was 583. Resident deceased upon re-check after calling PCP to report status change.		this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client received the COVID-19 vaccine on 1/5/21 by the Vaccine clinic. Plans were for Hospice services. Client tested positive for COVID-19 by rapid testing on 1/8/21. On 1/10/21 at 0900 Client was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic. Client tested positive for COVID-19 by rapid testing on 1/21/21, with c/o hurting all over and loose stools. She became non-verbal on 1/23/21 with poor intake. On 1/24/21 at 0537 Client was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient has been under Hospice services for almost a year. She began to demonstrate a large amount of oral secretions on 1/10/21 at 2130. She was suctioned and a Rapid COVID-19 test was performed, which		No prior vaccinations for

was negative. The COVID-19 Rapid test was repeated on 1/11/21 and was positive. Oxygen saturation was noted to be 78% on 1/12/21, and oxygen was initiated at 1133 at 3L per nasal cannula. Oxygen was increased to 4L at 1635 d/t shortness of breath. On 1/15/21 @ 0645 patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.

this event.

SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client tested positive for COVID-19 by rapid test on 1/8/21. On 1/9/21 at 1405 his oxygen saturation dropped to 86% and oxygen was initiated at 2L per nasal cannula. A non-productive cough was noted on 1/10/21 and oxygen was increased to 3L. On 1/12/21 Client became non-responsive with 30 second periods of apnea. Dexamethasone was initiated on 1/13/21. Lung sounds were noted with crackles on 1/15/21 at 1158 and at 2120 Client was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient tested positive for COVID-19 by rapid test on 1/6/21. She began to demonstrate a dry cough on 1/11/21. On 1/12/21 at 1723 her oxygen saturation dropped to 79% and oxygen was applied at 4L per nasal cannula. On 1/19/21 at 2130 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic #1. Patient tested positive for COVID-19 by rapid testing on 1/6/21. She demonstrated poor appetite and fluid/food intake and an IV of Normal Saline was initiated on 1/7/21. Oxygen saturation was initiated on 1/12/21 at 4L per nasal cannula. for shortness of breath. On 1/22/21 at 0310 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began to demonstrate a cough the evening of 1/5/2021, after receiving the COVID-19 vaccine earlier in the afternoon. A rapid COVID-19 test was performed and was positive. She began to demonstrate shortness of breath with exertion on 1/7/21, and lethargy on 1/12/21. Appetite and oral intake began to decline on 1/12/21, and Oxygen saturation dropped on 1/16/21 to 82%, and oxygen was initiated at 3L per nasal cannula. On 1/19/21 at 0414 patient was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
TESTED POSITIVE FOR COVID-19 1-7-2021, TRANFERRED TO HOSPITAL ON 1-18-2021. HE READMITTED TO THE FACILITY ON 1-21-2021 WITH HOSPICE SERVICES AND EXPIRED ON 1-25-2021.	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

COVID-19 + 1/11/2021, EXPIRED ON 1-24-2021 No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient tested Covid positive, cough, low oxygen levels, COVID Pneumonia, patient is now deceased

No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident was vaccinated on 12/31/20. Then on 1/14/21 he tested positive for SARS-CoV-2 on routine surveillance PCR testing. Another resident on the same hall was COVID positive on 1/11/21. Results of the PCR test were obtained on 1/16/21. He appeared asymptomatic at that time. Given his COVID positive status, all aerosol generating procedures had to be stopped. Overnight on 1/16/21 into 1/17/21, he had the onset of acute respiratory failure and was transported to the hospital. Per notes, he was put on BiPAP for several hours, but his CO2 level did not improve. Per prior advance directives completed with the resident and his two brothers, he had DNR/DNI orders. The hospital physician spoke with his brother and the decision was made to move to comfort care. He was discharged to inpatient hospice and died around 4pm on 1/18/21. This outcome does not appear to be vaccine-related, but death from COVID-19 infection is listed as a reportable event following COVID-19 vaccination.

No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received first dose of the COVID-19 Moderna vaccine on 1/19/2021 at an outside facility (no lot #, route, or site available to me in electronic charting). Pt began having hypoxia, SOB, and a dusky appearance of extremities on 1/29/2021 and was brought by EMS to our hospital. PT is a DNR and family had been looking into a hospice sign up due to dementia and general decline in the weeks prior to

No prior vaccinations for this event.

hospitalization. Pt tested positive on admission for COVID-19 via PCR test on 1/29/2021. Pt continued to have respiratory decline, was put on comfort care per wishes of family/advanced directives, and he passed away the evening of 1/30.

SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Tested positive for COVID19 on 12-30-2020, Admitted to Hospital on 1/5/2021 with active COVID, Patient died 1/29/2021.	No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1st COVID immunization 1/7/2021, COIVD positive results on 1/16/21, 1/24/21 O2 sats decreased to 78%, 1/24/21 reveived the Bamlanivimab infusion 50 ml/hr. 1/24/20 chest x ray 1/24/21 She was sent to hospital and admitted. 1/27/2021 Expired	No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
she was injected, sh stopped eating and talking, the doctor watched her for 2 days. had her transported to the hospital. i was told she had tested positive for COVID 2 times once at the home and once at the hospital. with in 2 DAYS at the hospital she wa on a ventilator 2 days later she died. i talked with the rehab center and confirmed she tested negative for COVID on Dec 27th 2020 and was given the Vaccine on the 29th Dec 202 was in the hospital 4 day later, was on a ventilator 4 days after that then died a few day later as her heart stopped beating. all the while i had POA and was not contacted by Hospital staff until after	No prior vaccinations for this event.

they had made the next step.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Vaccine-1/7 Covid positive-1/10 Hospitalized-1/17 Deceased-1/25 No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Pt received vaccine on 7 jan. 2021 Twelve days later, on 19 January 2021, Pt developed symptoms of COVID (cough, sore throat, fever, myalgias), on 20 Jan, pt admitted to hospital for worsening symptoms. Pt tested positive for COVID 19. Pt admitted to ICU where pt had complicated hospital course to include ARDS secondary to COVID pneumonia, nonSTEMI, with biventricular heart failure, on multiple pressor, rhabdomyolysis with acute kidney injury, requiring CRRT. Pt was in hospital for 10 days; he passed away on 31 Jan 2021. No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident vaccinated-1/7/21 Resident covid positive 1/11/21 Resident covid PNA-1/12/21 Resident hospitalized 1/16/21 Resident deceased 1/20/21 No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient tested positive for COVID-19 on 1/8/21. She demonstrated a decline in appetite and the ability to feed herself d/t this illness, but no respiratory or other symptoms. She received COVID-19 vaccine #2 on No prior vaccinations for

1/26/21. She demonstrated an SDTI wound to the Lt. heel on 1/27/21. On 1/31/21 she was noted to have a significant weight loss. She was admitted to services on 2/1/21 with comfort care orders. On 2/2/21 she was observed to be without vital signs. Orders were for DNR, and CPR was not initiated in accordance with that order. She was pronounced dead at 0112 on 2/1/21.	this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19**

	(PFIZER-BIONTECH)) (1200)
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.	
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Ongoing decline overall. Remained on Hospice with increased lethargy documented on 1/20/21 and progressively worsening thereafter.	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident on Hospice. 1/18 Hand Shaky. 1/19- Covid +19. 1/20 Desat 85% on RA, provided 2L O2 supplement= 97% 1/20 congestive cough, 1/28- RR-28;1/29- Hypoglycemia 1/30-NPO. 1/30-resident passed away.	No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Xrays showed covid Poss pockets all in her lungs on 15Jan; Xrays showed covid Poss pockets all in her lungs on 15Jan; This is a spontaneous report from a contactable consumer. An 85-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for covid-19 immunisation. Medical history included dementia. Concomitant medications were not reported. Patient popped hot 02Jan2021 along with 4 others on the hall she lived. Within 9 days 50+ patients were positive. All had the vaccine the same day. Patient was test positive on 02Jan2021. She was on day 12 of her quarantine when she started to get worse. She was unresponsive by 16Jan2021 and passed 18Jan2021. We were with her from 14Jan2021 to 18Jan2021. But had not been allowed to visit with her since Mar2020. And what post treatment pairs well with it? Publicly we hear Remdesivir and Bamlanivimab but these patients only received a general antibiotic and some vitamins. Death cause was Xrays showed covid Poss pockets all in her lungs on 15Jan2021. No autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information; Reported Cause(s) of Death: Xrays showed covid Poss pockets all in her lungs on 15Jan	No prior vaccinations for this event.

	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client was administered the vaccine while symptomatic (01/25/21) although client did not know he was symptomatic for COVID-19. He had been exposed to a family member who had tested positive and should have been in quarantine but wasn't either because it was not felt he was considered a close contact by his family opinion or his family member never notified public health of this close contact...?. Clinet had presented to the ED following day after vaccination for shortness of breath and fatigue and an antigen test showed he was positive for COVID-19. He was sent home that same day 01/26/21. He was back in ED on 01/28/21 for worsening symptoms and admitted to hospital and later placed on ventilator. He passed away on 02/09/2021 (date of death was per his wife).		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/15: Pfizer vaccine dose 1 administered 1/16: Fever, chills 1/22: Sore throat, coughing w/white phlegm, taking Tylenol and Mucinex. Fever and chills from 1/16 subsided. Had telehealth consultation with PA. Per her notes, patient said he gets these symptoms annually, requested for an antibiotic. PA referred him for a COVID test. Ordered hydrocodone/chlorphen ER suspension for his cough and an antibiotic. Antibiotic was recommended if symptoms do not subside. 1/23: COVID test administered 1/25: Reported positive for COVID 1/26: Telehealth session w/PA: she informed patient of his positive test, advised to quarantine and seek medical help at hospital if symptoms worsen. Patient reported that his sore throat mostly subsided but is still coughing at night. Said that the pharmacy didn't receive the prescription order for the antibiotic, so this was re-ordered. 1/31: Partner found him dead at 8:18AM on his bed. Death certificate issued by state says cause of death: COVID. Autopsy was not performed. Buried on 2/9/21.		No prior vaccinations for this event.

SARS-COV-2 TEST POSITIVE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
7 days after receiving the vaccine, patient suffered excessive diarrhea and slight coughing. 9 days after vaccine, patient was tested for Covid 19, and received positive results. Patient was transported to hospital via ambulance but hospital returned her to the nursing home since chest was clear, no respiratory issues, and no fever. 10 days after receiving the vaccine, patient was turned over to hospice care but still in the nursing home. Hospice was called in to provide better physician advice and access 24/7. 14 days after receiving vaccine, patient began experiencing excruciating body aches, coughing, low oxygen levels, and no appetite. 18 days after vaccine, patient died.	No prior vaccinations for this event.	

SARS-COV-2 TEST POSITIVE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death 2/12/21	No prior vaccinations for this event.	

SARS-COV-2 TEST POSITIVE COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

COVID 19 symptoms and a positive test was confirmed on 1/6, employee noted previous exposure to positive family members Narrative: Employee noted exposure to COVID prior to presenting for 1st dose of vaccine on 1/5/21. On 1/6/21 employee reported the onset of symptoms and was tested and was confirmed COVID positive that day. Positive result was reported to employee health on 1/8/21. Employee Health continued to track employees progress and was informed of the need for hospitalization on 1/14/21. Course of hospitalization noted the need for intubation and significant issue with comorbid condition (rheumatoid arthritis). Employee died on 2/9/2021. Unable to confirm a direct connection to Vaccine vs. COVID infection, but felt it should be reported.	No prior vaccinations for this event.

	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Unresponsive, Increase BP and H. Hospital Dx Renal Failure No prior vaccinations for this event.		
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer 1/22/2021. RNA+ 2/4/2021. S/S SOB, cough, confusion. COVID assoc. resp. failure, stage 4 lung cancer, COPD, HTN, former smoker. patient in hospice and died 2/10/2021.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of vaccine on 1/7/21 at a community Public Health clinic. On 1/29/21 he received a second dose at the community Public Health clinic. On 2/5/21, the patient presented to the ED with complaints of shortness of breath worsening over the last 2 weeks. Patient reported that he had decreased exercise capacity and increased coughing with sputum production intermittently. Patient reported that he had been feeling chilled, but no fevers. Patient was admitted and treated with Decadron and Remdesivir. Patient experienced increased oxygen requirement. Patient was a DNI and did not want to be on life support. After discussion with the patient and family, patient was moved to comfort care. passed away on 2/11/21.		No prior vaccinations for this event.
	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home.		No prior vaccinations for

Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.	this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
THE RESIDENT WAS ROUTINELY TESTED FOR COVID ON 1/29/21 AND POSITIVE RESULTS RETURNED ON 1/30/21; WAS ASYMPTOMATIC AT FIRST, BUT DEVELOPED SYMPTOMS ON 1/31/21 THAT PROGRESSED AND THE RESIDENT DIED ON 2/7/21	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending.	No prior vaccinations for this event.

Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

SARS-COV-2 TEST POSITIVE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on

No prior vaccinations for this event.

2/19/21.

	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death 2/25/21	No prior vaccinations for this event.	

SARS-COV-2 TEST POSITIVE COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/14/21 - Resident complained of SOB. SPO2 66% on RA, vs 105/66-96-20 T98.2 O2 administered Pox 97% Binax test revealed (+) COVID results. Resident transferred to COVID wing. Family (HCP) updated and declined transfer to hospital Resident continued with fever, hypoxia and lethargy. Family elected CMO and Hospice notified. Resident died on 1/16/2021 @ 930AM.	No prior vaccinations for this event.

	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
contracted covid after first dose Narrative: First covid vaccine dose 12/31/2020, tested positive for covid 1/7/2021, died from complications 1/25/2021	No prior vaccinations for this event.	

	SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Caller is nephew of patient. Patient was admitted to Hospital on 2/15/21 with Covid like symptoms and decreased O2 sat. He tested positive for Covid 2/15/21. Treated with Remdesivir. Patient status continued to decline and he passed away in hospital 2/22/21 0612.	No prior vaccinations for this event.	

SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/13/21 Patient had covid like symptoms 2/15/21 Patient admitted to Hospital with covid like sx and decreased O2 sat; tested positive for Covid on 2/15/21; treated with Remdesivir and convalesent Plasma. Sx worsened and patient died 2/26/21..	No prior vaccinations for this event.
SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric	No prior vaccinations for this event.

treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his

stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

SARS-COV-2 TEST POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The same day that the person was vaccinated he started feeling dizzy and had difficulty breathing. He was hospitalized from February 5 to February 23. Patient died in the hospital on February 23, 2021	No prior vaccinations for this event.
SCAN WITH CONTRAST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12	No prior vaccinations for this event.

admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

SCAN WITH CONTRAST ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family,

No prior vaccinations for this event.

code blue not called. Patient expired at 01:53 on 1/19/21.

SCRATCH

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient (now deceased) received 1st dose of Pfizer-BioNTech vaccine around December 21, 2020 and was noticed to be scratching, fatigued, and unresponsive by a family member on December 24, 2020. He received the second dose of the same vaccine around January 22, 2021. Pockmarks and bleeding scratch marks were noted by a family member on the patient's face prior to this second dose. On January 28, 2021 a family member was alerted that the patient was suffering from severe bullous pemphigoid- a skin condition that has never been experienced by the patient, has been reported to be related to COVID-19 viral infection, and to T-cell responses promoted by vaccines. A corticosteroid was given, but did not work. Blisters developed to the point hands had to be dressed.

No prior vaccinations for this event.

SCREAMING

COVID19 (COVID19 (MODERNA)) (1201)

Patient obtained initial dose of Moderna vaccine on Thurday, Jan 14. No adverse effects reported during initial 15 minute post vaccine waiting period. Saturday morning (Jan 16), patient developed severe cough, labored breathing, and fever. Additionally patient mental status changed suddenly, became non-communicative (unable to speak, but would scream if she was touched). O2 status was irregular, dropping to 78. Sunday morning, EMT and then hospice was hospice called. Monday morning, after hospice emergency kit was initiated, patient passed away.

No prior vaccinations for this event.

SCREAMING

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received the vaccine at an outside healthcare facility on 2/11/21. At approximately 1 pm she screamed out and fell out of her chair. EMS was called and patient was found to be in Vfib. ACLS was performed for approximately 42 minutes prior to arrival at ED. At that time the patient had been pulseless for 25 minutes. Patient received 450 mg of amiodarone, epinephrine x7, sodium bicarbonate x2, and 7 AED shocks. In the ED 3 more doses of epinephrine were given, one more dose of sodium bicarbonate, and 5 additional shocks. ROSC was not achieved and time of death was called at 1416.	No prior vaccinations for this event.
SECRETION DISCHARGE	**COVID19 (COVID19 (MODERNA)) (1201)**
hypoxia, secretions,cough, dyspnea Narrative: ALS patient on hospice with ongoing history of aspiration pna, receiving tube feeds. Developed incr in secretions, hypoxeia, temp and with recently noted clogged feeding tube.	No prior vaccinations for this event.
SECRETION DISCHARGE	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident expired on 2/5/21 at 03:35pm, about 25 hours after second dose of vaccine. At breakfast, resident was spitting a lot of secretions, coughing up liquids from nose and phlegm, facial swelling, which were all symptoms that he was struggling with prior to both doses of COVID vaccine, but had increased more than prior incidences on 2/5/21. Gurgling noted in upper airways, hyscolamine given, bath given to loosen secretions, morphine given. Family notified and came into facility for compassionate care visit around 1300. 1400 HR was 3 and RR was 2, but increased back to 60 and 12 within 20 minutes. Then resident expired at 1535.	No prior vaccinations for this event.
SECRETION DISCHARGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

(02/15/2021): vaccine (02/16/2021) : severe body aches and weakness, increased congestion and mucous production. (02/16-17/2021) : death possibly during the night	No prior vaccinations for this event.
SEDATION	**COVID19 (COVID19 (MODERNA)) (1201)**
"My grandpa had a stroke on the 15th of February. He claimed he had been feeling ""off"" for a few days, but didn't say anything. A blood clot had formed in his brain. He was doing better and about to go to rehab to strength his right side of his body. On the 22nd he took a turn for the worst. He was having trouble breathing and they sedated and partially paralyzed him to put a tube in his mouth. I believe another blood clot had formed and oxygen wasn't properly going through his body. They could not stabilize him, and he passed away the same day."	No prior vaccinations for this event.
SEIZURE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient suffered a cardiac arrest and was unable to give details about her symptoms. Per husband, patient did not complain of any symptoms after vaccine administration. She began seizing without warning which was complicated by cardiac arrest of uncertain etiology	No prior vaccinations for this event.
SEIZURE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient has a history of advanced melanoma with brain metastasis. He developed seizure disorder as well and had some mild seizures at home over the prior month. He received the vaccine at 4pm and was monitored in the office for 15 minutes. He then went home with his daughter whom he lives with. He ate dinner with her and read until 8pm when he went to his room. She found him in his room at 9pm unresponsive with seizures. Hospice was alerted and recommend oral valium. He continued to be unresponsive and	No prior vaccinations for this event.

expired the following day at 7:30 pm.

SEIZURE **COVID19 (COVID19 (MODERNA)) (1201)**

My Mother was given the Covid Vaccine (1st Dose) on 12/28/2020. Later that night we received a call from the nursing facility that my Mother was having uncontrollable seizures and had to be transported to the nearby hospital. The ER doctor confirmed that my Mother had tested positive to Covid. She was treated for Covid and was on life support. A few days later we received a call that my Mother had a major stroke. She passed away on January 4, 2021

No prior vaccinations for this event.

SEIZURE **COVID19 (COVID19 (MODERNA)) (1201)**

Patient received vaccine at Public Health Clinic. Patient ended up having a seizure 3 days later and ended up in the hospital. Found to have right lobe pneumonia and low depakote level. Patient noted to have multiple seizures at hospital, issues with stabilizing HR and BP, and passed away on 1/20/21.

No prior vaccinations for this event.

SEIZURE **COVID19 (COVID19 (MODERNA)) (1201)**

Developed vomiting, seizure and cardiac arrest, V Fib No prior vaccinations for this event.

SEIZURE **COVID19 (COVID19 (MODERNA)) (1201)**

Pt received second Moderna COVID-19 vaccination administered in left arm at her assisted living facility by Pharmacist at 1153 on 2/19/2021. Pt was monitored for vaccine reaction with no known adverse reaction. Approximately 18 hours post-vaccine, she was found deceased in her sleep at 0540 on 2/20/21. Per circumstances/pt history, it is presumed that the patient aspirated while sleeping, perhaps secondary to a

No prior vaccinations for this event.

seizure. Coroner was notified and declined as coroner's case. VAERS notification being made due to pt death within 24 hours of receiving a vaccine.

	SEIZURE	**COVID19 (COVID19 (MODERNA)) (1201)**
2/12/2021 woke up with sore arm and back. 2/13/2021 woke up with headache around 1am. Headache and nausea all morning. Mid-late afternoon started having seizures. Admitted to Hospital 2/15/2021 expired. Reported per wife on 2/25/2021.		No prior vaccinations for this event.
	SEIZURE	**COVID19 (COVID19 (MODERNA)) (1201)**
"""Feeling Hot"" without fever and nausea 10 hours post vaccine and resolved within 1 hour. Seizure, Hypotension, Unresponsive followed shortly by cardiac arrest and pulseless electrical activity 21 hours post vaccine. Pronounced dead 22 hours post vaccine"		No prior vaccinations for this event.
	SEIZURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
brought by EMS to ED; seizures at home in bed; 6 Epi and 1 bicarb; no hx of seizure		No prior vaccinations for this event.
	SEIZURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 10 minutes after receiving the COVID- 19 vaccine resident displayed seizure activity, staring straight ahead and strong allover muscle jerking of both the up and lower extremities, color became gray,		No prior vaccinations for

activity lasted approximately 3 minutes, resident then became relaxed, color returned to normal, BP-140/80, 97.8, 60, 16, sleeping the remainder of the shift,. Resident continued to decline until resident CTB on 1/19/21		this event.
	SEIZURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began with vomiting and diarrhea. C/O chest pain. Bradycardia. Hypotension. 2 seizures in 45 minutes after not having one in years. We gave fluids. Gave Zofran. Comfort measures. Pt passed at midnight. Was completely fine one day before. Had minimal issues with COVID though did have a pneumonia that was treated w ATB early on and resolved.		No prior vaccinations for this event.
	SEIZURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP		No prior vaccinations for this event.

improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th

time at 08:18. Family at beside, Mother asks for code to be stopped."

SEIZURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pfizer-BioNTech COVID- 19 Vaccine EUA: Wife of patient called Primary Care Physician to inform that patient had received dose #2 of Pfizer COVID vaccine, and later that evening experienced a seizure and expired.	No prior vaccinations for this event.
SEIZURE LIKE PHENOMENA	**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.	No prior vaccinations for this event.
SEIZURE LIKE PHENOMENA	**COVID19 (COVID19 (MODERNA)) (1201)**
Short version The patient has long-standing health issues. The patient received the first dose of Moderna COVID-19 vaccine on 1/16/2021 (unknown location). The patient suffered an event in his home on 1/24/2021. CPR and treatment was begun and he was transported to the ED. He was pronounced dead in the ED at 0846. Long version 70-year-old male with past medical history of CAD with pacemaker, A. fib,	No prior vaccinations for this event.

COPD, hypertension/hyperlipidemia presenting in cardiac arrest. 911 call at 0724. Per EMS, patient was witnessed by family to have seizure-like activity and then collapsed and became unresponsive. Patient was noted by family to be pulseless and CPR was started right away. Patient received two doses of epi by police were on scene first (AED defibrillation x2) and six doses of epi (plus 6 more AED shocks) by EMS when they arrived. Patient had CPR performed for 45 minutes prior to arriving at the hospital. On route, patient had episodes of paced rhythm and V. fib. Patient received one amp of bicarb and one amp of calcium en route. Patient also received 300 mg of amiodarone en route. Arrived in ED at 0810 Patient received ongoing compressions, shocks and additional medications (epinephrine x6, lidocaine IV, sodium bicarbonate) until time of death called at 0846 in the ED.

SEIZURE LIKE PHENOMENA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37,	No prior vaccinations for this event.

she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

SEIZURE LIKE PHENOMENA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.	No prior vaccinations for this event.

SENSATION OF FOREIGN BODY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19	No prior vaccinations for this event.

VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat

raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the

expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death

	SEPSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.		No prior vaccinations for this event.
	SEPSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident c/o nausea evening of 1/29 (nausea common for her post dialysis), had a large emesis at approx 2220, 0030 (unusual for resident to vomit)- received Zofran per order. Skin cool and damp, Blood sugar 147 (checked due to h/o diabetes and poor intake). At approx 230am Blood pressured checked and noted to be 52/29. Resident transferred to ER, intubated and transferred to higher level of care where she passed away on 1/30 at 736pm. Resident's medical notes indicated likely shock, cardiogenic in nature, sepsis (source unknown) along with a multitude of other co-morbidities that resident has.		No prior vaccinations for this event.
	SEPSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
sepsis; respiratory failure; Fever; Unresponsive; A spontaneous report was received from Pfizer concerning a 56-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced respiratory failure, sepsis, fever and sudden death. The patient's medical history was not provided. No		No prior vaccinations for this event.

relevant concomitant medications were reported. On 04 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient began to have a fever. She was sent to the emergency room for evaluation. That evening, she died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 11 Jan 2021. The cause of death was reported as respiratory failure and sepsis. Plans for an autopsy were unknown/not provided.; Reporter's Comments: This is a case of 56-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sepsis, fever, respiratory failure and sudden death. Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Respirtory Failure; Sepsis

	SEPSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.		No prior vaccinations for this event.
	SEPSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21		No prior vaccinations for this event.

	SEPSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."		No prior vaccinations for this event.
	SEPSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received her first covid vaccine on 1/27/21. on 1/30/21 she presented to the emergency department complaining of nausea, she had a negative work up, felt better and was sent home. on 2/5/21 she returned to the emergency department more ill-appearing and complaining of ""feeling sick"". she had fatigue, chills, decrease in activity level. her work up at this visit revealed multiple metabolic abnormalities, sepsis and bacteremia. She ultimately passed away at this visit with at cause of death listed as acute liver failure, pneumonia, and DIC>"		No prior vaccinations for this event.
	SEPSIS	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Fall; fatigued; arm pain; AML; Sepsis secondary to AML; This is a spontaneous report from a contactable consumer. An 88-year-old female patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot# EL3249), via an unspecified route of administration on 19Jan2021 17:30 in right arm at single dose for covid-19 immunization. Medical history included hypertension, hyperlipidemia, OA (osteoarthritis), cognitive impairment. No other vaccine in four weeks was administrated. Concomitant medication in two weeks included atorvastatin, aspirin, calcium, gabapentin, losartan and memantine hydrochloride (NAMENDA). The patient previously took lisinopril and tetracycline and both experienced allergies. The patient had no covid prior vaccination. The patient initially had no symptoms but arm pain in Jan2021, no bleeding or bruising from injection. On 31Jan2021 19:00, patient felt fatigued. Patient suffered fall on 01Feb2021. She was admitted to hospital. All cell lines were down in Feb2021. She was diagnosed with AML (acute myeloid leukemia) in 2021. She expired 07Feb2021. Events resulted in emergency room/department or urgent care, hospitalization, life threatening illness (immediate risk of death from the event) and patient died. The patient received the treatment of blood and platelet transfusions, bone marrow biopsy, cytogenetic testing, antibiotics, intubation for events. The patient died on 07Feb2021 due to sepsis secondary to AML. An autopsy was not performed. Outcome of events were fatal.; Reported Cause(s) of Death: arm pain; fatigued; fall; Sepsis secondary to AML; Sepsis secondary to AML

No prior vaccinations for this event.

SEPSIS

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Death Narrative: Patient received first dose of COVID vaccine on 1/30/21. Reported by his wife to agency that he passed away at an outside hospital on 2/14/21. By report of his wife: ""due to sepsis (related to bed sores) and aspiration pneumonia"""

No prior vaccinations for this event.

SEPSIS

COVID19 (COVID19

	(PFIZER-BIONTECH)) (1200)
PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO WITHDRAWL EXTRME MEASURES	No prior vaccinations for this event.
SEPSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
SEPSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident expired on 2/24/21, under hospice care. No prior vaccinations for this event.	
SEPSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began having SOB and cough on 2/18/21, the day after his first vaccine. Had a routine physician appointment for diabetes on 2/15/21 with no documentation of these complaints. Presented to the hospital on 2/23, soon after required intubation. Admitted with severe pneumonia, diffuse colitis, and sepsis. Condition continued to worsen until patient passed away on 2/24/21 @ 1632.	No prior vaccinations for this event.

SEPSIS	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with	No prior vaccinations for this event.

cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

	SEPSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
DEATH Narrative: Presented to ED via EMS c/o increasing shortness of breath, O2 sat mid to high 80s on 4L. When EMS arrived , pt was in distress, intubated by EMS and transported to ED. Pt had a PEA arrest en route but resuscitated w/ return of spontaneous circulation after receiving a dose of epinephrine and chest compressions. Pt was hypotensive on arrival to ED. He was started on sepsis protocol , volume resuscitation and empiric antibiotics. Once stabilized, he was admitted to icu at hospital. Removed from respirator 2/22/21		No prior vaccinations for this event.
	SEPSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Day After - severe headache, 2 days after headache continues, itchy scalp, day 3 rash visible at hair line headache continues, more confusion than normal, day 4 on site nurses check rash and think it is dermatitis, day 5 continues to get work nurse practitioner was to visit next day, day 6 NP thinks that she has UTI and sends her to hospital (2/11/21). Hospital determines - Rash is Shingles, UTI present, - MRSA is now present in shingles which is on right back of head and right neck and face. Next Sepsis is diagnosed. Since 2/11/21 patient was not conscious. 2/20/21 famiy is notified that she should be moved to Hospice. Moved to hospice on 2/20/21. The patient, my mother, died on 2/23/21 official cause of death is UTI.		No prior vaccinations for this event.
	SEPTIC SHOCK	**COVID19 (COVID19 (MODERNA)) (1201)**

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.	No prior vaccinations for this event.	
SEPTIC SHOCK		**COVID19 (COVID19 (MODERNA)) (1201)**
Death on 1/17/21. Death certificate reports: Septic Shock, UTI, Pneumonia, Chronic Renal Failure	No prior vaccinations for this event.	
SEPTIC SHOCK		**COVID19 (COVID19 (MODERNA)) (1201)**
1/31/2021 12:50 Nursing Note Note Text: Res had low BP, low O2 sats, 30 breaths per minute, eyes open wide, making confused utterances. Started supplemental oxygen via NC, 2L, then 3L. Sats went up to 93% for a while, Sprvsr called. Unable to auscultate Left lung sounds. Called to update Res daughter. Called to page NP, writer went back to assess Res and O2 sats were 88%, turned O2 to 4LPM, called 911 for transport to Hospital ED. Left around 1030. NP called back afterwards, was updated. Family updated that Res was sent to Hospital ED. Note Text: Received phone call from daughter as well as information from hospital. Resident has pneumonia with septic shock. She is on abx and had thoracentesis performed for large pleural effusion. [linked]	No prior vaccinations for this event.	
SEPTIC SHOCK		**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of	No prior vaccinations for this event.	

HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse

SEPTIC SHOCK	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Admitted to hospital after vaccination with Acute hypoxemic respiratory failure, Septic shock; Aneurysm of arteriovenous dialysis fistula; expired 1/16/2021	No prior vaccinations for this event.
SEPTIC SHOCK	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was an 87 y/o female admitted for septic shock. She was started on and eventually maxed on 3 pressors. CT abd showed colonic obstruction with dilatation of large and small bowel. Patient was made DNR in the ED. Palliative care consulted on case. Family opted for comfort care. Patient was asystole on monitor. No spontaneous breath/cardiac sounds ausculted. Patient did not withdraw to pain. Pupils fixed and dilated. She was pronounced and 1230 on 1/28/21	No prior vaccinations for this event.
SEPTIC SHOCK	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO WITHDRAWL EXTRME MEASURES	No prior vaccinations for this event.
SERRATIA INFECTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"	No prior vaccinations for this event.

SERUM FERRITIN INCREASED	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a	No prior vaccinations for this event.

possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced

pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

	SERUM FERRITIN INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.		No prior vaccinations for this event.
	SHIFT TO THE LEFT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from		No prior vaccinations for this event.

facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note:

""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory failure"""

	SHOCK	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mother died suddenly on February 3rd. She went into shock/cardiac arrest and appeared to have		No prior vaccinations for this

internal bleeding. No autopsy has been performed. Unsure if it was related to the COVID vaccine.	event.	
SHOCK	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Patient had an unwitnessed cardiac arrest while outside walking his dog. AED in the field initially advised shock and was shocked 3 times without effect. At the time EMS ALS arrived, patient was in PEA arrest. He was transferred to Hospital with CPR in progress. Time of death called at 1857.	No prior vaccinations for this event.	
SHOCK HAEMORRHAGIC	**COVID19 (COVID19 (MODERNA)) (1201)**	
jaundice->hemolytic anemia-> hemorrhagic shock->multi organ failure->death pt admitted to ICU 2/16 with Hgb=3.4, treated with steroids, supportive care , pressors, pt died 2/20/21	No prior vaccinations for this event.	
SINUS ARREST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family,	No prior vaccinations for this event.	

code blue not called. Patient expired at 01:53 on 1/19/21.

SINUS ARRHYTHMIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccinated 2/20. At that time, had symptoms of incarcerated hernia, went to ED for evaluation. Not felt to warrant hospital admission. Returned two days later with agitation, altered mental status, and incarceration. Went to OR, uncomplicated hernia repair. Postoperatively, did not recover mental status. Went into arrythmias POD 4, hypotension ensued, had multiple interventions and evaluations without satisfying answers for clinical course.	No prior vaccinations for this event.

SINUS BRADYCARDIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.	No prior vaccinations for this event.

SINUS TACHYCARDIA

COVID19 (COVID19 (MODERNA)) (1201)

Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29

No prior vaccinations for this event.

SINUS TACHYCARDIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was

No prior vaccinations for this event.

transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

SINUS TACHYCARDIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/9/2021 observed with elevated respirations of 38-42 per minute, BP manually 72/50. pulse is jumping rapidly between 110-16 bpm. oxygen sat 76% RA, resident refusing oxygen at first attempt, allowed oxygen to be placed, is now 84% on 4L. resident shaking head yes that he is hurting, and yes that he would take medication for pain. Dr. notified, branch block. Received order for morphine 2mg per hr as needed for elevated respirations and pain. Dr. also gave orders to D/C Tamsulosin and finasteride. Resident continue with decreased O2 sats and elevated respirations. Absence of vital signs on 1/10/21 at 826PM.	No prior vaccinations for this event.
SINUSITIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Lethargy/altered level of consciousness lead to hospital admission. Multiple interventions during hospitalization. Final hospital diagnoses: Acute respiratory failure with hypercapnia, acute pansinusitis.	No prior vaccinations for this event.
SKIN DISCOLOURATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No reactions immediately after vaccine was given. Resident has dementia, has had multiple hospitalizations related to a renal stone recently. Had a tooth that was bothering her, went to see her dentist and it was extracted on 1/6/21. On 1/10 they noted feet and ankles are dark purple with white splotches appears to be mottling. Minimally responsive to voice and touch. Not eating. Compassionate visit with family. Family did not want hospice, did not feel it was needed, said, what more could they do for her than you're already	No prior vaccinations for this event.

doing? On 1/11 at 1950 was determined to be deceased.

	SKIN DISCOLOURATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received first dose of the COVID-19 Moderna vaccine on 1/19/2021 at an outside facility (no lot #, route, or site available to me in electronic charting). Pt began having hypoxia, SOB, and a dusky appearance of extremities on 1/29/2021 and was brought by EMS to our hospital. PT is a DNR and family had been looking into a hospice sign up due to dementia and general decline in the weeks prior to hospitalization. Pt tested positive on admission for COVID-19 via PCR test on 1/29/2021. Pt continued to have respiratory decline, was put on comfort care per wishes of family/advanced directives, and he passed away the evening of 1/30.		No prior vaccinations for this event.

	SKIN DISCOLOURATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 10 minutes after receiving the COVID- 19 vaccine resident displayed seizure activity, staring straight ahead and strong allover muscle jerking of both the up and lower extremities, color became gray, activity lasted approximately 3 minutes, resident then became relaxed, color returned to normal, BP-140/80, 97.8, 60, 16, sleeping the remainder of the shift,. Resident continued to decline until resident CTB on 1/19/21		No prior vaccinations for this event.

	SKIN DISCOLOURATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and		No prior vaccinations for

2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.		this event.
	SKIN DISCOLOURATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at		No prior vaccinations for this event.

home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away

SKIN DISCOLOURATION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2	No prior vaccinations for this event.

high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good

recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

SKIN EXFOLIATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Presented from clinic with 3-4 days of extensive rash. There were multiple areas of skin sloughing on bilateral upper extremities and abdominal wall.	No prior vaccinations for this event.

SKIN LACERATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
All residents had been in isolation due to multiple cases of COVID in the facility. Resident voiced no health related complaints. He continued to visit with staff and required moderate assist with toileting. Resident had fall 0130 on 1-15-2021, which resulted in laceration with surgical repair. Resident was noted to change in mental status and respirations on morning of 1-16-2021 during morning blood sugar check. Resident had O2 @1.5l/m via n/c and respirations of 10 with periods of apnea and unresponsive to verbal stimuli. Blood sugar was 583. Resident deceased upon re-check after calling PCP to report status change.	No prior vaccinations for this event.

SKIN LACERATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the	No prior vaccinations for this event.

cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."

SKIN ULCER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.	No prior vaccinations for this event.
SKIN WARM	**COVID19 (COVID19**

	(MODERNA)) (1201)
Redness and warmth with edema to right side of neck and under chin. Resident was on Hospice services and expired on 1.1.21	No prior vaccinations for this event.
SKIN WARM	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was noted to have increase weakness on 1/15/2021. Resident was warm to touch with low grade fever of 99.3 F. Resident was up propelling self in w/c on 1/16/2021 he was pleasant, accepted medications and ate lunch. He was found slumped over in his w/c not responding and vital signs absent.	No prior vaccinations for this event.
SKIN WARM	**COVID19 (COVID19 (MODERNA)) (1201)**
death of unknown cause; Swelling on Right side of the neck and under chin; Warmth on right side of neck and under chin; Redness on right side of neck and under chin; A spontaneous report was received from a healthcare professional concerning an 89-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events of redness, warmth and swelling on right side of neck and under chin, and death of unknown cause. The patient's medical history included Alzheimer's and chronic obstructive pulmonary disease (COPD). No concomitant medications were reported. On 29 Dec 2020, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: Unknown) intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient experienced the events of redness, warmth and swelling on right side of neck and under chin. There was no indication that the patient was transferred out to hospital, which was unlikely because she was under hospice care. On 01 Jan 2021, the patient died due to an unknown cause of death. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2020. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns a 89-year-old, female subject with a medical history of Alzheimer's and chronic obstructive pulmonary disease	No prior vaccinations for this event.

(COPD) who experienced redness, warmth and swelling on R side of neck and under chin and expired from an unknown cause. The events of redness, warmth and swelling on R side of neck and under chin occurred 2 days after administration of the first and only dose of the mRNA-1273 vaccine and patient expired 4 days after mRNA-1273 vaccine administration. Lot # of the vaccine was not provided. De-challenge and re-challenge are not applicable. The events of redness, warmth and swelling on R side of neck and under chin are temporarily associated with the administration of the mRNA-1273 and thus, a causal relationship cannot be excluded. Due to limited information, the fatal outcome was considered unrelated to mRNA-1273 administration pending additional information. Fatal outcome is confounded by the patient's underlying condition and advanced age.; Reported Cause(s) of Death: Unknown cause of death

SKIN WARM	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
view 2/5/2021 09:23 e Progress Note Note Text: Patient passed away in the facility this morning. view 2/5/2021 08:39 Orders - Administration Note Note Text: Resident passed. view 2/5/2021 08:33 Nurses Note Note Text: Body released to funeral home at this time. Personal effects sent with resident include: 1 pair of glasses, 1 yellow wedding band, 1silver spoon ring, 1 ring with black and clear stones. Resident has own teeth view 2/5/2021 08:32 Nurses Note Note Text: cause of death per CRNP failure to thrive. view 2/5/2021 07:44 Orders - Administration Note Note Text: Take and document temp & PO2 every 4 hours for MONITORING Resident passed. view 2/5/2021 06:49 Nurses Note Note Text: Son returned call and was updated of resident's passing this am view 2/5/2021 06:33 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Unknown Resident expired @ 0604 [linked] view 2/5/2021 06:06 Nurses Note Note Text: Res found without pulse or respirations. Pronounced at 0604. Updated. N/o's for RN to pronounce, release body to funeral home, dispose of medications per facility policy. Daughter updated. Funeral Home called to release body. view 2/5/2021 05:26 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Pulse	No prior vaccinations for this event.

ox 60% on O2 @ 5L/min via mask. Resps 44 per minute. view 2/5/2021 01:57 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/5/2021 00:52 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Residents resps are 40 per minute, pulse ox 76% on O2 @ 5L/min via mask. Resps are labored, shallow and rapid. view 2/5/2021 00:48 Nurses Note Note Text: Nonresponsive to verbal and tactile stimulation. Appears comfortable. view 2/4/2021 22:01 Nurses Note Note Text: Resident resting comfortably, breathing becoming increasingly shallow, wearing O2 via mask at 5L via mask, no dyspnea noted, feet are mottled, oral and peri care provided Q2H. No s/s of pain or discomfort. view 2/4/2021 21:40 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective [linked] view 2/4/2021 19:32 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger medicated for air hunger, RR 28 to 32/ min view 2/4/2021 19:22 Nurses Note Note Text: Daughter updated on N/O to increase Morphine Sulfate 20mg/mL 0.25mL to Q2H prn from Q6H prn. view 2/4/2021 18:06 Nurses Note Note Text: POA Daughter and daughter aware of residents current condition. view 2/4/2021 11:58 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/4/2021 11:13 Nurses Note Note Text: Pt. noted to be lethargic at this time. Does respond to verbal and tactile stimuli by opening her eyes but non verbal currently. Skin warm and dry. No mottling or apnea observed at this time. O2 sat 88% with O2 at 2 LPM via n/c. On increased to 3 LPM via mask as pt. noted to be mouth breathing. Respirations 28. F/U O2 sat 93%. HOB elevated. Pt. medicated with morphine by LPN. Daughter updated on pt.'s condition. Does not want pt. sent out to hospital and would like comfort measures to continue. Daughter also in agreement with delay in d/c d/t pt.'s condition.CRNP updated on pt.'s condition, delay in d/c and daughter's wishes. No n/o's at this time. view 2/4/2021 10:56 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB Resident showing s/s of discomfort. SOB at this time and high respirations. Repositioned, changed for incontinence care and mouth care provided. view 2/4/2021 10:34

Progress Note Note Text: Spoke with RN regarding change in condition. Updated Sr Living regarding change. Recommendation to cancel d/c/transfer for today, see how resident does through the weekend and re-evaluate on Monday. Daughter updated on cancellation of d/c today. view 2/4/2021 10:04 Nurses Note Note Text: Daughter aware that resident's O2 sat was 88% on room air on 3-11 shift and that oxygen was applied via nasal cannula. view 2/4/2021 10:03 Nurses Note Note Text: N/O: Discharge 2/4/21 with scripts to Sr. Living. Daughter aware. view 2/4/2021 09:53 Nurses Note Note Text: Pt. to be d/c'd to another facility this am as per MD order. Pt. alert and responsive. Skin assessment done as per facility policy. No pressure areas noted at this time. No s/sx of pain or discomfort observed at this time. V.S. 97.0 67 20 O2 sat 95% with O2 at 2 LPM via n/c. view 2/4/2021 07:45 Nurses Note Note Text: Resident seen by Dr. for discharge. Orders pending at this time. view 2/4/2021 07:36 Nurses Note Note Text: CRNP and Dr. updated on O2 sat 88% on RA with f/u of 93% with O2 on at 2 LPM as well as rest of VS, 3-11 shift 2/3/21. No n/o's at this time. view 2/3/2021 21:17 Nurses Note Note Text: Resident Sp02 88% on RA. Pulse 124. Respirations 40. PRN morphine given and O2 applied via NC at 2L/min. After recheck pulse ox up to 93%, pulse 100, and respirations 22. Resident appears comfortable at this time. view 2/3/2021 20:05 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective [linked] view 2/3/2021 19:48 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN given for SOB after elevation of HOB not effective. view 2/3/2021 11:51 Nurses Note Note Text: CRNP updated rapid COVID test done for d/c tomorrow was negative. No n/o's at this time. view 2/3/2021 11:44 Nurses Note Note Text: Daughter notified of rapid covid swab being negative. view 2/3/2021 09:50 Orders - Administration Note Note Text: Obtain Rapid Covid test on 2/3/2021 for discharge. Please give copy of results to Social Worker every day shift for covid testing for 1 Day Completed and negative. view 2/3/2021 08:45 Skilled Nursing Note Reason for skilled service: Therapy describe skilled service: Nursing, therapy assessment: V.S. 97.8 79 18 138/84 Orientation: Oriented to self only. Oxygen: O2 sat 94% on RA Edema: Trace edema noted BLE. Pedal pulses present. Pain: Denies pain or discomfort at this time. Nursing note: Pt. alert and responsive. Skin warm and dry. Lung sounds diminished. No respiratory distress observed at this time. Abdomen soft. BS+ in all 4 quads. Continent/Incontinent of B&B. 1 assist with ambulation, transfers. 1 assist with ADL's. Working with therapy on gait training, therapeutic exercise,

therapeutic activities & neuromuscular reeducation. view 2/2/2021 14:37 Progress Note Note Text: Per health professional at Sr Living, prepared to accept patient to their Memory Care Unit 2/4. Transportation arranged for 11 AM per family request. Daughter (POA) updated on d/c time on 2/4/21. Facility requesting rapid COVID test completed prior to d/c and results sent to them. All other information sent for continuity of care.

SLEEP APNOEA SYNDROME	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse	No prior vaccinations for this event.
SLOW RESPONSE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was	No prior vaccinations for this event.

treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.

	SLUGGISHNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine given on 12/29/20 by Pharmacy. On 1/1/21, resident became lethargic and sluggish and developed a rash on forearms. He was a Hospice recipient and doctor and Hospice ordered no treatment, just to continue to monitor. When no improvement of codition reported, doctor and Hospice ordered comfort meds (Morphine, Ativan, Levsin). Resident expired on 1/4/2021		No prior vaccinations for this event.
	SLUGGISHNESS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
family states seemed short of breath since after the covid vaccine. Staff said beginning on 1/22/21 the patient seemed sluggish, more tired, and nausea noted. She stayed in her room more after the vaccine because worried about giving/getting COVID to others. was talking on the phone at 11:30 PM on 1/26/21 to staff person about temperature of room. at 12:15 AM on 1/27/21 staff noted not breathing, started CPR and called EMS. When EMS arrived they stopped the code because she was too long deceased.		No prior vaccinations for this event.
	SMALL INTESTINAL OBSTRUCTION	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient experienced an episode of emesis and loss of consciousness several hours after vaccine on		No prior vaccinations for

2/16/21. He was taken by EMS to the hospital and was noted to be hypoxic and hypotensive. He was admitted to the hospital and subsequently intubated. He was also found to have a small bowel obstruction and a nasogastric tube was placed to decompress the bowel. He required pressor support as well. He expired on 2/17/21.

this event.

SMALL INTESTINAL OBSTRUCTION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency

No prior vaccinations for this event.

department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

SMALL INTESTINAL OBSTRUCTION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"death Narrative: 71 yo male who passed away on 1/29/2021, medical cause of death ""cholangiocarcinoma, interval between onset and death 14 months. Since patient passed away within 42 days of the covid19 vaccine administration, we are required to complete a report to VAERS. Vaccine (Pfizer) was administered without complications. The patient denied any prior severe reaction to this vaccine or its components or a

No prior vaccinations for this event.

severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy. Synopsis- 1/23 71 yo male presented to ED with upper GI bleed. PMH: DM, HTN, cholangiocarcinoma of biliary tract requiring recurrent paracentesis, COPD, perigastric and lower esophageal varices (not on beta blockers due to bradycardia). Pt has had 2 episodes of coffee ground emesis. Lactic 2.6, ammonia 52. Rec'd protonix, octreotide, and ceftriaxone in ED. Family has been previously encouraged to speak to palliative care but has never been willing to. GI consulted. 1/24 EGD completed. No signs of active bleed. MDs recommending hospice. CT + for small bowel ileus. 1/26 Requires placement of NG tube to suction. Palliative care consulted. 1/27 Paracentesis completed. 4100mls removed. 1/28 Pt changed to palliative status. 1/29 Pt passed away."

SOMNOLENCE

COVID19 (COVID19 (MODERNA)) (1201)

on 12/24/2020 the resident was sleepy and stayed in bed most of the shift. He stated he was doing okay but requested pain medication for his legs at 250PM. At 255AM on 12/25/2020 the resident was observed in bed lying still, pale, eyes half open and foam coming from mouth and unresponsive. He was not breathing and with no pulse

No prior vaccinations for this event.

SOMNOLENCE

COVID19 (COVID19 (MODERNA)) (1201)

Patient had mild hypotension, decreased oral intake, somnolence starting 3 days after vaccination and death 5 days after administration. He did have advanced dementia and was hospice eligible based on history of aspiration pneumonia.

No prior vaccinations for this event.

SOMNOLENCE

COVID19 (COVID19 (MODERNA)) (1201)

Accelerated decline in condition with decreased input, decreased responsiveness,

No prior vaccinations for this event.

somnolence, and death

	SOMNOLENCE	**COVID19 (COVID19 (MODERNA)) (1201)**
Per granddaughter's report, pt became very weak within hours of receiving the first dose of the Moderna COVID-19 vaccine and could not get out of bed the next morning without assistance, reported difficulty seeing, and did not recognize some family members. By Sunday, 1/31, pt was unable to be awakened, would not eat, and had low urinary output. Granddaughter reports that the morning of 2/1 he was awake and ate a small amount and seemed to be improving although still weak and unable to get out of bed. Granddaughter reported he died 2/1 around 10am in the morning.		No prior vaccinations for this event.

	SOMNOLENCE	**COVID19 (COVID19 (MODERNA)) (1201)**
extreme fatigue. could not awaken for more than few seconds. When briefly awake she was coherent and not confused. slept deeply from 4pm and could not wake to eat or drink. No fever, bp normal, blood oxygen ok. Blood sugar at 11pm was 230. Gave her 15u lantus at 11pm (normally 25u). Was sleeping at 2:30am but had died at next check at 3:30am.		No prior vaccinations for this event.

	SOMNOLENCE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"CC:full arrest HPI:HPI and ROS limited due to patient's condition. History is via EMS, medical record, and son. Per Son patient had Covid vaccine on Saturday morning. Slept all day Sunday. Woke up Sunday night a bit ""like coming out of a deep sleep per son, around 10 pm. Shortly after that patient was having a hard time breathing. Emergency called. Arrested around the time EMS arrived. King airway, I/O and CPR initiated. Patient has been in v fib. Was shocked multiple times, given 4 rounds of epi, bicarb and		No prior vaccinations for this event.

amiodarone. ACLS continued on arrival. Multiple rounds of epi, and attempted defib. Patient given epi, bicarb. Rhythms included fine v fib, asystole, and PEA. Unrecoverable with no cardiac motion. Time of death 11:50 pm."

SOMNOLENCE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient noted to have irregular breathing in bed and unable to arouse. Provided life saving measures in the field x 30 minutes and transferred to hospital. Noted to have heart arrhythmia which suspected to cause cardiac arrest.	No prior vaccinations for this event.

SOMNOLENCE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom received the Covid 19 vaccine on Jan 5, 2021 and became very about a week later. I was informed that she tested positive for Covid 19 on January 14th. One January 17th she became very tired and weak and would not eat. Hospice called me and told me that she was in a decline state. I saw her on January 25 and 26 and she was just sleeping and could not open her eyes. Her vitals were good and she seemed to understand when I talked to her - she would squeeze my hand and moan but she could not talk or open her eyes. My mom passed away on January 27, 2021 just 22 days after receiving the Covid 19 vaccine. She was very think to begin with and being to weak and tired to eat resulted in her losing even more weight. Some of the other residents were given fluids to help and they recovered. My mom was not given fluids. I believe there were 20 deaths in her care home for the month of January when they vaccinated. This was an alarming number of deaths for the home. The facility had very few Covid deaths in 2019 and 2020. I asked every week if they had any Covid and or Covid deaths and this amount was shocking to me and the workers there.	No prior vaccinations for this event.

	SPECIFIC GRAVITY URINE INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.
	SPECIFIC GRAVITY URINE NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of		No prior vaccinations for this event.

chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

SPECIFIC GRAVITY URINE NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-

No prior vaccinations for this event.

ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2

through

	SPEECH DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received vaccine on 1/4/2021. He was in Hospice for CHF and renal failure, but was able to get up in his wheelchair and eat and take medications and talk. On 1/5/2021 am, he was noted to be very lethargic an could only mumble, could not swallow. No localizing neurologic findings. He was too lethargic to get up in chair.		No prior vaccinations for this event.
	SPEECH DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
Staff walked into resident's room around 10:00am and noted resident's left side of his face was flaccid. Nurse was called and upon assessment resident noted to have an unequal hand grasp with left worse. He was able to talk but was mumbled and hard to understand. Physician, hospice, and family were notified. Resident had a stroke at 10:06 am on 1/8/2020. He lost all ability to use his left side. Resident passed away on 1/11/2020.		No prior vaccinations for this event.
	SPEECH DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient obtained initial dose of Moderna vaccine on Thurday, Jan 14. No adverse effects reported during initial 15 minute post vaccine waiting period. Saturday morning (Jan 16), patient developed severe cough, labored breathing, and fever. Additionally patient mental status changed suddenly, became non-communicative (unable to speak, but would scream if she was touched). O2 status was irregular, dropping to 78. Sunday morning, EMT and then hospice was hospice called. Monday morning, after hospice emergency kit was initiated, patient passed away.		No prior vaccinations for this event.

	SPEECH DISORDER	**COVID19 (COVID19 (MODERNA)) (1201)**
I video chatted with her Thursday after receiving the vaccine. My mom was in poor health but she was talking in complete sentences and responded appropriately. She was upright in bed and made eye contact. She smiled and denied pain. By Sunday, she was extremely weak and unable to sip water with a straw. Her health had changed dramatically and rapidly. She moaned in pain and was very fatigued. Her condition continued to deteriorate over the week and she stopped talking and was constantly sleeping. They started antibiotics for the oozing cancer lesion and then morphine for pain and end of life care. She passed away on January 22nd which was 15 days post vaccination.		No prior vaccinations for this event.
	SPEECH DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.		No prior vaccinations for this event.
	SPEECH DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic. Client tested positive for COVID-19 by		No prior vaccinations

rapid testing on 1/21/21, with c/o hurting all over and loose stools. She became non-verbal on 1/23/21 with poor intake. On 1/24/21 at 0537 Client was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.	for this event.
SPINAL COMPRESSION FRACTURE	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene when EMS arrived. Autopsy showed a left temporal subdural hematoma.	No prior vaccinations for this event.
SPINAL CORD INJURY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures	No prior vaccinations for this event.

growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

SPINAL FRACTURE	**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"	No prior vaccinations for this event.
SPINAL MYELOGRAM NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with	Influenza Vaccine

inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.	
SPINAL OPERATION	**COVID19 (COVID19 (MODERNA)) (1201)**
death Narrative: unclear of details, s/p spine surgery on 2/2/21 and discharged on 2/6/21	No prior vaccinations for this event.
SPINAL OSTEOARTHRITIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 Vaccine] treatment under Emergency Use Authorization(EUA): He presented 10 days after first COVID-19 Vaccine with Progressive neurological deficits with bulbar manifestations - dysarthria, dysphagia and bilateral arm weakness and incoordiantion, worse on right. MRI brain was negative for acute stroke and MRI cervical, showed degenerative changes. Transferred from community hospital to tertiary center where the diagnosis was made of AIDP. He was intubated at that time in Neuro ICU. Given Steroids and IVIG but no improvement and was either will need to have Trach and PEG vs CMP and family honored the patient's wishes and made him CMO. signs of severe demyelination and AIDP was diagnosed.	No prior vaccinations for this event.
SPINAL STENOSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma	No prior vaccinations

workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene when EMS arrived. Autopsy showed a left temporal subdural hematoma.		for this event.
SPUTUM CULTURE		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.		No prior vaccinations for this event.
SPUTUM DISCOLOURED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21		No prior vaccinations for this event.
SPUTUM DISCOLOURED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to

No prior vaccinations for this event.

urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

SPUTUM DISCOLOURED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/15: Pfizer vaccine dose 1 administered 1/16: Fever, chills 1/22: Sore throat, coughing w/white phlegm, taking Tylenol and Mucinex. Fever and chills from 1/16 subsided. Had telehealth consultation with PA. Per her notes, patient said he gets these symptoms annually, requested for an antibiotic. PA referred him for a COVID test. Ordered hydrocodone/chlorphen ER suspension for his cough and an antibiotic. Antibiotic was recommended if symptoms do not subside. 1/23: COVID test administered 1/25: Reported positive for COVID 1/26: Telehealth session w/PA: she informed patient of his positive test, advised to quarantine and seek medical help at hospital if symptoms worsen. Patient reported that his sore throat mostly subsided but is still coughing at night. Said that the pharmacy didn't receive the prescription order for the antibiotic, so this was re-ordered. 1/31: Partner found him dead at 8:18AM on his bed. Death certificate issued by state says cause of death: COVID. Autopsy was not performed. Buried on 2/9/21.	No prior vaccinations for this event.

STAPHYLOCOCCAL BACTERAEMIA

COVID19 (COVID19 (MODERNA)) (1201)

Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.

No prior vaccinations for this event.

STAPHYLOCOCCAL INFECTION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Day After - severe headache, 2 days after headache continues, itchy scalp, day 3 rash visible at hair line headache continues, more confusion than normal, day 4 on site nurses check rash and think it is dermatitis, day 5 continues to get work nurse practitioner was to visit next day, day 6 NP thinks that she has UTI and sends her to hospital (2/11/21). Hospital determines - Rash is Shingles, UTI present, - MRSA is now present in shingles which is on right back of head and right neck and face. Next Sepsis is diagnosed. Since 2/11/21 patient was not conscious. 2/20/21 famiy is notified that she should be moved to Hospice. Moved to hospice on 2/20/21. The patient, my mother, died on 2/23/21 official cause of death is UTI.

No prior vaccinations for this event.

STAPHYLOCOCCUS TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately

No prior vaccinations for this event.

declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.

STAPHYLOCOCCUS TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.	No prior vaccinations for this event.
STARING	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received Moderna COVID vaccine on 12/30/2020 at a Pharmacy clinic where he was a resident. Nurses at the facility reported that he was responsive and showed no signs of any adverse effects until 1/2/2021 when he was observed slightly unresponsive and staring at the ceiling and trembling. He had a fever of 101F at this time. The facility ordered labs and a rapid COVID test (all of which came back normal) and started IV antibiotics. A few hours later, patient began bleeding from his eyes, nose, and mouth and was sent to the local ER. The patient refused being admitted to the ICU for possible sepsis/hemorrhage and died the following day on 1/3/2021. All healthcare professionals involved agreed that this was not likely due to the vaccine, but needed to be reported nonetheless.	No prior vaccinations for this event.

	STARING	**COVID19 (COVID19 (MODERNA)) (1201)**
1/31/2021 12:50 Nursing Note Note Text: Res had low BP, low O2 sats, 30 breaths per minute, eyes open wide, making confused utterances. Started supplemental oxygen via NC, 2L, then 3L. Sats went up to 93% for a while, Sprvsr called. Unable to auscultate Left lung sounds. Called to update Res daughter. Called to page NP, writer went back to assess Res and O2 sats were 88%, turned O2 to 4LPM, called 911 for transport to Hospital ED. Left around 1030. NP called back afterwards, was updated. Family updated that Res was sent to Hospital ED. Note Text: Received phone call from daughter as well as information from hospital. Resident has pneumonia with septic shock. She is on abx and had thoracentesis performed for large pleural effusion. [linked]		No prior vaccinations for this event.
	STARING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.		No prior vaccinations for this event.
	STARING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 10 minutes after receiving the COVID- 19 vaccine resident displayed seizure activity, staring		No prior vaccinations for

straight ahead and strong allover muscle jerking of both the up and lower extremities, color became gray, activity lasted approximately 3 minutes, resident then became relaxed, color returned to normal, BP-140/80, 97.8, 60, 16, sleeping the remainder of the shift,. Resident continued to decline until resident CTB on 1/19/21	this event.
STENOTROPHOMONAS INFECTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe.	No prior vaccinations for this event.

Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

STENT PLACEMENT

COVID19 (COVID19 (MODERNA)) (1201)

Approximately 2 weeks after the first COVID vaccine she developed shortness of breath that was much more significant than she had previously. This was the first time she had expressed this symptom to me as being something she was concerned about and difficult for her to manage (we have spoken almost daily for many years). Within 24 hours of the second dose of the mRNA vaccine, they called an ambulance to get her and she was taken to the hospital and diagnosed with bacterial pneumonia. The doctors said it was unrelated, but I found a study with a different vaccine (LAIV) that also seemed to increase the incidence of bacterial pneumonia. They hypothesized through diverting the immune system. So while I don't think the vaccine gave her the bacteria, I do think it may have caused her immune system to be temporarily compromised allowing the bacteria to grow out of control. I feel this is important to report to look for these types of patterns as perhaps it can help others avoid the death spiral that happened to my mother. There were also intervening events between her hospitalization and her death including two successful surgeries (one for a broken hip and another to put in stents in her leg). So to summarize, the first vaccine was within about 2 weeks of the onset of her breathing problems. Within 24 hours of the second vaccine she was hospitalized and diagnosed with bacterial pneumonia. As she was battling bacterial pneumonia in the hospital she broke her hip and was found to have reduced peripheral circulation and had 2 surgeries to correct those. They were successful according to the surgeons, however she died within a week or so of the surgeries. She had other comorbidities as well which I'm sure predisposed her such as diabetes, hypertension and cancer for many years.

Breathing issues ~2 weeks after first dose of mRNA vaccine in the series but were not nearly as acute or severe as they were fol

STENT PLACEMENT

COVID19 (COVID19 (PFIZER-

	BIONTECH)) (1200)
she was hurting at her chest/ Chest pain; on her left arm hurt real bad that's what the clot on her left arm; on her left arm hurt real bad that's what the clot on her left arm; She passed away; heart attack; This is a spontaneous report from a contactable consumer. An 87-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Jan2021 at single dose for COVID-19 immunisation. Medical history included diabetes mellitus, for which she was taking a pill like an hour before she would take her meal. On Monday (Jan2021) the patient experienced was hurting at her chest/ chest pain, her left arm hurt real bad as she had a blockage in her left arm/clot on her left arm, and they wanted to put in a stent and after the surgery it went well and she all go home in two days. The patient was hospitalized in Jan2021 due to the events. She had a heart attack and that the chamber between the dividers had a hole in it and her heart tissue was too thin so much thin she couldn't repair it. The patient passed away on 26Jan2021. The patient was tested negative for COVID-19 on unknown date. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: She passed away	No prior vaccinations for this event.
STREPTOCOCCUS TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.	No prior vaccinations for this event.
STREPTOCOCCUS TEST POSITIVE	**COVID19 (COVID19**

(MODERNA)) (1201)

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.

No prior vaccinations for this event.

SUBARACHNOID HAEMORRHAGE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

No prior vaccinations for this event.

SUBARACHNOID HAEMORRHAGE

COVID19 (COVID19 (UNKNOWN)) (1202)

5 days after receiving his COVID vaccination the patient had a spontaneous (nontraumatic) subarachnoid hemorrhage which was fatal. The patient had previously been stable on his coumadin dosing with therapeutic INRs for the past several months per his wife. At time of presentation his blood pressure in the ER was elevated to 223/94 and his INR was risen to 3.1

No prior vaccinations for this event.

SUBDURAL HAEMATOMA

COVID19 (COVID19 (MODERNA)) (1201)

on 1/13/2021 at 3:40am Cliff called for assistance. He lost his balance and had fallen. Cliff refused vitals, refused emergency department, denied hitting his head. As the day progressed patient developed a headache, diarrhea, and vomiting. He again declined the offer for the emergency room. At supper time wife and staff found Cliff unresponsive, 911 was called and he was taken to the emergency department. The ER did a CT scan and found an acute subdural hematoma. Patient was placed on comfort cares and expired at 3pm on 01/14/2021. Cliff did not have a history of falls.

Influenza vaccine 10/06/2020, age 88, fever, chills, vomiting, malaise

SUBDURAL HAEMATOMA

COVID19 (COVID19 (MODERNA)) (1201)

On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene when EMS arrived. Autopsy showed a left temporal subdural hematoma.

No prior vaccinations for this event.

SUBDURAL HAEMATOMA

COVID19 (COVID19

	(MODERNA)) (1201)
Patient presented to emergency room on 2/1/2021 with a chief complaint of having a chronic headache and fatigue following receipt of the Moderna vaccine 10 days prior. Following examination by the physician, the patient was diagnosed with an acute subdural hematoma. The patient subsequently underwent decompressive surgery, however demonstrated worsening neurologic status over the next several days and ultimately expired on 2/4/2021.	No prior vaccinations for this event.
SUBDURAL HAEMORRHAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient family had been noticing onset confusion for a few weeks prior to vaccine and event. Patient was taken to ED when found unconscious and died of a subdural hemorrhage a few days after vaccine clinic at retirement home.	No prior vaccinations for this event.
SUBDURAL HAEMORRHAGE	**COVID19 (COVID19 (MODERNA)) (1201)**
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021	No prior vaccinations for this event.
SUBDURAL HAEMORRHAGE	**COVID19 (COVID19**

(UNKNOWN)) (1202)

5 days after receiving his COVID vaccination the patient had a spontaneous (nontraumatic) subarachnoid hemorrhage which was fatal. The patient had previously been stable on his coumadin dosing with therapeutic INRs for the past several months per his wife. At time of presentation his blood pressure in the ER was elevated to 223/94 and his INR was risen to 3.1

No prior vaccinations for this event.

SUDDEN CARDIAC DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Patient expired three days after receiving first dose of Moderna COVID-19 vaccine. The death certificate states cause of death is sudden cardiac arrest.

No prior vaccinations for this event.

SUDDEN CARDIAC DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Client unexpectedly collapsed and passed away on 1/13/21 from suspected sudden cardiac death. Prior to her death, she was in skilled care for rehabilitation following hospitalization from 12/21-12/31/20 for an acute lower GI bleed. Her hospitalization and skilled care stay were complicated by delirium and she was being treated for delirium with olanzapine (Zyprexa) at time of death.

No prior vaccinations for this event.

SUDDEN CARDIAC DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Resident passed away unexpectedly on 1/27/21 from presumed sudden cardiac death.

No prior vaccinations for this event.

SUDDEN CARDIAC DEATH

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

Sudden cardiac death No prior vaccinations for this event.

SUDDEN CARDIAC DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Sudden cardiac death. Autopsy report: right coronary artery thrombosis. No prior vaccinations for this event.

SUDDEN DEATH COVID19 (COVID19 (MODERNA)) (1201)

had a vaccination on 12/31/2020 late morning passed away early morning 01/01/2020. This is a 93 year old with significant heart issues. EF of 20% among other comorbidities. He died suddenly approximately 0430, it is unlikely it was related to receiving the vaccine. No prior vaccinations for this event.

SUDDEN DEATH COVID19 (COVID19 (MODERNA)) (1201)

Sudden death without warning symptoms 4 days after vaccine. Many medical problems which most likely explain the outcome but spouse feels it is related and it is a new vaccine. Monitor for pattern? No prior vaccinations for this event.

SUDDEN DEATH COVID19 (COVID19 (MODERNA)) (1201)

Sudden Death within 24 hours of vaccine No prior vaccinations for this event.

SUDDEN DEATH COVID19 (COVID19 (MODERNA)) (1201)

93 y/o with complex medical history (severe COPD on oxygen, diastolic CHF, CKD3, myelofibrosis, marginal zone lymphoma of spleen with recent progression and no active treatment, chronic anemia, afib, CAD, No prior vaccinations for this event.

pulmonary artery hypertension, h/o bladder cancer, hypertension, hypothyroidism, h/o bilateral PE, sick sinus syndrome s/p pacemaker, h/o Hodgkin's disease). Has had multiple hospitalizations over the last 3 months for dyspnea, most recently in 12/2020. Enrolled in palliative care. Has had multiple transfusions (most recently 01/13/21) for his chronic anemia due to myelofibrosis, and recently started on darbepoetin. No documented history of anaphylaxis to medications or prior vaccinations. He received COVID19 vaccine (Moderna) on 01/16/21. He passed away suddenly at home on 01/17/21. Symptoms: & cardiac arrest Treatment:

SUDDEN DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**

Patient sudden death reported by family. No further details available at this time. No prior vaccinations for this event.

SUDDEN DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**

Patient had a CVA and passed away suddenly 1/10/21 No prior vaccinations for this event.

SUDDEN DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**

Sudden death 2/7/21 @ 0309 Started acute encephalopathy & required intubation Soon after intubation went into cardiac arrest Likely severe acidosis.	No prior vaccinations for this event.

SUDDEN DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
He had sudden death on Feb 4th. Unclear if this could be related to vaccination but since it was close in timing report has been filed. No known immediate reaction to vaccination.	tetanus toxoid

SUDDEN DEATH	**COVID19 (COVID19**

(MODERNA)) (1201)

Patient died suddenly on 2/1/21 from unknown causes according to his son. No prior vaccinations for this event.

SUDDEN DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

Since I was not with my husband I can only tell you what was told to me. He walked out of the store toward our car. Someone watched him, concerned, because he was walking very slowly (normally has a slow gait because of leg braces and toe amputations so I don't know if it was unusually slow). The woman saw him fall and she ran to help-administered CPR immediately-and told me he died instantly. Medics tried to resuscitate and failed to bring a pulse. (My husband left our home around 11:15 to drop a package off at store. The store is one mile from our home. At around 12:30 a deputy came to my door and when I saw him my knees buckled. I knew something horrible happened.

No prior vaccinations for this event.

SUDDEN DEATH

COVID19 (COVID19 (MODERNA)) (1201)

"Agency contacted 2/19 In evening by employer representative- client Died Suddenly after work"""

No prior vaccinations for this event.

SUDDEN DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Sudden Death on 2/17/2021 No prior vaccinations for this event.

SUDDEN DEATH **COVID19 (COVID19 (MODERNA)) (1201)**

On January 1, 2021, patient was admitted to Medical Center with COVID. Tested positive on January 2, 2021. Spent 10 days in hospital. Once recovered from pneumonia and fever gone, on January 10, 2021, she was

No prior vaccinations

transferred to Rehabilitation Center for continued treatment. She spent 16 days there. She developed UTI and CDIF infections and was on/off oxygen. She started physical therapy. She was scheduled to be released to go home on January 27, 2021. On January 26, 2021, the day before going home, Rehabilitation Center gave her the Moderna vaccine. On January 27, the day she went home, she started feeling very weak and couldn't walk. My dad tried lifting her and they both fell to the ground. My dad called 911 and she was taken to Medical Center, with high fever and possible stroke symptoms (which later was negative). Two days later, she had difficulty breathing and was put on a ventilator. She was on a ventilator for about three days. They took it off and she slowly started recovering. The doctors did all kinds of tests (blood clot in lung, heart, etc.) and all was negative. The only thing they could trace it to was an adverse reaction to the vaccine. After spending 11 days at hospital and treating her for various infections, her heart stopped and she passed away suddenly.		for this event.
	SUDDEN DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient unexpectedly died on 2/17 after 14 days of receiving first dose of COVID-19 vaccine. EMS presumed it could be from possible myocardial infarction.		No prior vaccinations for this event.
	SUDDEN DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had sudden death 1 week after 2nd COVID vaccine. Had complained of dizziness throughout the week leading up to it.		No prior vaccinations for this event.
	SUDDEN DEATH	**COVID19 (COVID19 (MODERNA)) (1201)**
Unresponsive; A spontaneous report was received from Pfizer concerning a 32-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had a sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 28 DEC 2020, prior to the onset of		No prior vaccinations for this event.

the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 04 JAN 2021, at 7:20 am, the patient died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 04 Jan 2021. The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter's Comments: This case concerns a 32-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had a sudden death. The cause of death was unknown. Plans for an autopsy were not provided. Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

SUDDEN DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Unresponsive; A spontaneous report was received from Pfizer concerning a 45-year old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had a sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 28 Dec 2020, approximately 24 hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 29 Dec 2020, the patient was found deceased at home. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 29 Dec 2020. The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter's Comments: Very limited information regarding this event has been provided at this time.; Reported Cause(s) of Death: unknown cause of death

No prior vaccinations for this event.

SUDDEN DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Unresponsive; A spontaneous report was received from Pfizer concerning a 50-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had a sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 31 Dec 2020, the patient received

No prior vaccinations for this event.

their first of two planned doses of mRNA-1273 (lot/batch: unknown) intramuscular for prophylaxis of COVID-19 infection. On 31 Dec 2020, the patient died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 31 Dec 2020. The cause of death was unknown. Plans for an autopsy were unknown.; Reporter's Comments: This case concerns a 51 year old, female patient, who experienced an unexpected event of Death, after receiving 1st dose of mRNA-1273 (Lot# unknown). Very limited information regarding this event has been provided at this time. There is no contact information and no further follow up information is expected.; Reported Cause(s) of Death: unknown cause of death

SUDDEN DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Unresponsive; A spontaneous report was received from Pfizer concerning a 52-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had a sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 08 Jan 2021, approximately 2 hours prior to the onset of event, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 08 Jan 2021, the patient was monitored for the appropriate amount of time by nursing staff, following vaccination. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 08 Jan 2021 at 2:15pm. The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter's Comments: This case concerns a 52-year old, female patient, who experienced a sudden death 1 day after administration of first dose of mRNA-1273. The cause of death was not provided. Plans for an autopsy were unknown. Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

No prior vaccinations for this event.

SUDDEN DEATH

COVID19 (COVID19 (MODERNA)) (1201)

Unresponsive; A spontaneous report was received from Pfizer concerning a 56-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had a sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 08 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 09 Jan 2021, the patient was found deceased in her home. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 09 Jan 2021. The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death	No prior vaccinations for this event.	
SUDDEN DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**
sepsis; respiratory failure; Fever; Unresponsive; A spontaneous report was received from Pfizer concerning a 56-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced respiratory failure, sepsis, fever and sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 04 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient began to have a fever. She was sent to the emergency room for evaluation. That evening, she died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 11 Jan 2021. The cause of death was reported as respiratory failure and sepsis. Plans for an autopsy were unknown/not provided.; Reporter's Comments: This is a case of 56-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sepsis, fever, respiratory failure and sudden death. Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Respirtory Failure; Sepsis	No prior vaccinations for this event.	
SUDDEN DEATH		**COVID19 (COVID19 (MODERNA)) (1201)**

Sudden death; A spontaneous report was received from Pfizer concerning a 60-year old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 05 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 08 Jan 2021, the patient died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 08 Jan 2021. The cause of death was unknown/not reported. Plans for an autopsy were unknown/not provided.; Reporter's Comments: Very limited information regarding the event has been provided at this time and is insufficient for causality assessment. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death No prior vaccinations for this event.

SUDDEN DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident died suddenly and expectantly on 01/05/2021 No prior vaccinations for this event.

SUDDEN DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Sudden death 18 hours post vaccine . No prior vaccinations for this event.

SUDDEN DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Sudden death No prior vaccinations for this event.

SUDDEN DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

sudden death No prior vaccinations for this event.

SUDDEN DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Sudden death No prior vaccinations for this event.

SUDDEN DEATH COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

My mother died suddenly on February 3rd. She went into shock/cardiac arrest and appeared to have internal bleeding. No autopsy has been performed. Unsure if it was related to the COVID vaccine. No prior vaccinations for this event.

SUDDEN DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient died suddenly 2/14/2021 No prior vaccinations for this event.

SUDDEN DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Ventricular fibrillation/sudden death No prior vaccinations for this event.

SUDDEN DEATH **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Sudden death two weeks after first dose of vaccine was administered. No previous symptoms or signs. Family opted not to do an autopsy so cause of death (stroke or heart attack) not known. No prior vaccinations for this event.

SULPHUR DIOXIDE TEST **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P No prior vaccinations for this event.

67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

SUPRAVENTRICULAR TACHYCARDIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 1/9/2021 observed with elevated respirations of 38-42 per minute, BP manually 72/50. pulse is jumping rapidly between 110-16 bpm. oxygen sat 76% RA, resident refusing oxygen at first attempt, allowed oxygen to be placed, is now 84% on 4L. resident shaking head yes that he is hurting, and yes that he would take medication for pain. Dr. notified, branch block. Received order for morphine 2mg per hr as needed for elevated respirations and pain. Dr. also gave orders to D/C Tamsulosin and finasteride. Resident continue with decreased O2 sats and elevated respirations. Absence of vital signs on 1/10/21 at 826PM.

No prior vaccinations for this event.

SUPRAVENTRICULAR TACHYCARDIA

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."

No prior vaccinations for this event.

SURGERY

COVID19 (COVID19 (MODERNA)) (1201)

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.

No prior vaccinations for this event.

SURGERY

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to emergency room on 2/1/2021 with a chief complaint of having a chronic headache and

No prior vaccinations

fatigue following receipt of the Moderna vaccine 10 days prior. Following examination by the physician, the patient was diagnosed with an acute subdural hematoma. The patient subsequently underwent decompressive surgery, however demonstrated worsening neurologic status over the next several days and ultimately expired on 2/4/2021.

for this event.

SURGERY

COVID19 (COVID19 (MODERNA)) (1201)

Approximately 2 weeks after the first COVID vaccine she developed shortness of breath that was much more significant than she had previously. This was the first time she had expressed this symptom to me as being something she was concerned about and difficult for her to manage (we have spoken almost daily for many years). Within 24 hours of the second dose of the mRNA vaccine, they called an ambulance to get her and she was taken to the hospital and diagnosed with bacterial pneumonia. The doctors said it was unrelated, but I found a study with a different vaccine (LAIV) that also seemed to increase the incidence of bacterial pneumonia. They hypothesized through diverting the immune system. So while I don't think the vaccine gave her the bacteria, I do think it may have caused her immune system to be temporarily compromised allowing the bacteria to grow out of control. I feel this is important to report to look for these types of patterns as perhaps it can help others avoid the death spiral that happened to my mother. There were also intervening events between her hospitalization and her death including two successful surgeries (one for a broken hip and another to put in stents in her leg). So to summarize, the first vaccine was within about 2 weeks of the onset of her breathing problems. Within 24 hours of the second vaccine she was hospitalized and diagnosed with bacterial pneumonia. As she was battling bacterial pneumonia in the hospital she broke her hip and was found to have reduced peripheral circulation and had 2 surgeries to correct those. They were successful according to the surgeons, however she died within a week or so of the surgeries. She had other comorbidities as well which I'm sure

Breathing issues ~2 weeks after first dose of mRNA vaccine in the series but were not nearly as acute or severe as they were fol

predisposed her such as diabetes, hypertension and cancer for many years.

SURGERY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer Covid Vaccine in the AM on 2/9/21. Arrived to emergency department later the same day complaining of nausea, weakness, fatigue, Vomiting, Diarrhea. Post operative diagnosis, Ischemic colon/toxic megacolon.	No prior vaccinations for this event.

SURGERY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal tunnel and sent her home. The morning or March 18th , 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.	No prior vaccinations for this event.

SUTURE INSERTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.	No prior vaccinations for this event.

SWELLING	COVID19 (COVID19 (MODERNA)) (1201)
death of unknown cause; Swelling on Right side of the neck and under chin; Warmth on right side of neck and under chin; Redness on right side of neck and under chin; A spontaneous report was received from a healthcare professional concerning an 89-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced events of redness, warmth and swelling on right side of neck and under chin, and death of unknown cause. The patient's medical history included Alzheimer's and chronic obstructive pulmonary disease (COPD). No concomitant medications were reported. On 29 Dec 2020, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: Unknown) intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient experienced the events of redness, warmth and swelling on right side of neck and under chin. There was no indication that the patient was transferred out to hospital, which was unlikely because she was under hospice care. On 01 Jan 2021, the patient died due to an unknown cause of death. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2020. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns a 89-year-old, female subject with a medical history of Alzheimer's and chronic obstructive pulmonary disease (COPD) who experienced redness, warmth and swelling on R side of neck and under chin and expired from an unknown cause. The events of redness, warmth and swelling on R side of neck and under chin occurred 2 days after administration of the first and only dose of the mRNA-1273 vaccine and patient expired 4 days after mRNA-1273 vaccine administration. Lot # of the vaccine was not provided. De-challenge and re-challenge are not applicable. The events of redness, warmth and swelling on R side of neck and under chin are temporarily associated with the administration of the mRNA-1273 and thus, a causal relationship cannot be excluded. Due to limited information, the fatal outcome was considered unrelated to mRNA-1273 administration pending additional information. Fatal outcome is confounded by the patient's underlying condition and advanced age.; Reported Cause(s) of Death: Unknown cause of death	No prior vaccinations for this event.

	SWELLING	**COVID19 (COVID19 (MODERNA)) (1201)**

itchy skin, swelling, disorientation that led to a fall No prior vaccinations for this event.

	SWELLING	**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away; tired; nonresponsive; cold; difficulty breathing; swelling; sore arm; feeling weird and funny; A spontaneous report (United States) was received from a consumer concerning a 63 year old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and the patient experienced limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal and the patient passed away . Medical history included treatment for tuberculosis and dialysis. Concomitant medication included calcium acetate, Renvela, glipizide, omeprazole, aspirin, vitamin D, losartan, furosemide, rifampin, and Sensipar. On 14 Jan 2021, the patient received the first of their first planned doses of mRNA-1273 (lot number 030L20A) for prophylaxis of COVID-19 infection. On 13 Jan2021, the patient tested negative for COVID-19). On 16 Jan 2021, the patient experienced a sore arm, and feeling weird/funny. On 17Jan2021, the patient experienced difficulty breathing and swelling. On 18 Jan 2021, the patient declined dialysis, was tired and wanted to lay down. At 8 am, the patient was found nonresponsive and cold and is believed to have passed away around 4 am. The coroner tested the deceased for COVID-19 and the test was positive. No autopsy was reported. No death certificate was issued at the time of the report but the reporter believes it will list cause of death as COVID complications. Action taken with the mRNA-1273 was not applicable. The outcome of the events of limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal, was fatal. On 18 Jan 2021, the patient was died. Cause of death was COVID-19. Autopsy details were not provided.; Reporter's Comments: The events developed on four days after first dose of mRNA-1372. Dyspnea, unresponsive to stimuli, and death were consistent with infection in pandemic set up confounded by age of patient and refusal of dialysis Cause of death was reported as COVID-19. Autopsy details were not provided. Based on reporter's causality the events are assessed as unlikely related to mRNA-1273.; Reported Cause(s) of Death: COVID-19	No prior vaccinations for this event.

SWELLING FACE		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident expired on 2/5/21 at 03:35pm, about 25 hours after second dose of vaccine. At breakfast, resident was spitting a lot of secretions, coughing up liquids from nose and phlegm, facial swelling, which were all symptoms that he was struggling with prior to both doses of COVID vaccine, but had increased more than prior incidences on 2/5/21. Gurgling noted in upper airways, hyscolamine given, bath given to loosen secretions, morphine given. Family notified and came into facility for compassionate care visit around 1300. 1400 HR was 3 and RR was 2, but increased back to 60 and 12 within 20 minutes. Then resident expired at 1535.	No prior vaccinations for this event.	
SWELLING FACE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient had swelling around her jaw after her second shot of the covid , Pfizer vaccine (.5 ml IM) on the Friday morning, January 29th, I took her to a follow up appointment with the cardiologist at 3:00 pm, as a follow up to a small heart attack event with hospitalization two weeks previously, at the cardiologist she was given the ok/all is well. That next morning early, she had a 911 event at her assisted living apartment and was sent back to the hospital, having had another heart attack. Patient died on the following Thursday, February 4, 2021. I do not know if the vaccination had any cause for my mothers death; but I feel it is necessary to report this series of heart attacks after she received the pfizer vaccine. Her Certificate of Death records the cause of death as ""Coronary Artery Disease""."	No prior vaccinations for this event.	
SYNCOPE		**COVID19 (COVID19 (MODERNA)) (1201)**
syncopal episode - arrested - CPR - death	No prior vaccinations for this event.	

SYNCOPE **COVID19 (COVID19 (MODERNA)) (1201)**

Pt collapsed at home approx 5:30 pm and died No prior vaccinations for this event.

SYNCOPE **COVID19 (COVID19 (MODERNA)) (1201)**

"Narrative: Patient with severe aphasia and only able to say ""hey, hey, hey"" or ""uh huh"" or shake his head no as a way to communicate. Patient previously able to ambulate with significant limp and hyperextension of right knee, but mostly wheelchair bound over last several years as he had had a slow and steady decline in overall health and mobility. Patient developed aggressive behavior of shouting ""hey"" and grabbing of groin in 2016. This was worked up with CT scans, labs, referral to urology, neurology, and referrals to psychiatry. The exact etiology of this action was never able to be affirmed, but thought to be more psychiatrically related. It improved significantly with addition of antipsychotics, worsened when antipsychotics were reduced, and improved again with addition of injectable antipsychotic on 12-10-2020.Patient suffered from falls on occasion given his significantly impaired physical mobility. His last documented fall was 8-31-2019. Patient began utilizing wheelchair most of time following that fall. No significant injuries noted in documentation of the falls. In the last 3 months, patient would often refuse medications. He would sometimes indicate that they would cause dizziness, and other times he would simply refuse. We attempted to hide medications in his food/fluid (with wife's blessing) and when he detected this he would occasionally refuse to eat. Patient previously on DOAC. After pharmacy review in 12/2020 it was recommended to discontinue this as no clear indication to continue use. He was high fall risk and would often refuse this medication as well since 10/2020. Noted to be in NSR on EKGs and decision made to discontinue the DOAC. Patient had no evidence of adverse effects noted after vaccination on December 28th. Patient seen by provider on the morning of his death (1/4/2021) with no noticeable significant change in health condition. Temperature 36.8Con January 4th at 19:45. During routine bedtime cares, patient suddenly collapsed and death was pronounced January 4, 2021 at 20:05. Autopsy was requested from next of kin and no autopsy was granted. Symptoms: & DEATH Treatment:"

No prior vaccinations for this event.

SYNCOPE **COVID19 (COVID19**

	(MODERNA)) (1201)
My dad got the Moderna Vaccine on Tuesday, January 12, 2021 in his left arm at the Mall injection site for the Health Department. He was told that the side effects could mean his arm hurting, tiredness, headache, and even a low grade fever. Additionally, the site informed us both (as I was with him to get the injection) that this was all normal and not to seek medical attention unless these symptoms last longer than 72 hours. That evening, my dad was experiencing all of those symptoms, and went to bed at 7pm. A little after 10am on Wednesday, January 13, 2021, when he awoke, my dad went to the bathroom vomiting. This was where he collapsed and went into cardiac arrest. Fire/Rescue was dispatched about 10:30am after my mom started CPR. County Fire Rescue EMTs and Paramedics continued CPR and other attempts at reviving him all the way to Hospital Emergency Department. He was pronounced dead at 12:14pm on Wednesday, January 13, 2021. We have no doubt my dad, following the instructions of the injection facility, thought he was just experiencing the side effects of the vaccine. He had no chance. Had this injection been done in the RIGHT arm, perhaps he could have recognized the arm numbness being that of an impending heart attack. We really miss Dad. He served this country with distinction for over 50 years, and we believe his country failed him.	No prior vaccinations for this event.
SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
patient received the Moderna Covid 19 vaccine on 1/23/2021 around 5:45pm wife called management today and reported that he had collapsed and passed away today around noon	No prior vaccinations for this event.
SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient was tested positive for Covid-19 on 12/9/20. Patient received Covid Vaccine on 1/21/21. Patient was observing for 15 minutes in treatment room by Nursing staff. Patient denied any signs/symptoms adverse effect: headache, dizziness & weakness, difficulty breathing, muscle pain, chills, nausea and vomiting, and fever . Patient seated on treatment table appeared to be relaxed, respiration even and unlabored. Health	No prior vaccinations for this event.

teaching provided. Patient educated to report any changes in condition to staff immediately. Patient verbalized understanding and able to verbalize signs and symptoms and adverse effects to be aware of related vaccine. On 1/22/21: patient was seen by medical provider for ""altered behavior"". Per medical provider's documentation: ""Patient was fallen on 1/2/21 and was sent out to outside hospital on 1/4/21. CT head: no intracranial abnormality, age-related changes. Patient had labs (B12, RPR, folate) were within normal limit"". We did MMSE today: 22/30 score ""mild dementia"" On 1/23/20: ""Patient was inside his cell. He was walking towards cell door to obtain his breakfast, when custody witnessed him collapse and activated the alarm. Nursing staff arrived at cell front at 06:34 am and found the patient pulseless and unresponsive, and CPR was immediately initiated. AED was attached at 06:35 am and no shock advised. AMR then arrived and patient did not have ROSC, and was pronounced dead at 06:54 am.""""		
	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
CARDIAC ARREST THAT LEAD TO DEATH - IT WAS REPORTED BY EMS THAT THE PT HAD RECEIVED THE VACCINE ABOUT 30 MINS PRIOR. HE ARRIVED HOME, BECAME SHORT OF BREATH & COLLAPSED. 911 WAS CALLED AND HE WAS TRANSPORTED VIA EMS TO HOSPITAL (16:17) WHERE HE LATER EXPIRED (23:01).		No prior vaccinations for this event.
	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
Narrative: Patient experienced cardiac arrest with PEA and a witnessed collapse upon arrival to the emergency department on 1/24/21. Patient received his first dose of the COVID vaccine on 01/15/2021and felt poorly thereafter. He was describing shortness of breath to his wife and requiring 5L of O2 at home to maintain saturations in 80s, while he usually was on 3L to maintain saturations in the mid 90s. He had been oriented but more fatigued than normal and described bilateral shoulder pain (which was not new for him) as well as indigestion. Took Tylenol with some relief. He had decreased PO intake and less appetite. The patient's wife		No prior vaccinations for this event.

encouraged him to come to the hospital daily for a week prior to admission, but the patient did not want to because he felt his side effects were secondary to the vaccine. Symptoms:RespDepression, Palpitations, Syncope & cardiac arrest Treatment: EPINEPHRINE 1 MG ONCE 3 rounds given ,CALCIUM CHLORIDE 1000 MG ONCE

	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
Client unexpectedly collapsed and passed away on 1/13/21 from suspected sudden cardiac death. Prior to her death, she was in skilled care for rehabilitation following hospitalization from 12/21-12/31/20 for an acute lower GI bleed. Her hospitalization and skilled care stay were complicated by delirium and she was being treated for delirium with olanzapine (Zyprexa) at time of death.		No prior vaccinations for this event.
	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
Moderna Vaccine Lot 029K20A Patient received second dose of vaccine on 2/2/21. Within 30 minutes patient had a near syncopal episode. She felt lightheaded and shortly after had episode of nonbloody vomiting. Hypotensive 81/69 and started on levophed. Alert and orientated. Lungs clear, abdomen benign on admission. Patient had no reaction when received first dose of the vaccine. Patient developed worsening shortness of breath, tachypnea, Afib with RVR, hypotension and required intubation and multiple pressors.		No prior vaccinations for this event.
	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
Received Covid vaccine in am. Last seen by family at 17:30 pm and observed to be well. About an hour later he collapsed, unresponsive. A 911 call was initiated at 18:29. Paramedics arrived to find the patient in cardiac arrest. CPR/ACLS was initiated, but resuscitation was unsuccessful. Pt. was transported to MC where he was		No prior vaccinations for this event.

pronounced dead at 19:32. There was no sing of an injection site reaction, nor of allergic reaction..

	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
Cardiac arrest resulting in death on the third day post vaccine administration, 0224. Reported syncopal event post toileting. Rescue measures attempted but not successful. Time of death 0358, 02/06/2021.		No prior vaccinations for this event.
	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
Given First Moderna covid vacc 1/19/2021. Doing well on multiple contacts from health care providers, then 2/5/2021 was driving, pulled over to the side of the road into a yard, got out of the car and told an observer that he could not breathe, collapsed face down in the snow, EMS called, unable to revive him.		No prior vaccinations for this event.
	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
This is the patient who passed away 2d after his second COVID vaccine. Of note, the 2/8 telephone note makes it sound like he was hospitalized at time of death - that is incorrect. His daugther listed as EM contact works in the eye clinic here. He had mild illness, completed 10d isolation but missed his scheduled booster dose on 2/2 due to isolation. He was called on 2/5 when there was a booster visit cancellation and received his booster dose on that day. His daugther reported that he was doing fine and looking well on 2/7 AM, ate breakfast, shortly after stood up and just collapsed.		No prior vaccinations for this event.
	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
Received first 1/15/2021 with no adverse reaction. Received 2nd dose 2/9 @ 0846 with no adverse reaction		No prior vaccinations

or report of feeling ill. Traveled to store and arrived approx. 2 hours after receiving vaccine. Daughter stated patient felt well and had to go to the restroom to have BM. Collapsed in bathroom. Transported by ambulance to Hospital @ 1439 in cardiac arrest. Was in PEA and went in v fib back to PEA. Resuscitation efforts initiated and patient expired with time noted at hospital records at 15:11.	for this event.	
SYNCOPE		**COVID19 (COVID19 (MODERNA)) (1201)**
Short version The patient has long-standing health issues. The patient received the first dose of Moderna COVID-19 vaccine on 1/16/2021 (unknown location). The patient suffered an event in his home on 1/24/2021. CPR and treatment was begun and he was transported to the ED. He was pronounced dead in the ED at 0846. Long version 70-year-old male with past medical history of CAD with pacemaker, A. fib, COPD, hypertension/hyperlipidemia presenting in cardiac arrest. 911 call at 0724. Per EMS, patient was witnessed by family to have seizure-like activity and then collapsed and became unresponsive. Patient was noted by family to be pulseless and CPR was started right away. Patient received two doses of epi by police were on scene first (AED defibrillation x2) and six doses of epi (plus 6 more AED shocks) by EMS when they arrived. Patient had CPR performed for 45 minutes prior to arriving at the hospital. On route, patient had episodes of paced rhythm and V. fib. Patient received one amp of bicarb and one amp of calcium en route. Patient also received 300 mg of amiodarone en route. Arrived in ED at 0810 Patient received ongoing compressions, shocks and additional medications (epinephrine x6, lidocaine IV, sodium bicarbonate) until time of death called at 0846 in the ED.	No prior vaccinations for this event.	
SYNCOPE		**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope.	No prior vaccinations for this event.	

ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.

SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive MI, PE or ruptured AAA"". Death certificate notes indicate ""signficant conditions contributing to death after cardiac arrest; ASCVD""."	No prior vaccinations for this event.

SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
"The patient came to the Emergency Room at approx 3:30 am on 02/03/2021 with pain in right arm (same arm the COVID vaccine had been administered in approx 12 hours earlier) and feeling generally unwell. Patient was concerned about possibility of gout flare or that something was wrong with her arm. Elevated blood pressure was noted; this was attributed to anxiety. She was evaluated, given 500 mg Tylenol, and discharged since the pain was decreasing and blood pressure was stabilized. Patient instructed to follow-up with physician. The next day, on 02/04/2021, the patient arrived at the Emergency Room by ambulance; cardiac arrest was the chief complaint. The patient's daughter stated the patient had been ""feeling generally poor and then suddenly collapsed."" Daughter described ""gurgling respirations"" and being unresponsive. 911 was called, police arrived within 5 minutes and initiated CPR. Epinephrine, atropine, lidocaine and bicarb administered after arrival to Emergency Room. Shockable rhythm never demonstrated. Patient never	No prior vaccinations for this event.

recovered spontaneous respiration or movement. The death was called at 23:04. Coronary artery disease with cardiac arrest is the cause from the ER records; the coroner is putting COVID-19 vaccination in Part 1 of the death certificate."

	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient collapsed and could not be revived. There was no prior warning. She was otherwise in good condition for her age. The death was listed as probable cardiac arrest but no autopsy was performed. Since it occurred so close to the vaccine shot I thought someone may want to know.		No prior vaccinations for this event.
	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient described feeling nervous, anxious the next morning (Wednesday) after the vaccine. He later fell in the bathroom after using the restroom, his legs gave out (his words) and consequently was on the ground for 23 hours before being transported to the hospital. That was Thursday afternoon. He was diagnosed with COVID-19 on Saturday night and died the following Friday morning.		No prior vaccinations for this event.
	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received Covid Vaccine Moderna at 1145, multiple syncopal episodes at pharmacy, sent to ER. Outcome Death		No prior vaccinations for this event.
	SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was		No prior vaccinations

unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506	for this event.
SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**
ER admit for CP and Jaw pain, exhaustion, Aortic arteritis normal SED rate found on CT scan hospital admit IV medications required Solumedrol and Actemra questionable how much medications received d/t IV's not working. Released from care on 2/19 with prednisone . Symptoms still present off and on. 2/21 922pm CP Jaw Pain severe EMT's called EKG done reported no heart attack, pain better, EMTs left. 10/15 severe Pain collapsed with no pulse and no breathing, EMTs returned unable to obtain a shock-able rhythm time of death pronounced. reason for death on certificate Aortitis - hospitalist thinks aortic dissection d/t severe inflammation	No prior vaccinations for this event.
SYNCOPE	**COVID19 (COVID19 (MODERNA)) (1201)**

The coroner called Dr. on 3.2.2021 to advise that he had a witnessed collapse and Mr. was taken to the ED where he was pronounced.	No prior vaccinations for this event.	
SYNCOPE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Vaccine received at about 0900 on 01/04/2021 at her place of work, Medical Center, where she was employed as a housekeeper. About one hour after receiving the vaccine she experienced a hot flash, nausea, and feeling like she was going to pass out after she had bent down. Later at about 1500 hours she appeared tired and lethargic, then a short time later, at about 1600 hours, upon arrival to a friends home she complained of feeling hot and having difficulty breathing. She then collapsed, then when medics arrived, she was still breathing slowly then went into cardiac arrest and was unable to be revived.	No prior vaccinations for this event.	
SYNCOPE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Actual event and cause of death were unknown; This is a spontaneous report from a non-contactable consumer. A 90-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 06Jan2021 at single dose for COVID Prevention. The relevant medical history included aortic valve replacement from Nov2019. Concomitant medications were not reported. The consumer stated that she was taking the reporting responsibilities to report that a friend of hers, informed that the patient passed away on Friday, and had received the COVID vaccine on Wednesday. The consumer stated that it was unknown to her at this time, if the friend had called to complete a report herself, regarding the incident. Their conversation was very brief. The patient was 90 years old, and it was her friend's mother that was the patient. Actual event and cause of death were unknown. The patient had her vaccine on Wednesday 06Jan2021, and then the patient collapsed in front of the reporter at Friday night on 08Jan2021 and passed away that same day. The autopsy was unknown.	No prior vaccinations for this event.	

The outcome of the event was fatal. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Actual event and cause of death were unknown

SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Symptoms: Palpitations & Syncope Treatment: EPINEPHRINE 1 MG ONCE ,EPINEPHRINE 1 MG ONCE ,SODIUM BICARBONATE 50 ML ONCE	No prior vaccinations for this event.

SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
She had the first dose of Pfizer vaccine at the Campus on Friday 1/15 at 4:30 pm. After the vaccine, she had no new symptoms or signs of vaccine reaction and MD friend reports that he checked her pulse which was not elevated from baseline. On 1/16, she awakened and continued to feel at her recent baseline. However, in the early afternoon, she complained of headache, nausea/epigastric pain, and chest heaviness. These apparently were not unusual symptoms for her to feel intermittently. Per her niece, who has a home O2 sat device, her 02 sat that morning was 97 with a HR of 87 irregularly irregular. She was afebrile. (continue on page 2)	No prior vaccinations for this event.

SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On Saturday, 1/16/2021, Patient went to the grocery store. Upon her return, she indicated she was experiencing N/V and some throat swelling. Patient subsequently collapsed and expired before she could be brought to an emergency room. During investigation by Coroners Office, it has been reported that Patient may have gotten some takeout food while she was out. Labs are pending and the Coroners	No prior vaccinations for this event.

investigation is ongoing. Spouse believes that her death was caused by the vaccine.

SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Was at work on 1/26/21 and collapsed, no known complaints a the time. CRP was initiated immediately, transported to ER and pronounced dead	No prior vaccinations for this event.
SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
dead; Collapsed; bnt162b2 was given to patient with immunocompromised w/ reportable conditions; bnt162b2 was given to patient with immunocompromised w/ reportable conditions; This is a spontaneous report from a contactable nurse. A 40-year-old male patient receive first dose of bnt162b2 (Lot number: EK9231, Brand: Pfizer), intramuscular in left arm on 21Jan2021 15:15 at single dose for COVID-19 immunization. Medical history included immunocompromised w/ reportable conditions from an unknown date and unknown if ongoing, positive for Covid in September from Sep2020 to an unknown date. The patient's concomitant medications were not reported. The patient experienced dead, collapsed on 26Jan2021. Therapeutic measures were taken as a result of collapsed. The outcome of collapsed was unknown. The patient died on 26Jan2021. It was not reported if an autopsy was performed. Received Covid vaccine here on 21Jan2021, was at work on 26Jan2021 and collapsed, no known complaints at the time, CPR (cardiopulmonary resuscitation) was initiated immediately, transported to ER (Emergency room) and pronounced dead. Unknown if other vaccine in four weeks. The patient had COVID prior vaccination. Unknown If COVID tested post vaccination.; Sender's Comments: Based on the information currently provided, the patient was immunocompromised and had prior COVID infection. The death and syncope more likely are associated with the patient underlying medical conditions. More information such medical history, concomitant medications, treatment indication and event term details especially death cause and	No prior vaccinations for this event.

autopsy results are needed for fully medical assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Dead		
	SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient expired. Per Emergency MD note: ""This is a 72-year-old male with what sounds like diabetes, atrial fibrillation, and hypertension who presents via EMS in cardiac arrest. It sounds like he received his Covid vaccine last week. Initially he had some mild effects from it. However over the last day or so he has felt very unwell. He apparently called his wife today and told her that he was not feeling well and so she returned home. Shortly thereafter he attempted to get up from his chair. He then collapsed and fell forward onto his face. Sounds like his wife had some difficulty rolling him over to perform CPR. When EMS arrived they found him in PEA. He received a total of 5 rounds of epinephrine. At some point they did have return of spontaneous circulation. However just prior to arriving in the emergency department they lost pulses again. The patient was intubated with an 8 oh endotracheal tube prior to arrival."""		No prior vaccinations for this event.
	SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious,		No prior vaccinations for this event.

but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

	SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
73-year-old man s/p first dose of Pfizer at 10:20 AM Ambulated comfortably to exit after 20 minutes in observation but 10:45 collapsed while exiting the building 10:47 CPR initiated 10:49 medical team/EMS found no pulse, agonal respirations, ventricular fibrillation Paramedics and team performed ACLS; of note patient was intubated 7.5 ETT with bilateral breath sounds on ventilation; paramedic reported easy intubation with no apparent throat swelling; 11:02 transported to Emergency Department 11:30 Pronounced dead at Emergency Department		No prior vaccinations for this event.

	SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

My mom only had site soreness after her covid vaccine on 1/21 which resolved within a couple days. However, she died in the early morning hours of 1/25, she was fine the day before, no sign of injury. We found her collapsed on the ground and although we tried cpr she was already dead. She had gone to the hospital on 12/28 for shortness of breath, angina and symptomatic anemia, her ekg was unchanged and blood work normal except for anemia. The cardiologist did not think a cardiac cath was needed. Her shortness of breath improved with a blood transfusion and a dose of lasix (no heart failure).	No prior vaccinations for this event.	
SYNCOPE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Individual collapsed 9 days post-vaccination with no known reason. Despite being healthy prior to vaccination, individual's condition deteriorated rapidly. Individual passed away on 1-17-2021.	No prior vaccinations for this event.	
SYNCOPE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia	No prior vaccinations for this event.	
SYNCOPE		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/4/21, at around 3:00pm he began feeling very tired and he began burping in the evening. The following morning, he woke up early and was still burping and not feeling well. At around 5:00am, he	No prior vaccinations for	

collapsed. My mother called 9-1-1 and began giving CPR. The parademics arrived and tried to revive him, and transported him to the hospital but at 6:11am, he was pronounced dead of a heart attack. He was healthy.		this event.
	SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and		No prior vaccinations for this event.

expired at 1545h on 2/13/2021."

	SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient was not vaccinated at hospital. Caregiver reports that patient was vaccinated with second dose on Monday 2/15/21. Tuesday patient experienced n/v/d. Went to an ED on Wednesday and was cleared and sent home. Thursday reported shortness of breath to her caregiver and then collapsed. Patient was brought to as PEA arrest and ultimately died.		No prior vaccinations for this event.

	SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to		No prior vaccinations for this event.

EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

	SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Extreme difficulty breathing upon exertion, collapsed shortly after walking started, loss of conciousness, and death		No prior vaccinations for this event.

	SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was into the clinic on the afternoon of 2/23/21 for a COVID-19 vaccine. He had a podiatry clinic visit after his vaccine same day. It was reported by the patients family physician that patient stated he didn't feel well and suddenly collapsed at home at approximately 4:45 pm. Emergency medical personnel were not able to revive him. Patient died at approximately 4:45 pm on 2/23/21.		No prior vaccinations for this event.

	SYNCOPE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
within 24 hours after her second injection she developed chills, had a syncopal episode and had, difficulty		No prior vaccinations for

breathing. this progressed over the next day when she had a second syncopal episode and her dyspnea and confusion worsened EMT was called and she was brought to the hospital. she was in flash pulmonary edema and with her history of severe aortic stenosis she was admitted to the cardiac icu. she had no prior history up to that time of pulmonary edema and was functioning without distress in her home. she had a history of covid in early april, manifesting primarily as severe confusion, from which she recovered.		this event.
	SYSTEMIC INFLAMMATORY RESPONSE SYNDROME	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."		No prior vaccinations for this event.
	TACHYCARDIA	**COVID19 (COVID19**

		(MODERNA)) (1201)
Congestion, Hypoxia, SOB, Tachycardia, Weakness. Started on O2 @ 3L, HOB elevated, Tylenol supp	No prior vaccinations for this event.	
TACHYCARDIA		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the Moderna COVID vaccine 1/28/21. He was tested for COVID 19 on 1/29/31. Results were received 1/30/21, at which time he was evaluated and found to be hypoxic with tachycardia. He was sent to the local ER and returned this same day. On 2/2/21, he was evaluated by the provider, who sent him to the emergency room with acute respiratory distress and poor O2 sats	No prior vaccinations for this event.	
TACHYCARDIA		**COVID19 (COVID19 (MODERNA)) (1201)**
Death within 30 days: Admit 2/8/21-2/13/21 s/p fall with left hip fracture (repaired), severe debility with recurrent falls discharged to SNF. Not doing well postop at the SNF, brought to ED due to failed foley insertion with bright red blood upon arrival to ER febrile, hypotensive, tachycardic, severe sepsis. Gran negative bacteremia likely from chronic ascites, family decided on comfort care and he expired within hours of admission.	No prior vaccinations for this event.	
TACHYCARDIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart	No prior vaccinations for this event.	

block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."

TACHYCARDIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

At approximately 12:15 pm the resident had a brief unresponsive episode that resolved quickly. Her Vital signs were stable and her mentation was at baseline. Later that evening approximately 10 pm she had labored respirations, shortness of breath, lethargy with bilateral crackles, Oxygen desaturated to 76% on room air, tachycardia and hypotension. She expired at 6:30 a.m. the following day.

No prior vaccinations for this event.

TACHYCARDIA

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"shortness of breath, chest xray with pulmonary edema, periorbital edema Narrative: 73 yo M w/ PMH HTN, HLD, EVAR (2013) for AAA c/b persistent type II endoleak s/p multilple repairs (2015 & 2017) c/b glue embolization down into the R CIA secured with additional stent placement with the R iliac limb, s/p b/l Iliac artery aneurysm stent 08/31/20, and PTSD. Former smoker, quit 12+ yrs ago. 11/1/20-11/6/20: Hospitalized for acute on chronic back pain, found to multiple hypermetabolic lesions in the axial skeleton. Diagnosed with epithelioid angiosarcoma. Patient discharged to facility. 12/17/20: Patient received his 1st COVID-19 vaccine w/o complications at facility. 12/21/20: Underwent cyberknife treatment. 12/31/20: Transferred from facility to ER for new O2 requirement, SOB, cough, chest X ray / pulm edema, tachycardic and new periorbital edema. 12/31/20: Admitted to ICU before transfer to acute care. 1/1/21: Pulmonary consult, ""Labs are notable for progressive left shift with bandemia, markedly elevated inflammatory markers (D-dimer, ESR, CRP, ferritin, LDH), mild elevation in procalcitonin, mild elevation in lactate that has improved, and negative viral panel including COVID-19 x2. CT chest is notable for b/l GGOs along with some interstitial infiltrates with an upper and particularly mid zone and perihilar predominance, septal thickening and crazy paving, and numerous cystic lesions or pneumatoceles. There is a lack of lobar consolidation and pulmonary nodules. Of note, PET/CT about 2 months ago only demonstrated some mild to moderate emphysema mostly in the upper lobes. Therefore, there has been a relatively dramatic change in a few months, suggesting a more subacute process, rather than an acute infectious process such as a viral pneumonia, including COVID-19 infection, in which the GGOs tend to be subpleural and peripheral. Overall, our suspicion for COVID-19 is relatively low, with negative testing x2 yesterday, negative testing a few weeks ago, and lack of sick contacts, but it is possible. Therefore, higher on the differential is a more subacute infection or chemotherapy-induced pneumonitis. Risk factors include malignancy, chemotherapy, and use of steroids (equivalence of about 27 mg of Prednisone in the form of Dexamethasone since 11/6/20 without PJP prophylaxis). These risk factors, along with consistent imaging and elevated LDH, make PJP quite likely. Fungal infection is less likely based on imaging. Chemotherapy-induced pneumonitis is a possibility, especially given the more subacute picture based on imaging. Both Gemcitabine and Docetaxel can cause pneumonitis. However, the patient has been on steroids, which is used to treat drug-induced pneumonitis, although this does not exclude it completely."" 1/2/21: Transferred to ICU for worsening hypoxemia as patient reached 40L/100% FIO2 and remained on COVID isolation/COVID patient under	No prior vaccinations for this event.

investigation per ID recommendation. 1/4/21: Isolation precautions discontinued due to lower suspicion for active COVID infection to explain current presentation 1/6/21: Went into atrial fibrillation w/o RVR overnight 1/6. Tolerating, with MAPs in low 60s and HR in high 90s/low 100s. Suspect due to being-1L yesterday from diuresis, lasix stopped. S/p amiodarone bolus + drip, albumin 5% bolus 1/5/21: Macrocytic anemia NOS w/ slowly worsening H/H s/p PRBC x 1 unit 1/7/21: Per ICU Life-sustaining treatment note, ""Following discussion w/ patient that his lung dx has been refractory to txt and hasn't improved despite maximal therapy, patient agreed to transition to hospice after he settles affairs. "" 1/7/21 Infectious Disease note: ""This is an immunocompromised host due to cancer on active chemotherapy (albeit ANC>4000 on admission) and notably had been on daily PO dexamethasone 1 mg TID (total daily dose 3 mg, equivalent to 20 mg PO prednisone) since 11/6/20 without any PJP ppx. There was elevated c/f COVID-19 infection in setting of patient's presenting symptoms, especially in conjunction with b/l GGOs on imaging. Has undergone multiple COVID test that have all resulted negative. Discussed radiographic findings with radiology colleagues, and overall, it is difficult to definitively narrow the differential with imaging alone, but overall density of GGOs seem to appear less likely PJP and more in line with chemical pneumonitis vs COVID, although less typical for viral pneumonia as well. Given false-negative COVID tests are not unheard of, especially in the immunocompromised population, patient was kept on isolation precautions as a PUI for abundance of caution. He is now off precautions. In setting of patient having been on prednisone for some time without PJP ppx, he was also started on treatment dose TMP/SMX. Beta-d-glucan has returned positive, and although not the ideal test for PJP, this can certainly support a potential dx of PJP. Unfortunately, DFA from sputum was not performed due to insufficient sample and currently the patient is unable to produce an additional sample for testing. He is tolerating the high-dose TMP/SMX; we adjusted the dose to three SS tablets TID based on his somewhat declining UOP. Other fungal etiologies are pending work-up as well. Lastly, patient's chemotherapy is known to cause pneumonitis, but per pulmonology team, he receives prophylactic dexamethasone with his chemo cycles that should help to prevent drug-induced pneumonitis. Remains on the differential for now and this should also be concurrently treated with the steroids he is receiving."" 1/10/21: Comfort care initiated. All non-comfort measures were discontinued. Time of death: Jan 10,2021@14:56; immediate cause of death per death note is ""hypoxic respiratory

failure"""

TACHYCARDIA	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

See initial report No prior vaccinations for this event.

TACHYCARDIA COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis. Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19

No prior vaccinations for this event.

vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

	TACHYCARDIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	New onset dizziness with hypotension, tachycardia, and vomiting blood. Sent to ER - told he went into cardiac arrest and died.	No prior vaccinations for this event.
	TACHYPHRENIA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
	he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was okay, but he was very agitated; reported as not like this prior to the vaccine. The patient was taken to urgent	No prior vaccinations for this event.

care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away

TACHYPNOEA

COVID19 (COVID19 (MODERNA)) (1201)

This patient has been under hospice care for over 2 years at the nursing home. She has had a steady decline with gradual weight loss. She was totally dependent in her care needs. She received the vaccine on 1/2/2021 as part of the facility vaccination campaign. No adverse events noted initially. On 1/3/2021 at 6:06 pm, she was noted on vital sign checks (done every 4 hours for first 72 hours after vaccination) with BP 64/52 but otherwise asymptomatic. Subsequent BP improved. On 1/4/2021 at 4:45 am, pt found with respiratory rate of 30 with otherwise normal vital signs. Tachypnea persisted, so she received liquid morphine 2.5 mg without improvement. Supplemental oxygen was applied. Tachypnea persisted. She had poor oral intake after that point had persistent tachypnea and worsening hypoxemia despite clear lungs on exam. She remained under hospice care and comfort measures were continued. No blood testing or imaging tests were done. She required increasing amounts of oxygen, became hypotensive, and died peacefully on 1/8/2021 at 7:45 pm.

No prior vaccinations for this event.

	TACHYPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Moderna Vaccine Lot 029K20A Patient received second dose of vaccine on 2/2/21. Within 30 minutes patient had a near syncopal episode. She felt lightheaded and shortly after had episode of nonbloody vomiting. Hypotensive 81/69 and started on levophed. Alert and orientated. Lungs clear, abdomen benign on admission. Patient had no reaction when received first dose of the vaccine. Patient developed worsening shortness of breath, tachypnea, Afib with RVR, hypotension and required intubation and multiple pressors.		No prior vaccinations for this event.
	TACHYPNOEA	**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine was administered at Nursing Facility. Patient is an 89-year-old female with prior medical history of CVA with dysphagia, history of possible dementia, GERD, hyperlipidemia, and a pacemaker. She is a resident from town. She was sent for hypotension with a blood pressure of 90/52, tachypnea respirations of 54, possible aspiration pneumonia. Status post Covid vaccine earlier today. History is limited as patient is nonverbal on my exam. Death within 24 hours of vaccination		No prior vaccinations for this event.
	TACHYPNOEA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no		No prior vaccinations for this event.

hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50.

Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

TASTE DISORDER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.	No prior vaccinations for this event.
TENDERNESS	**COVID19 (COVID19 (MODERNA)) (1201)**
Mentation has declined since hospital discharger for fall on 2/6/20201. Patient has also had significant poor oral intake. Brought in due to apneic episodes. Abdominal pain - diffuse tenderness (right sided) Elevated liver enzymes - likely secondary to dehydration Increased serum creatine kinase - likely due to dehydration	No prior vaccinations for this event.
TERMINAL STATE	**COVID19 (COVID19 (MODERNA)) (1201)**
Hypoxia, Decreased responsiveness, Narrative: 86yo male with PMHx HTN, Afib not on AC after head trauma, CVA, and colon cancer who was brought to the ED by his family on 2/17. Per documentation the pt	No prior vaccinations for

was in his usual state of health until 2/16. Received Moderna covid vaccine #2 on 2/16/21 at 0900, and was this event.
monitored for 15 minutes following immunization no noted issues. Later that night, had myalgias and took Tylenol. Per the family he slipped on the ice and fell on his butt. Overnight, had several dark stools and vomitus. was brought to the ED by his family because he was being less responsive. Pt arrived to the emergency department in extremis. No pulse identified. CPR immediately initiated for several rounds lasting about 25-30 minutes. ROSC unable to be achieved. Patient expired on 2/17 at 1941. Of note, per previous documentation had waxing and waning mental status at baseline. No symptoms noted with 1st dose of Moderna vaccine, which was administered on 1/16/21.

TERMINAL STATE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death - Hospice patient with metastatic CA admitted to facility and received vaccine during stay. No adverse sequelae noted from vaccine administration, but reporting as required because pt died 7 days later. Narrative: Reporting this event because patient died 7 days after receiving vaccine in the facility where he was in hospice care for metastatic cancer. Vaccine was administered by protocol without complications. The patient had been asked and denied any prior severe reaction to this vaccine or its components and gave permission to receive it. No vaccine adverse sequelae were documented after the immunization as monitored for 15 minutes nor in facility notes for 7 days after the immunization. The patient's death was felt to be due to underlying terminal illness.

No prior vaccinations for this event.

THROAT CLEARING

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other

No prior vaccinations for this event.

vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."

THROMBECTOMY	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/17/2021 patient woke and began her day as usual, was found down by family member 1 hour later conscious but unable to speak and unable to move her R side. She was admitted to the hospital - Initial NIHSS was 26 and CT imaging showed no acute hemorrhage but mild hypodensity of greater than 1/3 of the MCA territory (TPA not recommended). CTA did show distal L M1/M2 occulsion and she was transferred to larger facility for thrombectomy. Unfortunately the patient had persistent severe neurological deficits after thrombectomy. Was discharged home on hospice care and expired on 1/23/21.	No prior vaccinations for this event.
THROMBECTOMY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal tunnel and sent her home. The morning or March 18th , 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.	No prior vaccinations for this event.

THROMBOCYTOPENIA		**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine administered 02/08/2021 , by Thursday 02/11/2021 patient almost nonverbal, by Monday 02/15/2021 patient went to the hospital with bruising, sores on her stomach and clots reported as thrombocytopenia, deceased by Friday 02/19/2021.		No prior vaccinations for this event.
THROMBOCYTOPENIA		**COVID19 (COVID19 (MODERNA)) (1201)**
It was reported to staff that this gentleman suffered thrombocytopenia following his vaccine, a platelet infusion was done and he expired on 2-14-21		No prior vaccinations for this event.
THROMBOCYTOPENIA		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.		No prior vaccinations for this event.
THROMBOSIS		**COVID19 (COVID19 (MODERNA)) (1201)**
Vaccine administered 02/08/2021 , by Thursday 02/11/2021 patient almost nonverbal, by Monday 02/15/2021 patient went to the hospital with bruising, sores on her stomach and clots reported as thrombocytopenia, deceased by Friday 02/19/2021.		No prior vaccinations for this event.
THROMBOSIS		**COVID19 (COVID19**

		(MODERNA)) (1201)
"My grandpa had a stroke on the 15th of February. He claimed he had been feeling ""off"" for a few days, but didn't say anything. A blood clot had formed in his brain. He was doing better and about to go to rehab to strength his right side of his body. On the 22nd he took a turn for the worst. He was having trouble breathing and they sedated and partially paralyzed him to put a tube in his mouth. I believe another blood clot had formed and oxygen wasn't properly going through his body. They could not stabilize him, and he passed away the same day."	No prior vaccinations for this event.	
THROMBOSIS		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
she was hurting at her chest/ Chest pain; on her left arm hurt real bad that's what the clot on her left arm; on her left arm hurt real bad that's what the clot on her left arm; She passed away; heart attack; This is a spontaneous report from a contactable consumer. An 87-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Jan2021 at single dose for COVID-19 immunisation. Medical history included diabetes mellitus, for which she was taking a pill like an hour before she would take her meal. On Monday (Jan2021) the patient experienced was hurting at her chest/ chest pain, her left arm hurt real bad as she had a blockage in her left arm/clot on her left arm, and they wanted to put in a stent and after the surgery it went well and she all go home in two days. The patient was hospitalized in Jan2021 due to the events. She had a heart attack and that the chamber between the dividers had a hole in it and her heart tissue was too thin so much thin she couldn't repair it. The patient passed away on 26Jan2021. The patient was tested negative for COVID-19 on unknown date. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: She passed away	No prior vaccinations for this event.	
THROMBOSIS		**COVID19 (COVID19**

	(PFIZER-BIONTECH)) (1200)
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
THROMBOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient reported to Emergency room on 01/23/2021 with complaint of nausea. According to ER record patient reported he received a COVID 19 vaccine Pfizer the day before. Work up in the ER (CT ABD PELVIS) reveal a clotted of SMA. CT CHEST REVEALED BILATERAL PULMONARY EMBOLUS. THE PATIENT WAS TRANSFERRED TO THE STATE HOSPITAL. HE WAS SCHEDULED FOR EMERGENT VASCULAR SURGERY WHICH WAS CANCELLED AS THE PATIENT DIED SHORTLY AFTER HIS ARRIVAL.	No prior vaccinations for this event.
THROMBOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.	No prior vaccinations for this event.
THROMBOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Patient woke up on the morning of 2/6 with symptoms of a stroke. Rushed to hospital where clot found in brain. Recovered from initial stroke but then had another major stroke on 2/8 and never recovered.	No prior vaccinations for this event.
THROMBOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After the second vaccine dose she reported not feeling well with unspecified symptoms for a few days. On February 18th, 2021 she visited her doctor with numbness in her hand. They thought it may be carpal tunnel and sent her home. The morning or March 18th , 2021 she had a severe stroke and was transferred to Hospital and then to other hospital. She was in the hospital until Tuesday March 23rd when she was transferred back to her home for hospice care. She died on March 26th, 2021.	No prior vaccinations for this event.
THROMBOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
blood clot; death cause: Heart Problems; tired; nauseous; This is a spontaneous report from a contactable consumer. An 81-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot number EL3248), via an unspecified route of administration at single dose in the left arm on 19Jan2021 14:00 for covid-19 immunisation. Medical history included heart problems, pacemaker. Concomitant medication included heparin. The patient experienced death cause: heart problems on 20Jan2021, blood clot on an unspecified date with outcome of unknown that required hospitalization, tired on 19Jan2021 with outcome of unknown, nauseous on 19Jan2021 with outcome of unknown. The patient was hospitalized for blood clot from 16Jan2021 to 18Jan2021. The patient died on 20Jan2021. An autopsy was not performed. The events were described as follows: The patient was tired and nauseous about 3 hours after her vaccine. She had been in the hospital 16Jan2021 to 18Jan2021 for a blood clot. The patient died at her home on 20Jan2021 between 4 and 7 pm. No treatment required. The	No prior vaccinations for this event.

vaccine was administered at Hospital Facility. Prior to vaccination, the patient was not diagnosed with COVID-19 and since the vaccination, the patient had not been tested for COVID-19.; Reported Cause(s) of Death: death cause: Heart Problems

THROMBOSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"DEATH Narrative: patient's wife reported he had gone in an outside hospital, had held his brilinta as advised anticipating shoulder surgery ""and he threw a big clot and died.""""	No prior vaccinations for this event.
THROMBOTIC THROMBOCYTOPENIC PURPURA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had one occurrence of thrombotic thrombocytopenic purpura in 1996 for which she had plasma exchange therapy in 1996. No other occurrence since 1996 until she received her first dose of the Pfizer covid vaccine.	No prior vaccinations for this event.
THROMBOTIC THROMBOCYTOPENIC PURPURA	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt received dose #1 of COVID-19 vaccine (Pfizer-BioNTech) on 12/18/20 and dose #2 (Pfizer-BioNTech) on 1/8/21. On 1/30, patient was evaluated at urgent care due to back pain. No bloodwork done; metronidazole prescribed for 7 days. On 2/8, patient was admitted to outside hospital due to ongoing symptom progression. At time of admission, hgb 5 g/dL and plt 9k. Per Dr. (hematology/oncology), pt with schistocytes, LDH 1500, and elevated reticulocyte count consistent with thrombotic thrombocytopenic purpura (TTP). SCr >2 mg/dL. Patient immediately treated with plasma exchange and steroids, however	No prior vaccinations for this event.

continued to decline. Patient expired on 2/14/21.

	THYROID FUNCTION TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.

	TISSUE INJURY	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient tested positive for COVID-19 on 1/8/21. She demonstrated a decline in appetite and the ability to feed herself d/t this illness, but no respiratory or other symptoms. She received COVID-19 vaccine #2 on 1/26/21. She demonstrated an SDTI wound to the Lt. heel on 1/27/21. On 1/31/21 she was noted to have a significant weight loss. She was admitted to services on 2/1/21 with comfort care orders. On 2/2/21 she was observed to be without vital signs. Orders were for DNR, and CPR was not initiated in accordance with that order. She was pronounced dead at 0112 on 2/1/21.		No prior vaccinations for this event.

	TOOTHACHE	**COVID19 (COVID19 (MODERNA)) (1201)**
The patient went home around 11 am on 1-31-21 after her vaccine and 15 minute observation period. She was eating breakfast after at home and complained to a neighbor that her teeth hurt and she was		No prior vaccinations for

nauseated after eating. In the afternoon, she felt dizzy and had diarrhea accompanied with blood. Close to 9 PM, her son went to check on her. The patient was found on the floor--she was unresponsive and had purple lips. Her son called an ambulance and started chest compressions. The patient passed away at the hospital. The doctor has ordered an autopsy, and the results are pending.		this event.
	TOXIC EPIDERMAL NECROLYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Presented from clinic with 3-4 days of extensive rash. There were multiple areas of skin sloughing on bilateral upper extremities and abdominal wall.		No prior vaccinations for this event.
	TOXICOLOGIC TEST	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received COVID-19 (Moderna) vaccine from the Health Department on afternoon of January 8, 2021 and went to sleep approximately 2300 that night. Was found unresponsive in bed the following morning and pronounced dead at 1336 on January 9, 2021		No prior vaccinations for this event.
	TOXICOLOGIC TEST	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No symptoms or signs on the day 1st dose of vaccine was received (2/11/2021). 3 days later, (2/14/2021) patient experienced chills for approximately 6 hours, followed by severe (visible) chest spasms, and then cardiac arrest. 911 was called upon witnessing chest spasms, but cardiac arrest/death occurred before patient could be transported to the hospital.		No prior vaccinations for this event.

TOXICOLOGIC TEST NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN

No prior vaccinations for this event.

- CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

TRACHEAL ASPIRATE CULTURE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"Narrative: See ""Other Relevant History"" in Section 6 above Other Relevant Hx: 76yo man with a history of for C5 tetraplegia 2/2 cervical stenosis leading to neurogenic bowel/bladder (chronic suprapubic catheter) and chronic respiratory failure with tracheostomy, severe dysphagia s/p G tube placement and multiple aspiration pneumonias, COPD GOLD III, hx MRSA bacteremia (7/2018) and E coli bacteremia (12/2019). Patient transferred from Spinal Cord Injury until to ICU on 1/11/2021 due to worsneing dyspnea, hypoxia (80s) and tachycardia and was found to have acute hypoxic respiratory failure likely 2/2 multifocal pneumonia. CXR findings of ""There is interval increase in patchy airspace infiltrates and consolidation in bilateral lungs concerning for pneumonia"" Patient was started on vancomycin and pip/tazo on 1/11 and tracheal aspirate cultures were obtained for VAP diagnosis which ultimately grew Serratia liquifaciens and Proteus mirabilis.

No prior vaccinations for this event.

Infectious Diseases was consulted who recommended a switch to ertapenem therapy for a total 10 day course for VAP. UCx/BCx remained negative. On 1/20, a therapeutic bronchoscopy was completed with cultures growing Stenotrophomonas maltophilia and pan-S Klebsiella pneumoniae. The following day a chest tube was inserted and the course of ertapenem completed but vancomycin was continued. By 1/22, patient developed shock liver with ALT/AST 2135/1579 from normal range the day prior and SCr increased to 1.3 from baseline 0.7/cystatin C of 2.46 up from 1.15. Levofloxacin was added for Stenotrophomonas coverage. By 1/25, patient's clinical status continued to decline and Cardiology was consulted for new onset Afib with RVR. Discussion was documented with patient's family who requested DNR. Patient passed away in the early AM on 1/26. Demise does not appear to be related to COVID-19 vaccination but occurred in recent timeframe. Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib"

TRANSFUSION		**COVID19 (COVID19 (MODERNA)) (1201)**
pt received vaccine on 2/3. early on 2/4 developed chest pain, dyspnea, and was seen in ED and diagnosed with acute exacerbation of CHF and NSTEMI type 2, and anemia. on 2/5 transfusion was started and pt developed worsening dyspnea and then PEA arrest. Pt achieved ROSC and was transferred to the cardiac intensive care unit where he required vasopressor support. he subsequently declined and died on 2/7		No prior vaccinations for this event.
TRANSFUSION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My mom only had site soreness after her covid vaccine on 1/21 which resolved within a couple days. However, she died in the early morning hours of 1/25, she was fine the day before, no sign of injury. We found her collapsed on the ground and although we tried cpr she was already dead. She had gone to the hospital on 12/28 for shortness of breath, angina and symptomatic anemia, her ekg was unchanged and		No prior vaccinations for this event.

blood work normal except for anemia. The cardiologist did not think a cardiac cath was needed. Her shortness of breath improved with a blood transfusion and a dose of lasix (no heart failure).

	TRANSFUSION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."		No prior vaccinations for this event.

	TRANSFUSION	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.	No prior vaccinations for this event.
TREMOR	**COVID19 (COVID19 (MODERNA)) (1201)**
"On 1/15/2021 at 1800, resident noted to be lethargic and shaking, stating ""I don't care."" repeatedly. C/O head and neck pain. T100.6. Given Tylenol with no relief of pain. Order received for Aleve and administered.. Assisted to bed as usual in evening. Monitored during night shift and noted to be resting comfortably/sleeping.. Noted agonal breathing at 4:10 AM 1/16/2021 , T 99.4, Absence of vital signs at 4:15AM 1/16/21 and death pronounced at 4:40AM 1/16/21."	No prior vaccinations for this event.
TREMOR	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received Moderna COVID vaccine on 12/30/2020 at a Pharmacy clinic where he was a resident. Nurses at the facility reported that he was responsive and showed no signs of any adverse effects until 1/2/2021 when he was observed slightly unresponsive and staring at the ceiling and trembling. He had a fever of 101F at this time. The facility ordered labs and a rapid COVID test (all of which came back normal) and started IV antibiotics. A few hours later, patient began bleeding from his eyes, nose, and mouth and was sent to the local ER. The patient refused being admitted to the ICU for possible sepsis/hemorrhage and died the following day on 1/3/2021. All healthcare professionals involved agreed that this was not likely due to the	No prior vaccinations for this event.

vaccine, but needed to be reported nonetheless.

	TREMOR	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident reviewed for incident. Resident received the second dose of the Moderna Covid-19 vaccine lot# 016M20A Exp 5/2/2021 on 2/5/2021 from clinic through pharmacy. Resident had her temp/O2 taken on AM shift and was 98.6/93%, beginning PM shift 98.4/95%. A few hours later noted that resident to have chills and was shaking RN assessment completed and vitals taken resident noted to have temp of 102.2, oxygen 95%, pulse 110. Resident alert and oriented at that time and talking to staff. Reported findings to APNP with order to send to ER. 911 called, residents brother updated. Upon EMT arrival RN went down to residents room with EMT and resident had an emesis as resident was getting cleaned up resident went unresponsive. Pulse noted to still be present at that time, resident did briefly respond to sternal rub and then went unresponsive again. Resident full code and EMT transferred to gurney and said that if they lost a pulse in route that they would transfer to hospital B instead of hospital A being the closest facility. RN called brother and gave update. Facility notified from Hospital that resident had passed away.		No prior vaccinations for this event.
	TREMOR	**COVID19 (COVID19 (MODERNA)) (1201)**
He vaccine on 2/5/2021 I went to see my husband the next day he was shaking and his mouth was open shaking, and he had fever of 105, they gave him Tylenol suppositories and he passed away 2 hours later. They should not have given him should not have given him the vaccine that is on hospice, it was not the right decision. I am worried about the elderly and those very sick.		No prior vaccinations for this event.
	TREMOR	**COVID19 (COVID19 (MODERNA)) (1201)**
Day after second dose decedent had fever and tremors, subsided on day three (less than 72 hours)		No prior vaccinations for this

after dose with exterem wekness followed by death less than 72 hours after second dose		event.
	TREMOR	**COVID19 (COVID19 (MODERNA)) (1201)**
	Blood pressure went down until he died; Couldn't hear his heartbeat; neck was sweating; He was cold; Couldn't get up; Death; Sick; immediately very tired; he was tired; Hands were shaking; Slept for too long; A spontaneous report was received on 18 Feb 2021 from a consumer concerning a 81-years-old, male patient who received Moderna's COVID-19 vaccine and developed immediately very tired, hands were shaking, neck was sweating, was cold, sick, couldn't get up, couldn't hear his heartbeat and blood pressure went down until he died. Patients' medical history, as provided by patient's spouse, was emergency room(ER) admission in November 2020 because he had a congested chest (he had fluid around his heart). At that time, they gave him pills for kidney function. Other concomitant medication reported was Coumadin, blood thinner. Two weeks before receiving the vaccine, patient's EKG was normal. On 11 Feb 2021, in the morning, patient received their first of two planned doses of mRNA-1273(BATCH/LOT # 007M20A) probably in the right arm for the prophylaxis of COVID-19 infection. On 11 Feb 2021, approximately after 15 minutes of receiving vaccine, they left and patient was immediately very tired, his hands were shaking. So, patient's spouse made them down sleep for too long. On Friday, 12 Feb 2021 she tried to pick him up, but he was tired, exhausted, and sick. On Saturday, 13 Feb 2021, she brought him a coffee and he couldn't hold it because his hands were shaking, so she gave him the coffee and then made him pee on the bed because he couldn't get up. At lunch time she made him eat something and he fell sleep again. His wife was hanging around him all day and around 7:30pm she realized that he was cold, and his neck was sweating, she couldn't hear his heartbeat. So, she called emergency services and when they arrived, her husband's blood pressure went down until he died. Treatment for the events were not provided. Action taken with mRNA-1273 was not applicable. Patient was pronounced dead on 13 Feb 2021 20:00. The cause of death was not provided. The plans for an autopsy were not provided. The events of blood pressure went down until he died and couldn't hear his heartbeat were fatal. The outcome for the remaining events were unknown.; Reporter's Comments: This case concerns an 81 year old, male patient, who experienced a	No prior vaccinations for this event.

serious event of death among others, 2 days after receiving mRNA- 1273 (Lot# 007M20A). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

	TREMOR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No adverse effects from vaccination seen on 1/2/21. On 1/6/21 resident was seen by Dr and her baclofen pump was refilled with 20 ml Baclofen 4,000mcg/ml. ITB Rate increased by 6% to 455.5 mcg/day simple continuous rate over 3 days. On 1/8/21 at 0615 resident was shaking, lower extremities mottled, Sa02 70%, pulse 45. Oxygen started at 2 L/m per NC. At 0715 her primary physician was notified as well as her daughter. Oxygen increased to 4 L/min, sats at 83%. SOA noted, reported all over pain. At 0850 when they attempted to reposition the resident, she was not responsive. Licensed nurse assessed her and no heartbeat heard or pulse found.		No prior vaccinations for this event.

	TREMOR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated		No prior vaccinations for this event.

hospital bed. Patient committed suicide in home.

	TREMOR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Shaking and then became unresponsive No prior vaccinations for this event.

TREMOR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	

"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."	No prior vaccinations for this event.

	TREMOR	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident on Hospice. 1/18 Hand Shaky. 1/19- Covid +19. 1/20 Desat 85% on RA, provided 2L O2 supplement= 97% 1/20 congestive cough, 1/28- RR-28;1/29- Hypoglycemia 1/30-NPO. 1/30-resident passed away.	No prior vaccinations for this event.

	TREMOR	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
	heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, collapse of lung (caused hospitalization) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his big toe had turned gray on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown. The events his big toe had turned gray and his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically induced coma and reduce his body temperature that evening and started dialysis on 21Feb2021. They returned his body to normal temperature on 23Feb2021, his pulse was in the 130s/140s. They were starting to reduce the sedatives on 23Feb2021. The patient passed away on 23Feb2021. It was not reported if an autopsy was performed. No follow-up attempts are possible;	No prior vaccinations for this event.

information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: passed away

TRI-IODOTHYRONINE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.	No prior vaccinations for this event.
TRICUSPID VALVE INCOMPETENCE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt presented to ER with SOB on 01-29-2021. He was admitted to Healthcare with acute CHF exacerbation, elevated lactate, anemia and elevated d-dimer. Pt reports getting SOB getting up to go to the bathroom. Pt was intubated. He developed pulmonary edema. Pt expired on 02-02-2021 at 10:13 PM.	No prior vaccinations for this event.
TROPONIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus	No prior vaccinations for this event.

in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

TROPONIN	**COVID19 (COVID19 (MODERNA)) (1201)**
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.

TROPONIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.	No prior vaccinations for this event.

TROPONIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.	No prior vaccinations for this event.

TROPONIN	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.	No prior vaccinations for this event.

TROPONIN I INCREASED	COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.	No prior vaccinations for this event.
TROPONIN I INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506	No prior vaccinations for this event.
TROPONIN I INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was	No prior vaccinations for

not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

this event.

TROPONIN I INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no

No prior vaccinations for this event.

hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50.

Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

TROPONIN I INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fall 2/4 hospital admission 2/7/21 with death on 2/8/2021. Patient continued to decline on Bipap he was a DNR/DNI and family decided on comfort measures and he expired 2/8/2021.	No prior vaccinations for this event.
TROPONIN I NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was	No prior vaccinations for this event.

added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

TROPONIN INCREASED

COVID19 (COVID19

	(MODERNA)) (1201)
Pt presented to ER via EMS at 1556 3 days after receiving vaccine. pt was breathing approximately 50 times a minutes and o2 sats in the 70's upon arrival. NP decided to intubate, Rocuronium and Versed given. Pt became bradycardic and 1 amp of Atropine was given without improvement. No pulse felt, CPR started per ACLS protocol. 7 Epi's given. Time of death- 1632. After TOD pt was swabbed for COVID-19 and the results were positive.	No prior vaccinations for this event.
TROPONIN INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident c/o nausea evening of 1/29 (nausea common for her post dialysis), had a large emesis at approx 2220, 0030 (unusual for resident to vomit)- received Zofran per order. Skin cool and damp, Blood sugar 147 (checked due to h/o diabetes and poor intake). At approx 230am Blood pressured checked and noted to be 52/29. Resident transferred to ER, intubated and transferred to higher level of care where she passed away on 1/30 at 736pm. Resident's medical notes indicated likely shock, cardiogenic in nature, sepsis (source unknown) along with a multitude of other co-morbidities that resident has.	No prior vaccinations for this event.
TROPONIN INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was	No prior vaccinations for this event.

admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

TROPONIN INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29		No prior vaccinations for this event.
TROPONIN INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Admitted to hospital with sob upon exertion that started prior to vaccine. Hx COPD, HTN, CKD, hyperlipidemia, bladder cancer in remission. Stated he has been taking Eliquis and Xarelto between renal doctor and cardiologist Dr. Anticipating going home 2/5/21 but then turned blue and stopped breathing under a DNR. COVID test negative. Labs show acute on chronic renal failure with an elevated troponin likely from demand ischemia.		No prior vaccinations for this event.
TROPONIN INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed		No prior vaccinations

and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."		for this event.
	TROPONIN INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
ER visit 1/25/21 patient walked into a prompt care and collapsed, witnessed and pulseless CPR with ROSC after 6-7mins, no shock no meds. Awake and speaking upon arrival to ER. 2 plus pitting edema ble ER diagnosis Anasarca, cardiac arrest, hypotension, elevated troponin I levels, Acute kidney injury and syncope. ER notes reveal a syncopal episode in the shower prior to collapse at prompt care. Central line placed and plan to ship to another facility, patient continued to decline despite dopamine and dobutamine expired in ER prior to transfer.		No prior vaccinations for this event.
	TROPONIN INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.		No prior vaccinations for this event.
	TROPONIN INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH))**

		(1200)
PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.		No prior vaccinations for this event.
TROPONIN INCREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.		No prior vaccinations for this event.
TROPONIN INCREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident returned to the memory support unit at 1500. Resident was than toileted and transferred in to bed per his request. At 1515 resident was observed face down beside bed, resident sustained a 1inX1in		No prior vaccinations for

eccyhmotic/hematoma to the forehead. Neuro Checks with in normal limes Vital signs: 100/52, 100, 97.2, 28. Resident sent to ED for further medical evaluation via EMS.	this event.
TROPONIN INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Approximately 2 weeks post vaccination developed rapid AF, CHF. Admitted to Medical Center. Discharged home on hospice. Patient died at home on 2/13/2021. Reported to this reporter at second dose clinic on 2/16/21. Other details not known. Unknown if related to vaccine.	No prior vaccinations for this event.
TROPONIN INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute	No prior vaccinations for this event.

pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

	TROPONIN INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was tested for covid on 2/2/21 with positive resulted. Presented to Hospital ER on 2/10/21 with c/o of abdominal pain. Diagnosed with gastritis, prescribed metoclopromide and famotidine and dc home. Returned to ER on 2/13/21 with c/o of weakness, diarrhea, foot ulcer, and loss of appetite. Diagnosed: 1) Dyspnea and hypoxia secondary to Covid-19 2) Extensive bilateral lung infiltrates secondary to Covid-19 3) Increased Cr 4) Increased LFTs, ferritin, d-dimer, troponin secondary to Covid-19 5) Elevated procalcitonin placing the patient at high risk for sepsis 6) Chronic appearing Right foot wound without signs of secondary infection Patient transferred to a different hospital in another city.		No prior vaccinations for this event.

	TROPONIN INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Cardiogenic shock occurred on 2/10/2021, approximately 12 hours after patient received her 12th dose of pemetrexed/pembrolizumab and 4 days after COVID vaccine. Coronary angiography was done on 2/10/2021 and no significant coronary narrowing or blockage were noted. Baseline troponin on 2/10/21 was 0.02 and later on 2/10/21, troponins were 9.99 & 25.27. Creatinine increase from 1.2 to 3.4 within 24hours, and AST/ALT increased from 23 & 31 to 4,220 & 4,786 respectively on 2/11. Patient expired on 02/11/2021.		No prior vaccinations for this event.

TROPONIN INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)

No prior vaccinations for this event.

TROPONIN INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2

No prior vaccinations for this event.

42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these. Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was

pronounced at 2123 on 2/20/2021. Children were at bedside.

TROPONIN NORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
Presented to Urgent Care for weakness and confusion, transferred to ED, patient had a cardiac arrest and was unable to be resuscitated	No prior vaccinations for this event.	
TROPONIN NORMAL		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.	No prior vaccinations for this event.	
TROPONIN NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt develops left leg pain The day after vaccination in AM subsequently drove approximately 150 miles On his way back stopped at his brothers place for lunch. He then collapsed coning down the steps, EMS started CPR. took him to ER Resuscitated briefly but went into CardioPulm Arrest again and PEA Resucitaion for aprox 1 hour but was unsuccessful. Noted to have Left leg more swollen than Right by 3 to 4 CM presumed to have died from massive Pulmonary embolism and inferior wall myocardial ischemia	No prior vaccinations for this event.	
TROPONIN NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)	No prior vaccinations for this event.
TYPE 2 DIABETES MELLITUS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient with history advanced vascular dementia, hypertensive cerebrovascular disease and stroke, T2DM. Received her second dose of Pfizer COVID-19 vaccine at approximately 14:00 and was reported to have expired at home at 20:55. Dr. (Medical Director) spoke with patient's son/caregiver 2/4/21. Son reports that patient was in her usual health yesterday morning, deemed well enough by son to travel for vaccination. He reports she had no bothersome symptoms after either first or second vaccinations. Specifically denied rash, wheeze, and difficulty breathing. Son was with patient throughout the day. In the evening, when preparing for bed, he noted she became suddenly unresponsive in a similar fashion as she has done several times in past years. While in all previous such episodes she recovered within minutes, last evening she did not regain consciousness, experiences a brief period of labored breathing, and died. Patient's son called 911 and the patient's body was brought to the medical examiners. The medical examiner declined to proceed with autopsy. Patient's son is not interested in autopsy. Patient's son reports confidence that his mother's underlying hypertensive/diabetic cardiovascular disease is the natural cause of her death. Other Relevant Hx: Symptoms: & Death Treatment:	No prior vaccinations for this event.
ULTRASOUND ABDOMEN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
For the two days prior to presentation the patient had been complaining of chest pain, his breathing seemed to	No prior vaccinations

be labored Monday. He and the family thought the pain was due to shingles as he carried this diagnosis from a month ago. Patient had also received the COVID vaccine 2 days prior to presentation and assumed he was feeling unwell due to the vaccine. Family wanted to take him to the hospital yesterday and earlier today but he refused. She left him in his home earlier this afternoon prior to presentation and returned to check on him finding him unresponsive and apneic at which time EMS was activated. #cardiac arrest -- suspect primary cardiac given collateral from family at home, consider hypoxemia which was corrected with advanced airway and 100% FiO2, patient clinically euvolemic and with soft brown stool in diaper not suggestive of GI hemorrhage, attempt to address acidosis with CPR and bicarbonate, not hypoglycemia, on bedside ultrasound FAST neg and no pericardial effusion suggestive of tamponade and +lung sliding bil not spontaneous pneumothorax Assessment/Diagnosis: -cardiac arrest, cause unspecified

for this event.

ULTRASOUND CHEST

COVID19 (COVID19 (MODERNA)) (1201)

cough congestive heart failure death No prior vaccinations for this event.

ULTRASOUND SCAN **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Maternal exposure during pregnancy; Fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected; This is a spontaneous report from a contactable consumer (parent). This consumer reported information for both mother and fetus. This is a fetus report. A patient of unspecified age and gender (fetus) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269), transplacental on 04Feb2021 at 14:00 at single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medication included ergocalciferol (VIT D), folic acid (FOLATE), ascorbic acid/betacarotene/calcium sulfate/colecalciferol/cyanocobalamin/ferrous fumarate/folic acid/ nicotinamide/pyridoxine hydrochloride/retinol acetate/riboflavin/thiamine mononitrate/tocopheryl acetate/zinc oxide (PRENATAL VITAMINS) and sertraline hydrochloride (ZOLOFT) at 25 mg, all transplacental. It was reported that OB exam on 03Feb21 showed healthy baby at 7weeks 5days heartbeat detected 152 bpm; no abnormalities identified via ultrasound; labs and

No prior vaccinations for this event.

hormone levels all within normal ranges. No issues detected. Mother received 1st dose of vaccine on 04Feb2021. Per ultrasound on 20Feb2021, fetus stopped growing on 09Feb2021 (8 weeks 4 days); no heartbeat detected. Miscarriage occurred on 22Feb2021. The fetus died on 22Feb2021. It was not reported if an autopsy was performed.; Sender's Comments: Linked Report(s) : US-PFIZER INC-2021204433 same drug and reporter, different patient and event; Reported Cause(s) of Death: Fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected; Mother received 1st dose of vaccine 04Feb21. Per ultrasound on 20Feb21, fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected. Miscarriage occurred 22Feb21.

UNEVALUABLE EVENT

COVID19 (COVID19 (MODERNA)) (1201)

ARRIVED AT EVENT, CONSENT FORM COMPLETED, DID NOT REPORT HE HAD BEEN ILL, DID NOT REPORT THAT HE TOOK ANY FEVER REDUCING MEDICATIONS

No prior vaccinations for this event.

UNEVALUABLE EVENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Unknown

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI COVID19 (COVID19 (MODERNA)) (1201)

on 12/24/2020 the resident was sleepy and stayed in bed most of the shift. He stated he was doing okay but requested pain medication for his legs at 250PM. At 255AM on 12/25/2020 the resident was observed in bed lying still, pale, eyes half open and foam coming from mouth and unresponsive. He was not breathing and with no pulse

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

1/1/2020: Residents was found unresponsive. Pronounced deceased at 6:02pm No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI **COVID19 (COVID19 (MODERNA)) (1201)**

Resident had body aches, a low O2 sat and had chills starting on 12/30/20. He had stated that they had slightly improved. On 1/1/21 he sustained a fall with a diagnosis of a displaced hip fracture. On 1/2/21 during the NOC shift his O2 sat dropped again. He later went unresponsive and passed away.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

At approximately, 1855, I was alerted by caregiver, resident was not responding. Per caregiver, she was doing her rounds and found resident in bed, unresponsive, mouth open, observed gurgling noises and tongue hanging out of mouth. This primary caregiver observed resident at baseline and ambulating after dinner at approximately, 1800 less than an hour prior to incident. This PCG called 911 for EMS and gave report of incident. Resident was taken to Medical Center Emergency Department. At ER, CT scan and X-ray was performed. Per report from ER RN, CT scan and x-ray revealed an intracranial aneurysm and fluid in the lungs. Per RN, resident was still unresponsive and was admitted to Medical Center for observation and comfort measures. This primary caregiver reported to RN, resident recently received the first dose of COVID-19 vaccine on 1/2/21. Primary caregiver received a call from Castle RN at 0700, resident expired at 0615.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the

No prior vaccinations for this event.

hospital was unable to bring her back.

UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
Staff reported that patient was found Friday morning (Jan 8) sitting at a table with his head tilted forward and unresponsive to verbal or physical stimuli. Staff lowered patient to floor and started CPR. EMS was called and continued CPR at scene, however they were not able to revive patient. Patient was pronounced dead at the scene. Staff written statements following the death of patient show that he had a fall about 1 hr. prior. It is unknown if this fall contributed to patient's death. An autopsy has been requested.		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received COVID-19 (Moderna) vaccine from the Health Department on afternoon of January 8, 2021 and went to sleep approximately 2300 that night. Was found unresponsive in bed the following morning and pronounced dead at 1336 on January 9, 2021		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was found unresponsive at home with SpO2 20% 1/2/2021		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**	
RESIDENT 1ST DOSE OF MODERNA VACCINE ADMINISTERED ON 01/04/2021 AT 8:30PM, RESIDENT FOUND UNRESPONSIVE ON 01/05/2021.		No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

Patient received the vaccine on 12/22/20 without complication. It was reported today that the patient was found unresponsive and subsequently expired at home on 1/11/21.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

The patient passed away today, 1/13/2021. She was a hospice patient. She showed no adverse effects after receiving the vaccine on 1/12/2021. This morning she woke up as normal and during her morning shower she had a bowel movement, went limp and was non-responsive. The patient passed away at 7:45 am.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

Resident found unresponsive and without pulse at 05:45am. No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI **COVID19 (COVID19 (MODERNA)) (1201)**

Around 00:50am on 01/15/21, C.N.A. reported that the resident looked different and not responding. Initiated Code Blue and started CPR. 911 arrived and pronounced resident dead at 1:01 am.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to our Emergency Department via EMS in full code status; asystole. Patient expired. Per nursing, husband stated patient awoke this AM and reported pain in back between shoulders and in bilateral

No prior vaccinations for this event.

shoulders. Patient then went unresponsive and husband called EMS.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident was noted to have increase weakness on 1/15/2021. Resident was warm to touch with low grade fever of 99.3 F. Resident was up propelling self in w/c on 1/16/2021 he was pleasant, accepted medications and ate lunch. He was found slumped over in his w/c not responding and vital signs absent.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient woke apx 0200 complaining of nausea to group home staff. Vitals were checked at that time and WNL. Patient went back to bed. When staff went to wake patient apx 0530, he was unresponsive and had no pulse. Chest compressions were started and EMS called.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received her first dose of the Moderna COVID-19 Vaccination on Saturday January 16th 2021 at approximately 12pm. She completed all necessary screening forms and was deemed to be at low risk for serious allergic reactions. She tolerated the vaccination well, and no complications or immediate adverse events occurred. She was observed for a full 15 mins per CDPHE/CDC guidelines and left the Clinic in stable condition after her observation period was complete. On the morning of Tuesday, January 19th, 2021, the patient was found unconscious and unresponsive by her husband. She was transferred by Ambulance to Hospital shortly thereafter. She was diagnosed with a brain bleed that was determined to be inoperable. She was transferred to other Hospital for higher level care. She was seen by neurosurgery and diagnosed with a ruptured aneurysm. She was treated in the ICU for 24 hours, at which point her team determined that the severity of her brain bleed would not respond to treatment. Supportive cares were withdrawn on Wednesday	No prior vaccinations for this event.

Jan 20th, and she passed away shortly thereafter.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
began itching within 24 hours, within 5 days couldn't move on her own, by 6th day was having respiratory issues, by day 7 unresponsive, by day 8 dead	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient was tested positive for Covid-19 on 12/9/20. Patient received Covid Vaccine on 1/21/21. Patient was observing for 15 minutes in treatment room by Nursing staff. Patient denied any signs/symptoms adverse effect: headache, dizziness & weakness, difficulty breathing, muscle pain, chills, nausea and vomiting, and fever . Patient seated on treatment table appeared to be relaxed, respiration even and unlabored. Health teaching provided. Patient educated to report any changes in condition to staff immediately. Patient verbalized understanding and able to verbalize signs and symptoms and adverse effects to be aware of related vaccine. On 1/22/21: patient was seen by medical provider for ""altered behavior"". Per medical provider's documentation: ""Patient was fallen on 1/2/21 and was sent out to outside hospital on 1/4/21. CT head: no intracranial abnormality, age-related changes. Patient had labs (B12, RPR, folate) were within normal limit"". We did MMSE today: 22/30 score ""mild dementia"" On 1/23/20: ""Patient was inside his cell. He was walking towards cell door to obtain his breakfast, when custody witnessed him collapse and activated the alarm. Nursing staff arrived at cell front at 06:34 am and found the patient pulseless and unresponsive, and CPR was immediately initiated. AED was attached at 06:35 am and no shock advised. AMR then arrived and patient did not have ROSC, and was pronounced dead at 06:54 am.""""	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**

Patient received Moderna COVID vaccine on 12/30/2020 at a Pharmacy clinic where he was a resident. Nurses at the facility reported that he was responsive and showed no signs of any adverse effects until 1/2/2021 when he was observed slightly unresponsive and staring at the ceiling and trembling. He had a fever of 101F at this time. The facility ordered labs and a rapid COVID test (all of which came back normal) and started IV antibiotics. A few hours later, patient began bleeding from his eyes, nose, and mouth and was sent to the local ER. The patient refused being admitted to the ICU for possible sepsis/hemorrhage and died the following day on 1/3/2021. All healthcare professionals involved agreed that this was not likely due to the vaccine, but needed to be reported nonetheless.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
ON 1/21/2020 RESIDENT WAS EXPERINCING CHILLS AND LOOSE STOOLS. FOLLOWING THIS EPISODE BECAME UNRESPONSIVE, PALE, DIAPHORETIC AND BRADYCARDIC. PALLIATIVE CARE WAS PROVIDED. RESIDENT PASSED AWAY APPROX. 10 HOURS LATER.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

on 1/13/2021 at 3:40am Cliff called for assistance. He lost his balance and had fallen. Cliff refused vitals, refused emergency department, denied hitting his head. As the day progressed patient developed a headache, diarrhea, and vomiting. He again declined the offer for the emergency room. At supper time wife and staff found Cliff unresponsive, 911 was called and he was taken to the emergency department. The ER did a CT scan and found an acute subdural hematoma. Patient was placed on comfort cares and expired at 3pm on 01/14/2021. Cliff did not have a history of falls.

Influenza vaccine 10/06/2020, age 88, fever, chills, vomiting, malaise

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

Patient has a history of advanced melanoma with brain metastasis. He developed seizure disorder as well and had some mild seizures at home over the prior month. He received the vaccine at 4pm and was monitored in the office for 15 minutes. He then went home with his daughter whom he lives with. He ate dinner with her and read until 8pm when he went to his room. She found him in his room at 9pm unresponsive with seizures. Hospice was alerted and recommend oral valium. He continued to be unresponsive and expired the following day at 7:30 pm.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

UNKNOWN/ASYTOLE Narrative: Please refer to section 6. 68y/o male with h/o severe peripheral vascular disease with previous left AKA 2/3/20, s/p bilateral bypasses in the past. Pt recently underwent right AKA on 1/12/21. Per Hospital remote data 1/10/21 pt c/o shortness of breath, CXR demonstrated right lower lobe opacity & left basilar infiltrate. Pt s/p >10 days emperic IV abx. Moderna vaccine 0.5ml IM was administered via left deltoid on 1/22/21 around 16:21. On 1/23/21@05:14 code blue was called as pt found to be unresponsive, breathless and pulseless, facial cyanosis noted, CPR started immediately.Pt found to be in

No prior vaccinations for this event.

asystole. ACLS guideline followed but no return of spontaneous circulation, At 05:32 pt remained pulseless and breathless and was pronounced. Autopsy currently pending.		
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
Fever 101.1, unresponsive episode. Transferred to Hospital on 1/28. Diagnosis there was anemia and CHF, aware that he had vaccine day prior. Transfused with 2 units pRBC's. Transferred back to Nursing Home on 1/30 and passed away 0140 1/31/2021		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient's wife called the physician's office with increasing SOB. MD advised that the patient go to the ED. While dressing, the patient became unresponsive, 911 called. Patient expired in ED.		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
The patient went home around 11 am on 1-31-21 after her vaccine and 15 minute observation period. She was eating breakfast after at home and complained to a neighbor that her teeth hurt and she was nauseated after eating. In the afternoon, she felt dizzy and had diarrhea accompanied with blood. Close to 9 PM, her son went to check on her. The patient was found on the floor--she was unresponsive and had purple lips. Her son called an ambulance and started chest compressions. The patient passed away at the hospital. The doctor has ordered an autopsy, and the results are pending.		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**

Found unresponsive No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI COVID19 (COVID19 (MODERNA)) (1201)

spontaneous death, found unresponsive in cell after normal morning activities No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was seen at 0710 he was sleeping but at normal cognitive behavior Patient was again assessed at 0720 where he was noted to be unresponsive, BP 180/100s, HR 230s, he was a DNR therefore not CPR was administered. EMS arrived at facility patient was noted to be in full cardiac and respiratory arrest. Time of death 0735	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient awake at 0300. When going into the room to get him ready for dialysis he was cold to touch, unresponsive other than to sound, and nonverbal. O2 sat was 67 via finger probe. Oxygen immediately initiated and a venturi mask retrieved and initiated. When unable to arouse him via sternal rub this RN called 911. Send to ED. Febrile 39.2 and hypotensive 58/43. Admitted. unknown after that as patient expired in hospital.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/23/21 the patient had a single-car accident, slid off icy road into snowbank. She was seen in our ER, diagnosed w/ trauma and L4 compression fracture. She was transported to Hospital for further trauma workup. We believe she was treated and released. On 1/31/21 the patient had a headache but did not seek medical attention. In the morning of 2/1 she became unresponsive and was pronounced dead on the scene	No prior vaccinations for this event.

when EMS arrived. Autopsy showed a left temporal subdural hematoma.		
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
unresponsive Narrative: 74yo patient with pacemaker, type 2 DM, parkinson's and history of syncopal epsisodes presented to emergency dept on Jan 24th. He was observed and discharged on Jan 26th back to the home where he continued to have cognitive decline and later passed away on 2/2/2021		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
Received Covid vaccine in am. Last seen by family at 17:30 pm and observed to be well. About an hour later he collapsed, unresponsive. A 911 call was initiated at 18:29. Paramedics arrived to find the patient in cardiac arrest. CPR/ACLS was initiated, but resuscitation was unsuccessful. Pt. was transported to MC where he was pronounced dead at 19:32. There was no sing of an injection site reaction, nor of allergic reaction..		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
He had not been feeling well after his second Covid vaccination (on 01/23/2021) and was found unresponsive in his room at the nursing home (late evening on 02/02/2021). He was taken to a hospital where they did tests and he had pneumonia and kidney failure, but he was being transferred to a larger hospital when he arrested and died (02/03/2021)		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
DISCOVERED UNRESPONSIVE WITHOUT PULSE, RESPIRATIONS, HEART BEAT ON 2/7/21 AT		No prior vaccinations for this

0435 A.M. RESIDENT WAS DNR STATUS.		event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
the following morning the patient became unresponsive while taking a shower, became asystolic and died despite about an hour of ACLS and 8 rounds of epi		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient reported to be unresponsive on the morning after receiving his second dose of Moderna COVID-19 vaccine. Patient had expired during the night.		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received first dose of Moderna COVID-19 vaccine on 2/3/21. Primary Care physician received call		No prior vaccinations

from coroner's office 2/8/21 asking for information contributing to cause of death. Per Primary Care Physician notes, wife states she and patient took turns shoveling snow on 2/4/21. On one trip back into the house she found him unresponsive on the floor and called 911. Paramedics were unable to revive patient and he passed away (2/4/21).		for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had the first Moderna Covid vaccine on Thursday 1/21/2021. She had a bit of sore arm on that day and the day after. On Saturday 1/23/2021, she had a fever of 100.5 F (11AM), nausea, light headache and chills. The temperature went down after she took ibuprofen. Patient's husband enrolled her to V-Safe to report all the adverse effects she experienced. On Sunday 1/24/2021, her temperature was 98.3F. She still had nausea and no appetite. She and her husband watched a football game in their bedroom upstairs. Husband noticed that his wife was pacing around the room many times. At 7Pm, Husband went downstairs for dinner but she refused to come down to eat. He went upstairs around 8pm, TV was still on. He turned off TV and went down stairs again thinking his wife felt as sleep while watching TV. He went back upstairs for bed around 10:30 PM. Husband said his wife had a deviated septum so she would snore very loudly when asleep. He didn?t hear her snoring so he went to check on her and found her not responsive. Husband called emergency services. Paramedic came at 10:45 and said patient was passed. Husband sent many texts to V-safe after that to report the incident. No response was received from V-safe. Patient?s doctor told her husband that she died due to cardiac arrest.		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received vaccine on 2/5. We were told on 2/9 that the patient visited another emergency department on 2/6 but no information was given as to what prompted that visit. She was sent home. Daughter found her on 2/6 or 2/ 7 unresponsive and she died.		No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received COVID19 vaccine at clinic at 11:52 am, discharge post treatment stable. Got home around 2:30 pm went to bed. He usually got tired post dialysis. He did not wake up at 6 pm. His wife went check on him. found patient cold and unresponsive. 911 pulseless PEA. ER Medical hospital. Pronounced death at 7:40 pm		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident reviewed for incident. Resident received the second dose of the Moderna Covid-19 vaccine lot# 016M20A Exp 5/2/2021 on 2/5/2021 from clinic through pharmacy. Resident had her temp/O2 taken on AM shift and was 98.6/93%, beginning PM shift 98.4/95%. A few hours later noted that resident to have chills and was shaking RN assessment completed and vitals taken resident noted to have temp of 102.2, oxygen 95%, pulse 110. Resident alert and oriented at that time and talking to staff. Reported findings to APNP with order to send to ER. 911 called, residents brother updated. Upon EMT arrival RN went down to residents room with EMT and resident had an emesis as resident was getting cleaned up resident went unresponsive. Pulse noted to still be present at that time, resident did briefly respond to sternal rub and then went unresponsive again. Resident full code and EMT transferred to gurney and said that if they lost a pulse in route that they would transfer to hospital B instead of hospital A being the closest facility. RN called brother and gave update. Facility notified from Hospital that resident had passed away.		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (MODERNA)) (1201)**
"death. Per son pt was not feeling well after the vaccination ""like her legs were weak."" Son found the mom in her bed 1am on 2/12/2021 unresponsive."		No prior vaccinations for this event.

	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
My dad received his first COVID vaccine on January 14, 2021. On January 16, 2021 he ate breakfast around 7:00 am and went back to his room. When the staff checked on him around 8:00 am they found my dad unresponsive. His blood pressure was over 220 and his pulse was 43. They began manual CPR until the paramedics arrived, but my dad died.		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
I video chatted with her Thursday after receiving the vaccine. My mom was in poor health but she was talking in complete sentences and responded appropriately. She was upright in bed and made eye contact. She smiled and denied pain. By Sunday, she was extremely weak and unable to sip water with a straw. Her health had changed dramatically and rapidly. She moaned in pain and was very fatigued. Her condition continued to deteriorate over the week and she stopped talking and was constantly sleeping. They started antibiotics for the oozing cancer lesion and then morphine for pain and end of life care. She passed away on January 22nd which was 15 days post vaccination.		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
"Patient had COVID vaccination on 2/3 with no adverse s/s before leaving unit. Upon coming to treatment Friday 2/5 he reported to the RN that he had fallen on thursday 2/4 due to ""getting up fast"" did not hit head or hurt anything per RN discussion. Began treatment without difficulty. About 3/4 way through treatment was talking with staff and became unresponsive - code was called and pt expired after 30 minute resuscitation efforts."		No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI **COVID19 (COVID19 (MODERNA)) (1201)**

Patient was found unresponsive at 8 am on 2/12; patient was deceased No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI **COVID19 (COVID19 (MODERNA)) (1201)**

Short version The patient has long-standing health issues. The patient received the first dose of Moderna COVID-19 vaccine on 1/16/2021 (unknown location). The patient suffered an event in his home on 1/24/2021. CPR and treatment was begun and he was transported to the ED. He was pronounced dead in the ED at 0846. Long version 70-year-old male with past medical history of CAD with pacemaker, A. fib, COPD, hypertension/hyperlipidemia presenting in cardiac arrest. 911 call at 0724. Per EMS, patient was witnessed by family to have seizure-like activity and then collapsed and became unresponsive. Patient was noted by family to be pulseless and CPR was started right away. Patient received two doses of epi by police were on scene first (AED defibrillation x2) and six doses of epi (plus 6 more AED shocks) by EMS when they arrived. Patient had CPR performed for 45 minutes prior to arriving at the hospital. On route, patient had episodes of paced rhythm and V. fib. Patient received one amp of bicarb and one amp of calcium en route. Patient also received 300 mg of amiodarone en route. Arrived in ED at 0810 Patient received ongoing compressions, shocks and additional medications (epinephrine x6, lidocaine IV, sodium bicarbonate) until time of death called at 0846 in the ED.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI **COVID19 (COVID19 (MODERNA)) (1201)**

"Patient called EMS approximately 1pm on 2/15 with complaints of generalized weakness. Upon arrival EMS found her to be diaphoretic and she had a witnessed syncopal episode with question of v-fib and seizures. She became unresponsive and had no pulse. CPR was begun and she was transported to ED. She remained asystole throughout. CPR was initially continued in the ED for approximately 30 minutes and then stopped with Time of Death noted at 13:27. ED notes noted ""suspect given history that patient experienced massive

No prior vaccinations for this event.

MI, PE or ruptured AAA"". Death certificate notes indicate ""signficant conditions contributing to death after cardiac arrest; ASCVD""."

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was at a gym watching his daughter. He slumped over unconscious. EMS was called. He was found to be in fine ventricular fibrillation and resuscitation efforts failed. He was brought to Hospital ED where he was pronounced dead. He had underlying cardiac disease but his family requested I report this event as possibly related to the recent COVID vaccination.	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away; tired; nonresponsive; cold; difficulty breathing; swelling; sore arm; feeling weird and funny; A spontaneous report (United States) was received from a consumer concerning a 63 year old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and the patient experienced limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal and the patient passed away . Medical history included treatment for tuberculosis and dialysis. Concomitant medication included calcium acetate, Renvela, glipizide, omeprazole, aspirin, vitamin D, losartan, furosemide, rifampin, and Sensipar. On 14 Jan 2021, the patient received the first of their first planned doses of mRNA-1273 (lot number 030L20A) for prophylaxis of COVID-19 infection. On 13 Jan2021, the patient tested negative for COVID-19). On 16 Jan 2021, the patient experienced a sore arm, and feeling weird/funny. On 17Jan2021, the patient experienced difficulty breathing and swelling. On 18 Jan 2021, the patient declined dialysis, was tired and wanted to lay down. At 8 am, the patient was found nonresponsive and cold and is believed to have passed away around 4 am. The coroner tested the deceased for COVID-19 and the test was positive. No autopsy was reported. No death certificate was issued at the time of the report but the reporter believes it will list cause of death as COVID complications. Action taken with the mRNA-1273 was not applicable. The	No prior vaccinations for this event.

outcome of the events of limb discomfort, feeling abnormal, dyspnea, fatigue, swelling, unresponsive to stimuli, body temperature abnormal, was fatal. On 18 Jan 2021, the patient was died. Cause of death was COVID-19. Autopsy details were not provided.; Reporter's Comments: The events developed on four days after first dose of mRNA-1372. Dyspnea, unresponsive to stimuli, and death were consistent with infection in pandemic set up confounded by age of patient and refusal of dialysis Cause of death was reported as COVID-19. Autopsy details were not provided. Based on reporter's causality the events are assessed as unlikely related to mRNA-1273.; Reported Cause(s) of Death: COVID-19

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

"The patient came to the Emergency Room at approx 3:30 am on 02/03/2021 with pain in right arm (same arm the COVID vaccine had been administered in approx 12 hours earlier) and feeling generally unwell. Patient was concerned about possibility of gout flare or that something was wrong with her arm. Elevated blood pressure was noted; this was attributed to anxiety. She was evaluated, given 500 mg Tylenol, and discharged since the pain was decreasing and blood pressure was stabilized. Patient instructed to follow-up with physician. The next day, on 02/04/2021, the patient arrived at the Emergency Room by ambulance; cardiac arrest was the chief complaint. The patient's daughter stated the patient had been ""feeling generally poor and then suddenly collapsed."" Daughter described ""gurgling respirations"" and being unresponsive. 911 was called, police arrived within 5 minutes and initiated CPR. Epinephrine, atropine, lidocaine and bicarb administered after arrival to Emergency Room. Shockable rhythm never demonstrated. Patient never recovered spontaneous respiration or movement. The death was called at 23:04. Coronary artery disease with cardiac arrest is the cause from the ER records; the coroner is putting COVID-19 vaccination in Part 1 of the death certificate."

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

Patient was found unresponsive and had passed away. No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI **COVID19 (COVID19 (MODERNA)) (1201)**

Patient collapsed and could not be revived. There was no prior warning. She was otherwise in good condition for her age. The death was listed as probable cardiac arrest but no autopsy was performed. Since it occurred so close to the vaccine shot I thought someone may want to know.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

Pt was hospitalized Jan 18, 2021 after he had fallen outside overnight and lay there approximately 12 hours until he was found. Hypothermic & rhabdomyolis diagnosis. Gradually improved w/ strength & mental status - was in swing bed @ hospital. He got his first Covid 19 shot on 2-8-21. Was fine @ 0300 on 2-9-21 and @ 0430 he was found unresponsive. Dx: probable arrythmia & pronounced dead @ 0454. Noted on pain scale @ 2/8/21 @ 21:11, clients pain was a 7/10 They offered pain med & he refused They repositioned & distracted him @ 2047 on 2/8/21 Pain had decreased to 3/10 and nothing given. Then @ 0300 check he was sleeping and @ 0430 unresponsive.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

Per ED note: Brought in ED by EMS at 1945 for acute shortness of breath and hypotension. Patient was placed on supplemental oxygen and covid test completed. Patient was placed on BiPAP to maintain oxygen greater than 90%. Found to be in metabolic acidosis. Patient became unresponsive and pulse could not be palpated. Chest compressions were initiated. ACLS medications given and pulses regained. Patient lost pulse 30 mins later and never regained pulse. Per ED noted; likely developed a PE. Passed away at 2127

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**	
"Was given vaccine around 1:30Pm on 2-11-2021. He and his wife waited in the building for 15 minutes and then left. he denied complaint. (He was waiting to have both Covid shots before he went to cardiologist Re: CAD.) He had an alarm going off in his house, was going to basement to check it out. Police officer heard alarm, came into house, & heard a thud when Doc fell. He was in PEA (Pulseless Electrical Activity) when brought into ER. Given 5 ""rounds of Epinephrine with no response."	No prior vaccinations for this event.	
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**	
Individual developed severe body aches, severe shoulder discomfort, high fevers (documented max temp. 103.7 F). Daughter reported that she became non-responsive with high fevers, and when the fevers decreased she was more lucid. Her condition rapidly progressed to nausea vomiting, diarrhea and patient died on 2/9/2021.	No prior vaccinations for this event.	
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**	
Patient discovered unresponsive in cell, blue coloration to skin, vital signs, undetectable. CPR initiated, Ambulance summoned. Following EMS arrival with additional unsuccessful attempts to revive patient, patient was determined to have expired.	No prior vaccinations for this event.	
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**	
pt woke up at 0400 with fever, chills, and body aches progressing over 4 hours to the point when she	No prior vaccinations for	

became unresponsive. husband called 911, pt was declared dead at the time of EMS arrival around 1200	**UNRESPONSIVE TO STIMULI**	this event. **COVID19 (COVID19 (MODERNA)) (1201)**
Massive ischemic stroke with aspiration, unable to arouse on the morning of 1/21/2021 and placed on Hospice with death 1/24/2021		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
"""Feeling Hot"" without fever and nausea 10 hours post vaccine and resolved within 1 hour. Seizure, Hypotension, Unresponsive followed shortly by cardiac arrest and pulseless electrical activity 21 hours post vaccine. Pronounced dead 22 hours post vaccine"		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
30 hours after the first Covid vaccination, the resident was lethargic, non responsive with shortness of breathe.		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (MODERNA)) (1201)**
loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He		No prior vaccinations for this event.

was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

Hypoxia, Decreased responsiveness, Narrative: 86yo male with PMHx HTN, Afib not on AC after head trauma, CVA, and colon cancer who was brought to the ED by his family on 2/17. Per documentation the pt was in his usual state of health until 2/16. Received Moderna covid vaccine #2 on 2/16/21 at 0900, and was

No prior vaccinations for this event.

monitored for 15 minutes following immunization no noted issues. Later that night, had myalgias and took Tylenol. Per the family he slipped on the ice and fell on his butt. Overnight, had several dark stools and vomitus. was brought to the ED by his family because he was being less responsive. Pt arrived to the emergency department in extremis. No pulse identified. CPR immediately initiated for several rounds lasting about 25-30 minutes. ROSC unable to be achieved. Patient expired on 2/17 at 1941. Of note, per previous documentation had waxing and waning mental status at baseline. No symptoms noted with 1st dose of Moderna vaccine, which was administered on 1/16/21.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19

(MODERNA)) (1201)

Received vaccination at 14:20 2/26/21. Was observed until discharged at 15:15. Discharged per wheel chair to lobby in alert/stable condition, to wait on bus to take him home. At 18:00 his neighbor heard him fall, could not get patient to answer phone, found him unresponsive. Neighbor called 9-1-1, ambulance personnel could not revive patient. Coroner's office ruled his death as Natural Causes due to Hypertension, Cardiac disease, Diabetes, ESRD. There were no indication of anaphylactic reaction noted when I questioned the coroner's office. The Coroner's office/EMS were aware the patient had received the Moderna COVID 19 vaccination that day.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (MODERNA)) (1201)

No pulse and no heart beat; couldn't wake him up; passed away; A spontaneous report was received from a daughter concerning a 84-year old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) experienced no pulse or heartbeat, couldn't wake him up and passed away. The patient's medical history, as provided by the reporter, included high blood pressure and prostate cancer. No relevant concomitant medications were reported. On 19 Jan 2021, the patient had a blood pressure reading of 133/84 at a cardiology visit. On 13 Feb 2021, approximately 3 hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (batch number 031M20A) intramuscularly for prophylaxis of COVID-19 infection. On 13 Feb 2021 at 3:30 pm, the patient could not be woken up and was found with no pulse or heartbeat. Action taken with the drug in response to the events was not applicable. The outcome of the events, no pulse or heartbeat and couldn't wake him up, were not provided. The patient died on 13 Feb 2021. The cause of death was unknown.; Reporter's Comments: Very limited information regarding this event/s has been provided at this time. The patient's medical history of high blood pressure and prostate cancer remains the risk factors. The cause of death was unknown. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

No prior vaccinations for this event.

	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received vaccine per pharmacy at the facility at 5 pm. Approximately 6:45 resident found unresponsive and EMS contacted. Upon EMS arrival at facility, resident went into cardiac arrest, code initiated by EMS and transported to hospital. Resident expired at hospital at approximately 8 pm		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident found unresponsive without pulse, respirations at 04:30 CPR performed, expired at 04:52 by Rescue		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient did not display any obvious signs or symptoms; the vaccination was administered at approximately 10:00 AM and the patient continued throughout her day without any complaints or signs of adverse reaction. Patient was helped to bed by the nursing assistant estimated at around 9:00 PM. The facility received notification from the lab around 11:00 PM that the patient's COVID-19 specimen collection from Sunday, 1/3/21, detected COVID-19. When the nursing staff went to the room to check on the resident and prepare her to move to a COVID-19 care area the patient was found unresponsive, no movement, no chest rises, noted regurgitated small amount of food to mouth left side, lying on left side. Pupils non reactive.		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

"Pt last seen at 1200 by nurse for ID band check. No visible signs of distress noted. Pt states ""I just want to be left alone"". 1230 nurse was called to pt room. Pt was noted unresponsive, no pulse and respiration noted. CPR started immediately, at 1239 first shock given. 1245 EMT took over, at 1319 EMT called time of death"

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was okay, but he was very agitated; reported as not like this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for

No prior vaccinations for this event.

vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

loss of consciousness Narrative: Patient received COVID-19 vaccine dose #1 on 1/6/21 w/o complications. Per 1/6/21- 1/9/21 nursing notes, patient did not experience any injection site reactions, denied pain or tenderness at injection site, no dizziness, no n/v, remained afebrile. Around 1/9/21 @1810, patient became acutely nonresponsive after being helped to the edge of bed. Per nurses, he was previously awake/alert, talking and asymptomatic. Patient is DNR/DNI but facility rapid response emergency team called d/t patient's sudden change of condition. Emergency team helped patient into lying position. Per 1/9/21 ICU emergency team note, patient appeared comfortable w/ no palpable radial pulse and had minimal shallow agonal breathing. Pulse ox 94%, HR in 60s per machine. BP unmeasurably low by BP cuffx3. Resident passed at 18:20 pm.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19

	(PFIZER-BIONTECH)) (1200)
little bit of a reaction light headed after 5 minutes. vitals were low, so observed for 30 minutes after being light headed. Patient was found unresponsive and pronounced dead later that day.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
No adverse effects from vaccination seen on 1/2/21. On 1/6/21 resident was seen by Dr and her baclofen pump was refilled with 20 ml Baclofen 4,000mcg/ml. ITB Rate increased by 6% to 455.5 mcg/day simple continuous rate over 3 days. On 1/8/21 at 0615 resident was shaking, lower extremities mottled, Sa02 70%, pulse 45. Oxygen started at 2 L/m per NC. At 0715 her primary physician was notified as well as her daughter. Oxygen increased to 4 L/min, sats at 83%. SOA noted, reported all over pain. At 0850 when they attempted to reposition the resident, she was not responsive. Licensed nurse assessed her and no heartbeat heard or pulse found.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On day due for 2nd dose, Patient was found unresponsive at work in the hospital. Patient pupils were fixed and dilated. Full ACLS was initiated for 55 minutes with multiple rounds of bicarb, calcium chloride, magnesium, and epinephrine. Patient was intubated. Patient continued into V. Fib arrest and was shocked multiple times.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Cardiac arrest within 1 hour Patient had the second vaccine approximately 2 pm on Tuesday Jan 12th He works at the extended care community and was in good health that morning with no complaints. He waited 10-15 minutes at the vaccine admin site and then told them he felt fine and was ready to get back to work. He then was found unresponsive at 3 pm within an hour of the 2nd vaccine. EMS called immediately worked on him 30 minutes in field then 30 minutes at ER was able to put him on life support yet deemed Brain dead 1-14-21 and pronounced dead an hour or so later	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
71yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, VS taken at 10am, B/P 99/60, O2 sats, 95% (trach w/O2). At 11:30am, Patient showed no s/sx of distress, A&Ox3. At 11:50am, a nurse went to perform a COVID test and assessment (the facility is experiencing an outbreak), and found the patient unresponsive on the bathroom floor. CPR was immediately started; no shock advised per AED; 12:15pm EMS arrived and took over. At 12:38pm, EMT called time of death.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"83yo female resident who died after receiving Pfizer BioNTech vaccine. On 1/14/2021, the patient reportedly got up in the middle of the night with c/o feeling ""blah"", restlessness, and nausea. VS normal, no other s/sx. At 4:15am, the patient was asked to go back to bed, assisted by a nurse and GNA. At 6am, GNA was going to do morning VS and found the patient unresponsive, no pulse, no respirations. GNA notified the nurse. At 6:03am, CPR started and EMS called. At 6:15am, EMS arrived and took over. At or	No prior vaccinations for this event.

around 6:30am, EMT called time of death"

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Veteran was found by family slumped over and unresponsive at the breakfast table on 1/13/21, had expired	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received vaccination on January 15, 2021. She was found unresponsive with shallow respirations on the morning of January 16, 2021 and was sent to ER via ambulance. The resident was admitted to medical center ICU where she passed away later that day.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was	No prior vaccinations for this event.

made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Shaking and then became unresponsive No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

At approximately 930am I arrived at Memory Care. I met with the director of the facility and she directed me to where my team would be setting up. My team consisted of (technician), (nurse) and I. As we were setting up, the director asked how she can help. I explained to her that we would need a designated area for patients to be monitored after vaccination for 15 minutes and maybe even longer . I also explained that we would need one of her staff monitoring while we vaccinate. She agreed, and proceeded to designate her staff and the cafeteria area, facing the vaccination station,the monitoring station. Throughout the day, nurse and I were both vaccinating,while the staff of the facility would monitor the vaccinated patients. I would also stop occasionally to mix the vaccine and check the temperature of the aero safe. At approximately 12:50pm, the director rushed in and stated that a patient is not responding, and that she had been vaccinated. At that point, I grabbed epipens and a thermometer and I also instructed nurse to grab an Epipen and come with me. We followed the director to pt's room. Once we got to the room, the patient was in bed and there were 4 staff members standing bedside and one of them turned and stated the patient has passed. At that point I asked the staff how long ago did the patient get the vaccine, they stated about 30 minutes ago. They also stated that the patient was a hospice patient and that the patient had declined, and was rapidly detiorating and had not eaten or drank anything all day . They also stated that the patient had

No prior vaccinations for this event.

been monitored for 15 minutes post vaccination. I then left the room and grabbed the patients COVID Vaccine intake consent form. I looked at the answered questionaire and all the responses were circled NO. Patient had a temp of 96.5 at the time of vaccination.The vaccine administration information for Immunizer Section was filled out by Nurse. I then proceeded to ask the director once again if there were staff that was monitoring her for 15 minutes, the director stated they had staff monitoring her. She also stated the Hospice nurse has to announce her death, so they waited for the Hospice Nurse to come. I then called Corporate and explained the situation. After speaking to corporate, I also asked nurse, if she remembered the patient. She stated that she did and at the time of the vaccination the patient was not alert, there were two staff members with the patient. She was non oriented and she kept closing her eyes. At that point, Nurse stated that she asked the two staff members with her if this is how she usually is and if its ok to vaccinate her. Both Staff members stated that it its ok,this is how she is. The Nurse then proceeded to vaccinate. At approximately 3:10pm, as I was leaving I spoke to the director, and one of her Staff members. Staff that the patient has actually not eaten/ or drank anything for the past several days, including today(01/18/21). Staff also stated that on Friday, Jan 15th,2021, they had informed the family that the patient was rapidly detiorating. Staff also stated that the family knowingly gave the consent to vaccinate her. She also stated that the hospice Nurse believes that the death was primarily caused by her detiorating state. She also stated that the hospice Nurse informed that the death was not due to the Vaccine. Per Lead Pharmacist at the clinic.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/13/2021 12:00 PM: Patient received COVID-19 Vaccine. 1/14/2021 21:00: Nurse performed routine rounds and the patient appeared okay. 1/14/2021 22:00: CNA discovered patient unresponsive in bed, began CPR, and called 911. 1/14/2021 23:08: Pronounced deceased.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19

	(PFIZER-BIONTECH)) (1200)
"Patient's wife called this morning stating that her husband has passed away last night. After receiving first dose of Pfizer COVID-19 vaccine at around 0830, patient remained in the Immunizations Department for the 15-minute monitoring period. Per wife, patient's only complaint was pain at the injection site. At 1300, wife states that patient complaint of dizziness which ""dissipated after a few minutes"" followed by a headache which ""dissipated after a few minutes"" as well. Then patient complained of nausea, no vomiting and ""couldn't relax."" Per wife, from around 1400/1500, patient stayed on his recliner while still having a conversation with her--""he didn't get up to eat."" Last conversation they had was around 2000/2100. Per wife, at around 2100/2200, patient was quiet and when she checked on him, ""he wasn't responding anymore."" Wife then called 911, ""but they couldn't revive him.""""	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was was brought to the ED from facility which he received the vaccine via ambulance with BiPAP, hypoxia, and one dose of Epi of 0.3 mg. He then required intubation, and had struggled with hypoxia, even on increasing PEEP. CODE BLUE called in the ED for PEA. He was medicated for such (please see the code run sheet for details), and he came in and out of the code 5 times. After 95 minutes, with the wife at the bedside, and family conference by phone, the code was called, and he was pronounced at 18:20. He received in total 8 me of Epi, 3 shots of Atropine, 3 amps bicarb. He got lasix 40 mg, lovenox 60 mg subcutaneous once. He had a CVC into the right internal jugular, and levophed was started, then Epinephrine drip was started. Prior to the code he got steroids (solumedrol 125 mg, then later decadron 6 mg iv), benadryl iv, antibiotics (ceftraixone / zithromax), and lasix 40 mg. All this time while in the ED, the Rt was at the bedside, and lots of secretions from the lungs were aspirated, bloody color. á Code was the result of PEA secondary to hypoxia (	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

SON SAID PATIENT WAS FOUND UNRESPONSIVE AND CALLED 911 No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
At approximately 12:15 pm the resident had a brief unresponsive episode that resolved quickly. Her Vital signs were stable and her mentation was at baseline. Later that evening approximately 10 pm she had labored respirations, shortness of breath, lethargy with bilateral crackles, Oxygen desaturated to 76% on room air, tachycardia and hypotension. She expired at 6:30 a.m. the following day.	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

(Report per patients wife) Patient took his usual nap around 12pm. She found him lying in the bed unresponsvie at 2pm. EMS was not called. Patient's wife called the Funeral home.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient noted to have a change in status at 11:23PM that night. Her oxygen saturation had dropped from normal on room air to 82% and required oxygen. She was also noted to be lethargic with altered mental status and not responding verbally. She then began to mottle. Her oxygen saturation worsened to 51% on 4Liters of oxygen by the next day and she expired on 1/14/21.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Patient with inoperable pancreatic cancer received second Pfizer vaccine approximately 12:30 pm on 1/27/21. At approximataely 16:30, patient complained of abdominal pain and was given Levsin 0.125mg and morphine 5mg orally. At approximately 19:30 patient was found on the floor covered in a large amount of emesis, unresponsive without a pulse.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
All residents had been in isolation due to multiple cases of COVID in the facility. Resident voiced no health related complaints. He continued to visit with staff and required moderate assist with toileting. Resident had fall 0130 on 1-15-2021, which resulted in laceration with surgical repair. Resident was noted to change in mental status and respirations on morning of 1-16-2021 during morning blood sugar check. Resident had O2 @1.5l/m via n/c and respirations of 10 with periods of apnea and unresponsive to verbal stimuli. Blood sugar was 583. Resident deceased upon re-check after calling PCP to report status change.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client was being treated with antibiotics by her PCP for diverticulitis flare up. It had not been resolved on the date of her death which occurred 01/27/21, She was found unresponsive by staff, 911 contacted, and paramedics pronounced her deceased at 7:48 AM. After consultation with PCP manner of death was noted as cardiac arrest. PCP was to sign off on death certificate.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH))**

		(1200)
Client received the COVID-19 vaccine on 1/5/21 by the Vaccine clinic. Plans were for Hospice services. Client tested positive for COVID-19 by rapid testing on 1/8/21. On 1/10/21 at 0900 Client was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.	No prior vaccinations for this event.	
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Client recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic. Client tested positive for COVID-19 by rapid testing on 1/21/21, with c/o hurting all over and loose stools. She became non-verbal on 1/23/21 with poor intake. On 1/24/21 at 0537 Client was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.	No prior vaccinations for this event.	
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient has been under Hospice services for almost a year. She began to demonstrate a large amount of oral secretions on 1/10/21 at 2130. She was suctioned and a Rapid COVID-19 test was performed, which was negative. The COVID-19 Rapid test was repeated on 1/11/21 and was positive. Oxygen saturation was noted to be 78% on 1/12/21, and oxygen was initiated at 1133 at 3L per nasal cannula. Oxygen was increased to 4L at 1635 d/t shortness of breath. On 1/15/21 @ 0645 patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.	No prior vaccinations for this event.	
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (PFIZER-BIONTECH))**

		(1200)
Client tested positive for COVID-19 by rapid test on 1/8/21. On 1/9/21 at 1405 his oxygen saturation dropped to 86% and oxygen was initiated at 2L per nasal cannula. A non-productive cough was noted on 1/10/21 and oxygen was increased to 3L. On 1/12/21 Client became non-responsive with 30 second periods of apnea. Dexamethasone was initiated on 1/13/21. Lung sounds were noted with crackles on 1/15/21 at 1158 and at 2120 Client was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient tested positive for COVID-19 by rapid test on 1/6/21. She began to demonstrate a dry cough on 1/11/21. On 1/12/21 at 1723 her oxygen saturation dropped to 79% and oxygen was applied at 4L per nasal cannula. On 1/19/21 at 2130 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic #1. Patient tested positive for COVID-19 by rapid testing on 1/6/21. She demonstrated poor appetite and fluid/food intake and an IV of Normal Saline was initiated on 1/7/21. Oxygen saturation was initiated on 1/12/21 at 4L per nasal cannula. for shortness of breath. On 1/22/21 at 0310 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.		No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began to demonstrate a cough the evening of 1/5/2021, after receiving the COVID-19 vaccine earlier in the afternoon. A rapid COVID-19 test was performed and was positive. She began to demonstrate shortness of breath with exertion on 1/7/21, and lethargy on 1/12/21. Appetite and oral intake began to decline on 1/12/21, and Oxygen saturation dropped on 1/16/21 to 82%, and oxygen was initiated at 3L per nasal cannula. On 1/19/21 at 0414 patient was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was an 87 y/o female admitted for septic shock. She was started on and eventually maxed on 3 pressors. CT abd showed colonic obstruction with dilatation of large and small bowel. Patient was made DNR in the ED. Palliative care consulted on case. Family opted for comfort care. Patient was asystole on monitor. No spontaneous breath/cardiac sounds ausculted. Patient did not withdraw to pain. Pupils fixed and dilated. She was pronounced and 1230 on 1/28/21		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
After being observed for approximately 20 minutes and patient walked to her car without assistance I was called to assess the patient in the parking lot for troubles breathing. EMS was called as I made my way outside. Upon my arrival patient was leaning out of the car and stating that she could not breath. She was able to tell me that she was allergic to penicillin. Oxygen was immediately placed on the patient with		No prior vaccinations for this event.

minimal relief. Lung sounds were coarse throughout. She then began to vomit about every 20-30 seconds. Epipen was administered in the right leg with no relief. Patient continued to complain of troubles breathing and vomiting. A second epipen was administered in the patients right arm again with no relief. A few minutes later patient was given racemic epinephrine through the oxygen mask. There appeared to be mild improvement in her breathing as she appeared more comfortable, but still complaining of shortness of breath and vomiting. When EMS arrived patient was unable to transport herself to the stretcher. When EMS and clinical staff transferred patient to the stretcher she became unresponsive. She appeared to still be breathing. She did not respond to verbal stimuli. Per ED report large amount of fluid was suctioned from the patients lungs following intubation in the ambulance. When patient arrived to the ED she was extubated and re-intubated without difficulty and further fluid was suctioned. At that time patient was found to be in PEA, shock was delivered. Shortly thereafter no cardiac activity was found and patient pronounced dead.		
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/28/2021- Seen by FNP for indigestion, chest pressure and palpitations. EKG reviewed and referral made to Cardiology. 1/29/2021-1800 Presented to ED in cardiac arrest-onset PTA. Patient was found unresponsive by his wife at their home. The last known well was at 1530 when she called him on the phone. The patient was pronounced at ~1850.		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident found unresponsive in room this am at approx. 9:30 am. Resident was observed eating breakfast around 8:45 am. Housekeeper reported seeing resident between breakfast and time found unresponsive. Resident had voiced no complaints. Code was initiated until EMS arrived and transported resident to		No prior vaccinations for this event.

hospital. Resident expired.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Employee was found unresponsive in floor at her home. EMS arrived and person had expired.	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt son, reports patient passed away on 2/1/21 in the early hours. Pt wife, told Pt's son that patient started feeling ""bad"" with common cold like symptoms on 1/31/21, had a temp of 99.0. Pt's wife went to take a shower, when she got out patient was unresponsive. She called EMS, they pronounced patient deceased upon arrival. á Pt's son also reports patient and Pt's wife both had their 1st COVID-19 vaccine 13 days prior. He was told by EMT on sight to notify the facility where they received their vaccines. He did contact them and was told to notify PCP."	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received vaccination at 9:12 am, she was monitored and checked at the 15 minute interval 9:27 am, reassessed, vitals were fine. Within 20 (9:32 am) minutes of receiving the vaccine she was unresponsive, pupils were fixed at 9:45 am, no vital signs noted; hospice came out and reported her time of death 10:21 am. This person was on hospice.	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient's primary care provider received a death certificate to be signed for this patient. He spoke with the patient's husband and son, who reported that the patient had pain and swelling at the vaccine administration site after receiving the vaccine and was feeling unwell after receiving the vaccine. The patient's family reported that they found her unresponsive on 2/2/21 and called 9-1-1. The patient was pronounced dead upon arrival of emergency responders.		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
death. No known symptoms or complaints. found unresponsive in bed. Released to funeral home as the Medical Examiner will not perform and autopsy. Dr. will sign the DC.		No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
view 2/5/2021 09:23 e Progress Note Note Text: Patient passed away in the facility this morning. view 2/5/2021 08:39 Orders - Administration Note Note Text: Resident passed. view 2/5/2021 08:33 Nurses Note Note Text: Body released to funeral home at this time. Personal effects sent with resident include: 1 pair of glasses, 1 yellow wedding band, 1silver spoon ring, 1 ring with black and clear stones. Resident has own teeth view 2/5/2021 08:32 Nurses Note Note Text: cause of death per CRNP failure to thrive. view 2/5/2021 07:44 Orders - Administration Note Note Text: Take and document temp & PO2 every 4 hours for MONITORING Resident passed. view 2/5/2021 06:49 Nurses Note Note Text: Son returned call and was updated of resident's passing this am view 2/5/2021 06:33 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for		No prior vaccinations for this event.

pain/air hunger PRN Administration was: Unknown Resident expired @ 0604 [linked] view 2/5/2021 06:06 Nurses Note Note Text: Res found without pulse or respirations. Pronounced at 0604. Updated. N/o's for RN to pronounce, release body to funeral home, dispose of medications per facility policy. Daughter updated. Funeral Home called to release body. view 2/5/2021 05:26 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Pulse ox 60% on O2 @ 5L/min via mask. Resps 44 per minute. view 2/5/2021 01:57 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/5/2021 00:52 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger Residents resps are 40 per minute, pulse ox 76% on O2 @ 5L/min via mask. Resps are labored, shallow and rapid. view 2/5/2021 00:48 Nurses Note Note Text: Nonresponsive to verbal and tactile stimulation. Appears comfortable. view 2/4/2021 22:01 Nurses Note Note Text: Resident resting comfortably, breathing becoming increasingly shallow, wearing O2 via mask at 5L via mask, no dyspnea noted, feet are mottled, oral and peri care provided Q2H. No s/s of pain or discomfort. view 2/4/2021 21:40 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger PRN Administration was: Effective [linked] view 2/4/2021 19:32 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 2 hours as needed for pain/air hunger medicated for air hunger, RR 28 to 32/ min view 2/4/2021 19:22 Nurses Note Note Text: Daughter updated on N/O to increase Morphine Sulfate 20mg/mL 0.25mL to Q2H prn from Q6H prn. view 2/4/2021 18:06 Nurses Note Note Text: POA Daughter and daughter aware of residents current condition. view 2/4/2021 11:58 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective Follow-up Pain Scale was: 2 [linked] view 2/4/2021 11:13 Nurses Note Note Text: Pt. noted to be lethargic at this time. Does respond to verbal and tactile stimuli by opening her eyes but non verbal currently. Skin warm and dry. No mottling or apnea observed at this time. O2 sat 88% with O2 at 2 LPM via n/c. On increased to 3 LPM via mask as pt. noted to be mouth breathing. Respirations 28. F/U O2 sat 93%. HOB elevated. Pt. medicated with morphine by LPN. Daughter updated on pt.'s condition.

Does not want pt. sent out to hospital and would like comfort measures to continue. Daughter also in agreement with delay in d/c d/t pt.'s condition.CRNP updated on pt.'s condition, delay in d/c and daughter's wishes. No n/o's at this time. view 2/4/2021 10:56 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB Resident showing s/s of discomfort. SOB at this time and high respirations. Repositioned, changed for incontinence care and mouth care provided. view 2/4/2021 10:34 Progress Note Note Text: Spoke with RN regarding change in condition. Updated Sr Living regarding change. Recommendation to cancel d/c/transfer for today, see how resident does through the weekend and re-evaluate on Monday. Daughter updated on cancellation of d/c today. view 2/4/2021 10:04 Nurses Note Note Text: Daughter aware that resident's O2 sat was 88% on room air on 3-11 shift and that oxygen was applied via nasal cannula. view 2/4/2021 10:03 Nurses Note Note Text: N/O: Discharge 2/4/21 with scripts to Sr. Living. Daughter aware. view 2/4/2021 09:53 Nurses Note Note Text: Pt. to be d/c'd to another facility this am as per MD order. Pt. alert and responsive. Skin assessment done as per facility policy. No pressure areas noted at this time. No s/sx of pain or discomfort observed at this time. V.S. 97.0 67 20 O2 sat 95% with O2 at 2 LPM via n/c. view 2/4/2021 07:45 Nurses Note Note Text: Resident seen by Dr. for discharge. Orders pending at this time. view 2/4/2021 07:36 Nurses Note Note Text: CRNP and Dr. updated on O2 sat 88% on RA with f/u of 93% with O2 on at 2 LPM as well as rest of VS, 3-11 shift 2/3/21. No n/o's at this time. view 2/3/2021 21:17 Nurses Note Note Text: Resident Sp02 88% on RA. Pulse 124. Respirations 40. PRN morphine given and O2 applied via NC at 2L/min. After recheck pulse ox up to 93%, pulse 100, and respirations 22. Resident appears comfortable at this time. view 2/3/2021 20:05 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN Administration was: Effective [linked] view 2/3/2021 19:48 Orders - Administration Note Note Text: Morphine Sulfate (Concentrate) Solution 20 MG/ML Give 0.25 ml by mouth every 6 hours as needed for pain/SOB PRN given for SOB after elevation of HOB not effective. view 2/3/2021 11:51 Nurses Note Note Text: CRNP updated rapid COVID test done for d/c tomorrow was negative. No n/o's at this time. view 2/3/2021 11:44 Nurses Note Note Text: Daughter notified of rapid covid swab being negative. view 2/3/2021 09:50 Orders - Administration Note Note Text: Obtain Rapid Covid test on 2/3/2021 for discharge. Please give copy of results to Social Worker every day shift for covid testing for 1 Day Completed and negative. view 2/3/2021

08:45 Skilled Nursing Note Reason for skilled service: Therapy describe skilled service: Nursing, therapy assessment: V.S. 97.8 79 18 138/84 Orientation: Oriented to self only. Oxygen: O2 sat 94% on RA Edema: Trace edema noted BLE. Pedal pulses present. Pain: Denies pain or discomfort at this time. Nursing note: Pt. alert and responsive. Skin warm and dry. Lung sounds diminished. No respiratory distress observed at this time. Abdomen soft. BS+ in all 4 quads. Continent/Incontinent of B&B. 1 assist with ambulation, transfers. 1 assist with ADL's. Working with therapy on gait training, therapeutic exercise, therapeutic activities & neuromuscular reeducation. view 2/2/2021 14:37 Progress Note Note Text: Per health professional at Sr Living, prepared to accept patient to their Memory Care Unit 2/4. Transportation arranged for 11 AM per family request. Daughter (POA) updated on d/c time on 2/4/21. Facility requesting rapid COVID test completed prior to d/c and results sent to them. All other information sent for continuity of care.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Narrative: Patient with history advanced vascular dementia, hypertensive cerebrovascular disease and stroke, T2DM. Received her second dose of Pfizer COVID-19 vaccine at approximately 14:00 and was reported to have expired at home at 20:55. Dr. (Medical Director) spoke with patient's son/caregiver 2/4/21. Son reports that patient was in her usual health yesterday morning, deemed well enough by son to travel for vaccination. He reports she had no bothersome symptoms after either first or second vaccinations. Specifically denied rash, wheeze, and difficulty breathing. Son was with patient throughout the day. In the evening, when preparing for bed, he noted she became suddenly unresponsive in a similar fashion as she has done several times in past years. While in all previous such episodes she recovered within minutes, last evening she did not regain consciousness, experiences a brief period of labored breathing, and died. Patient's son called 911 and the patient's body was brought to the medical examiners. The medical examiner declined to proceed with autopsy. Patient's son is not interested in autopsy. Patient's son reports confidence that his mother's underlying hypertensive/diabetic cardiovascular disease is the natural cause of

No prior vaccinations for this event.

her death. Other Relevant Hx: Symptoms: & Death Treatment:

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was administered second dose of Pfizer vaccine in Nursing Home on 2/5/2021 around noon and was found unresponsive at 5:03AM the following day 2/6/2021. Patient arrived to Hospital in cardiopulmonary arrest and was pronounced dead.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Xrays showed covid Poss pockets all in her lungs on 15Jan; Xrays showed covid Poss pockets all in her lungs on 15Jan; This is a spontaneous report from a contactable consumer. An 85-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Dec2020 at single dose for covid-19 immunisation. Medical history included dementia. Concomitant medications were not reported. Patient popped hot 02Jan2021 along with 4 others on the hall she lived. Within 9 days 50+ patients were positive. All had the vaccine the same day. Patient was test positive on 02Jan2021. She was on day 12 of her quarantine when she started to get worse. She was unresponsive by 16Jan2021 and passed 18Jan2021. We were with her from 14Jan2021 to 18Jan2021. But had not been allowed to visit with her since Mar2020. And what post treatment pairs well with it? Publicly we hear Remdesivir and Bamlanivimab but these patients only received a general antibiotic and some vitamins. Death cause was Xrays showed covid Poss pockets all in her lungs on 15Jan2021. No autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported event of positive for corona virus infection for the lack of efficacy of the vaccine. However, based	No prior vaccinations for this event.

on the mechanism of action of the vaccine, it is unlikely the patient would have fully developed immunity for the vaccine to be effective, due to the number of days passed since the vaccine is given. Case will be reevaluated based on follow-up information; Reported Cause(s) of Death: Xrays showed covid Poss pockets all in her lungs on 15Jan

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident was weak, fatigued and had a fever of 101. F the following morning after receiving the 2nd dose of vaccine. Later in the day she was feeling better and vital signs were WNL. The next morning, she was found unresponsive and pronounced dead by paramedics.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and ACLS guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and ACLS guidelines initiated. á In reviewing patient's chart and nursing home	No prior vaccinations for this event.

notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this	No prior vaccinations for this event.

was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th time at 08:18. Family at beside, Mother asks for code to be stopped."

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
For the two days prior to presentation the patient had been complaining of chest pain, his breathing seemed to be labored Monday. He and the family thought the pain was due to shingles as he carried this diagnosis	No prior vaccinations for

from a month ago. Patient had also received the COVID vaccine 2 days prior to presentation and assumed he was feeling unwell due to the vaccine. Family wanted to take him to the hospital yesterday and earlier today but he refused. She left him in his home earlier this afternoon prior to presentation and returned to check on him finding him unresponsive and apneic at which time EMS was activated. #cardiac arrest -- suspect primary cardiac given collateral from family at home, consider hypoxemia which was corrected with advanced airway and 100% FiO2, patient clinically euvolemic and with soft brown stool in diaper not suggestive of GI hemorrhage, attempt to address acidosis with CPR and bicarbonate, not hypoglycemia, on bedside ultrasound FAST neg and no pericardial effusion suggestive of tamponade and +lung sliding bil not spontaneous pneumothorax Assessment/Diagnosis: -cardiac arrest, cause unspecified	this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient found unresponsive in room with no pulse or respirations. She was pronounced dead by paramedics at 06:25am on 2/5/2021.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
24 hours after shot had high fever 101, chills, weakness, became listless, family called 911, client became unresponsive and died in the Emergency room.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into	No prior vaccinations for this event.

cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,. Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.		
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
At 10:33 am Patient pushed her pendant for staff, staff arrived to her apartment and Patient was found unresponsive in her bathroom. Patient received her second COVID-19 Pfizer vaccine about 75 minuets prior to this, she had no adverse reaction's within the first hour of receiving the second dose. CPR was started until paramedics arrived, they took over and tried to resuscitate. Patient was pronounced dead at 11:33 am at scene.		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The individual received the vaccine around 12:00pm on 02/11/21. Around 9pm the individual went to lay down on the couch at home and started to have difficulty breathing. Within 30 minutes the individual became week and unresponsive. She was transported to the hospital where she was pronounced deceased at 11:44 pm on 02/11/21.		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Swollen leg/pain- taken to urgent care- became unresponsive - CPR initiated- expired

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was found unresponsive on her kitchen floor about 9:45 AM on February 10, 2021 approximately 18 hours after receiving her first Covid-19 vaccination. Exact time of the event is unknown. She was known to get up between 6:30 and 7:30 AM. It appeared that she had not eaten breakfast nor taken any medication that morning. She was taken by ambulance to Medical Center where a CT scan showed an unrecoverable massive brain hemorrhage. She died at approximately 3:50 PM after the respirator was removed. She was sent to the local Medical Examiner afterwards.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient (now deceased) received 1st dose of Pfizer-BioNTech vaccine around December 21, 2020 and was noticed to be scratching, fatigued, and unresponsive by a family member on December 24, 2020. He received the second dose of the same vaccine around January 22, 2021. Pockmarks and bleeding scratch marks were noted by a family member on the patient's face prior to this second dose. On January 28, 2021 a family member was alerted that the patient was suffering from severe bullous pemphigoid- a skin condition that has never been experienced by the patient, has been reported to be related to COVID-19 viral infection, and to T-cell responses promoted by vaccines. A corticosteroid was given, but did not work. Blisters developed to the point hands had to be dressed.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Unresponsive, Increase BP and H. Hospital Dx Renal Failure No prior vaccinations for this event.	
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received his first dose of Covid vaccine on Jan. 30, 2021. On Jan 31, 2021 at 6:08 AM, patient noted unresponsive per facility. Code blue was called and 911 dispatched. He expired in the ER.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and	No prior vaccinations for this event.

weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient was found unresponsive the following day and then pronounced deceased No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had COVID in Sept. Minimal symptoms. Received 1st dose 1/18 without adverse reactions. Second dose on 2/8-had complaints of arm soreness several days after then appeared in usual state of health. On 2/14 @ 2 hours after having lunch, patient was found unresponsive with Respirations 60, pulse 130, PO 84%, blood pressure 105/68. Patient with lots of white foam coming out of mouth. Temperature to 101.3. Patient DNR B and family deferred transfer, wanted comfort measures only. Nursing received order for MSIR. Patient continued with temps in 99-100 range with tylenol suppositories. Patient passed on 2/16.	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident did not exhibit any side effects from the vaccine. Staff spoke with him in his room at approximately 7:20am and returned to his room just a few minutes later and he was unresponsive. When the RN got to the room he had CTB. Physician documented heart failure and end stage kidney disease on the death	No prior vaccinations for this event.

certificate.

	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On the 25th he was home alone, he called 911 and let them know he thought he was having a stroke. EMS arrived and transported him to Hospital. It was massive stroke, he was not able to comprehend anything, he was put into Hospice the following day and passed away on the 27th. There was no autopsy preformed.		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
My dad received the Pfizer vaccination on 2/5/21. He was admitted into the hospital the next day for C-Diff bacterial infection. He had been on dialysis treatments for kidney failure treatment since 2017 and had recently been diagnosed with stage 3 colon cancer in June 2020. He had completed his final treatment of chemotherapy on 2/4/21 and several weeks prior had been determined cancer free. On Tuesday 2/9/21 he was released from the hospital and went home. Early Thursday morning 2/11/21 @ approximately 1:30 am CST his eyes rolled back in head and he stopped breathing and was non responsive. My mother called 911 and attempted CPR. Paramedics arrived and were able to successfully get a pulse then transferred him to the hospital. He was put on a ventilator @ the hospital and then transferred to a different hospital a few hours later. He lost pulse/heartbeat several times @ the 2nd hospital he was transferred to. We were not allowed to travel with him or see him b/c of all of the COVID restrictions. We were communicating with the ICU doctor by phone who ultimately communicated to us that there was nothing further that could be done to save his life. He subsequently passed away @ approximately 8:55 am CST on 2/11/21.		No prior vaccinations for this event.
	UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1/27/21 Emergency room: HPI Patient is a 77 y.o. male who presents after a syncopal episode with cyanosis and shortness of breath. Patient came from rehab where they stated he was sitting on his bed, his

No prior vaccinations for this event.

oxygen saturation dropped down to 76% on 4L and he became cyanotic. By the time EMS arrived, patient was back to 95% on 4 L. On arrival to the ER, he is 98-100% on 4L. He has a history of COPD and has a chronic cough due to this.Currently, he has no pain, no shortness of breath, no weakness, no cyanosis. He is afebrile and sitting comfortably in bed. 2/10/21 emergency room HPI Patient is a 77 y.o. male who presents with in full cardiac arrest. Patient is resident of local nursing home. According to nursing home staff, a tech was in his room talking with him as patient was laying in bed. Tech began walking out of patient's room and turned around to tell him one last thing when the tech noticed patient had gone unresponsive. Patient had no spontaneous respirations or pulse, subsequently CPR was started immediately. 911 was called. This occurred around 5:30 a.m.. á Upon EMS arrival on scene, they found a male unresponsive with CPR being performed. There was no spontaneous respirations or circulation. Thus, ET tube was placed and life support guidelines initiated. Patient was found to be in PEA, and according to EMS, patient was given a total of 6, 1 mg epinephrine IV push and 1, 1 Amp sodium bicarb. Patient was worked on at the scene for approximately 40 min before being transferred to ER. á Upon arrival to ER trauma room 1 patient is still in full arrest. ET tube in place with good ventilation. Patient remains in PEA. Chest compressions and life support guidelines initiated. á In reviewing patient's chart and nursing home notes, patient is a full code. Patient has a significant cardiac history including known coronary artery disease with 4 vessel CABG. Patient also has history of 3rd degree heart block and pacemaker placement. Patient has history of ischemic cardiomyopathy but last echo performed in 2020 shows ejection fraction of 45%.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident found unresponsive in his room. CPR performed and patient expired. No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Resident found unresponsive, CPR initiated and EMS called. EMS called time of death after arrival.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pale, Short of Breath, Hypoxic, Lethargic within minutes became unresponsive and died.	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Death. Patient was found unresponsive in the morning hours after her shot. No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Developed acute facial droop and slurred speech 2h after 1st dose of the vaccine on 2/17, found with R MCA stroke. Then became unresponsive on 2/27 and was found with an acute L MCA stroke. Was transferred from another hospital, was not a candidate for intervention, and was made comfort and died on 2/28	No prior vaccinations for this event.
UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On date on second dose, 2/27/2021, the pt began have fatigue and diarrhea at around 10:30 am. This continued to the following day. On 2/28/2021, the patient was last seen around 4:20 pm by his wife in their residence. She found him unresponsive at 5:30 pm in their bedroom. EMS was called and the decedent was declared deceased. The pt had his first dose on 2/9/2021. Both doses were given at the hospital. Per	No prior vaccinations for this event.

family, the pt had no adverse affects following the first dose.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
EMS responded to a call at his home; he was found unresponsive by family slumped over in a chair	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Pt received 2nd Pfizer BioNTech Covid 19 EUA vaccine @1:50 pm; Pt released from Observation @2:09 pm. Approximately 2:18 pm RN called to parking lot and observed pt having difficulties. Called for EMS & crash cart. Vitals taken 2:20 BP 83/55, no respirations noted, pt unresponsive. AED attached. EMS arrived 2:22 and took over care of pt. and transported @2:40 pm to Hospital. Per wife, pt has history of PE in Oct. 2020, HTN, diabetes with insulin pump, obesity, gastroparesis, home oxygen and uses motorized scooter. Wife also said pt had allergy to iodine not previously reported, and MD had stopped Zarelto subsequent to 1st Pfizer vaccine 2/8/21 ""due to breathing difficulty"". Patient was unable to be resuscitated. Time of death 14:59."	No prior vaccinations for this event.

UNRESPONSIVE TO STIMULI	**COVID19 (COVID19 (UNKNOWN)) (1202)**
Received first SARS-CoV2 vaccination yesterday at local store Experienced new symptoms of chills, nausea as well as worsening from baseline dyspnea at night. Wife states he had rough morning breathing and had sudden loss of consciousness and unresponsiveness and failed to respond to bystander CPR. He expired at his home.	No prior vaccinations for this event.

	UPPER RESPIRATORY TRACT INFECTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."		No prior vaccinations for this event.
	URINARY CASTS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o		No prior vaccinations

some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or for this event.

multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

URINARY INCONTINENCE

COVID19 (COVID19 (MODERNA)) (1201)

Patient had Covid-19 in October of 2020. He recovered. He received the vaccination on 12/30/2020 with no complaints. On 01-05-2021 it was noted to he was incontinent of urine and bilateral lower extremity edema. Lab work was completed showed acute kidney injury. He had decreased blood pressure and oxygen saturations on 01-06-2021 He was admitted to the hospital with rapid progression of symptoms and suggested multi-system failure. He had a long cardiac history. On 01-14-2021 he passed away with a diagnosis of Cardiomyopathic CHF, A.Fib contributory.

No prior vaccinations for this event.

URINARY INCONTINENCE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated at 11:30am. By 7pm he started presenting symptoms of fatigue, chest pain. Patient urinated and defecated in himself. Was not feeling well. Patient died at 10:30pm.

No prior vaccinations for this event.

URINARY LIPIDS PRESENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right

No prior vaccinations for this event.

middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

URINARY OCCULT BLOOD POSITIVE

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep

No prior vaccinations for this event.

his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

URINARY OCCULT BLOOD POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was	No prior vaccinations for this event.

added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

URINARY RETENTION

COVID19 (COVID19

(MODERNA)) (1201)

Death; kidney failure (unable to urinate); shortness of breath; required oxygen; A spontaneous report was received from consumer concerning an 87-year-old, female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced shortness of breath, kidney failure and death. The patient's medical history included advanced kidney and heart disease. No relevant concomitant medications were reported. On 06 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 17 Jan 2021, the husband reported that the patient experienced adverse events. Symptoms included shortness of breath and kidney failure (unable to urinate). The patient was admitted to the hospital and discharged to hospice. Oxygen was administrated for shortness of breath. Action taken with mRNA-1273 in response to the events was not applicable. On 20 Jan 2021, the patient died. The cause of death was unknown. Autopsy details were unknown.; Reporter's Comments: This case concerns a 87-year-old, female patient with the medical history of advanced kidney and heart disease, who experienced fatal unexpected event of dyspnea, renal failure and death. The events of dyspnea and renal failure occurred 12 days and the event of death occurred 15 days after the first dose of mRNA-1273 (Lot: unknown). The patient was admitted to the hospital and discharged to hospice. Oxygen was administrated for shortness of breath. The cause of death was unknown. Autopsy details were unknown. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. However, the history of advanced kidney and heart disease may remain as confounder. Additional information has been requested.; Reported Cause(s) of Death: Unknown cause of death

No prior vaccinations for this event.

URINARY RETENTION

COVID19 (COVID19 (MODERNA)) (1201)

She had pain in the injection site Tuesday night and then during Tuesday she got worse with nausea and some fever. By Wednesday she was complaining that she could not pee even though she was drinking a lot of fluids. She continued to complain it was the worst she ever felt and then at 0600 Thursday morning she

No prior vaccinations for this event.

woke us up and said she needed to go to the hospital. We arrived at the hospital just before 0700 and she immediately threw up in the trash can. We went into a treatment room and they took blood and started fluids as she became incoherent. She said she had taken Tylenol so they started a drug to counter that but her liver function was all wrong and they started to look for a hospital that could transplant a liver. She was air evade about 0930 to Medical center and just over 30 hours latter she was dead. There is a pending autopsy. She was a healthy 39 year old mother who got the shots because she worked as a surgical tech and she was the single mother of a 9 year old little girl.

URINARY SEDIMENT PRESENT

COVID19 (COVID19 (MODERNA)) (1201)

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol

No prior vaccinations for this event.

mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

URINARY SEDIMENT PRESENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was	No prior vaccinations for this event.

thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

URINARY TRACT INFECTION	**COVID19 (COVID19 (MODERNA)) (1201)**
ON 1/14/2021 TYPICAL UTI SYMPTOMS FOR RESIDENT DEVELOPED INCLUDING FEVER AND RIGIDITY. RESIDENT IS NON-VERBAL. IV ANTIBIOTICS WERE STARTED. FREQUENT UTI'S ARE COMMON FOR THIS RESIDENT.	No prior vaccinations for this event.
URINARY TRACT INFECTION	**COVID19 (COVID19 (MODERNA)) (1201)**
Death on 1/17/21. Death certificate reports: Septic Shock, UTI, Pneumonia, Chronic Renal Failure	No prior vaccinations for this event.
URINARY TRACT INFECTION	**COVID19 (COVID19 (MODERNA)) (1201)**
"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"	No prior vaccinations for this event.

URINARY TRACT INFECTION		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient received the vaccine on 1/31/2021. Patient complained of bleeding 2/7/2021. Went to clinic where labs were conducted. Patient had an INR of 12. Previous INR results were normal prior to vaccination. Patient was also diagnosed with UTI and given antibiotics. Patient was encouraged to go to ER. Patient died on 2/12/2021.		No prior vaccinations for this event.
URINARY TRACT INFECTION		**COVID19 (COVID19 (MODERNA)) (1201)**
Patient was admitted to hospital on 2-9-21 for urinary tract infection and tested positive for Covid. Developed pneumonia and expired on 2-12-21.		No prior vaccinations for this event.
URINARY TRACT INFECTION		**COVID19 (COVID19 (MODERNA)) (1201)**
Chest clear - Hospitalized for a UTI		No prior vaccinations for this event.
URINARY TRACT INFECTION	**COVID19 (COVID19 (MODERNA)) (1201)**	
Passed away; UTI; Abnormal bleeding; A spontaneous report was received from a healthcare professional concerning a patient who received the Moderna COVID-19 Vaccine (mRNA-1273) and experienced abnormal bleeding, UTI, and passed away. The patient's medical history included a long term history of anticoagulation therapy. Concomitant product use included anticoagulation therapy. On 31Jan2021 prior to the onset of the events the patient recieved their first dose of mRNA-1273 (Lot number:not reported) intramuscularly for prophylaxis of COVID-19 infection. On 07Feb2021, the patient complained of abnormal bleeding. Patient was seen at clinic on 10Feb2021 and was diagnosed with a UTI and given antibiotics. An INR was also completed that day due to patient having a long term history of anticoagulation therapy.		No prior vaccinations for this event.

Results of that showed the INR to be 12. Prior to vaccination, patient's INR was normal and no changes to medications and diet were made after vaccination and prior to complaint starting. On 12Feb2021 the patient passed away. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12Feb2021. The cause of death was unknown. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns an 82 year old male patient, with history of long term anticoagulation therapy (unknown indication), who experienced a fatal event of death and abnormal hemorrhage, 13 days after receiving second dose of mRNA- 1273 (Lot# Unknown). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death	
URINARY TRACT INFECTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Has underlying dementia and often with difficulty eating. 1 week after immunization she developed a stroke with left sided weakness and difficulty swallowing. Comfort measures instituted. Not sure if this is related to the vaccine, but thought I should report	No prior vaccinations for this event.
URINARY TRACT INFECTION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1 fall after first dose on 1/8/2021 at 1930; no injuries; 4 falls after second dose on 1/14/21 at 1545, 1/15/21 at 1700, 1/21/21/at 1220 and 1/21/21 at 1330 all falls with no injuries. Started Ceftriaxone 1 GM IM daily for 5 dyas on 1/21/21 for UTI: E. Coli	No prior vaccinations for this event.
URINARY TRACT INFECTION	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

See initial report

No prior vaccinations for this event.

URINARY TRACT INFECTION COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident was hospitalized for confusion, and hypotension and increased weakness; resident proceeded to have a NSTEMI and died on 5th day in hospital on 1/31/2021.

No prior vaccinations for this event.

URINARY TRACT INFECTION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Resident had slight/slow decline in health prior to vaccine but continued to be able to walk around with walker at community. The day of the vaccine she had a fever. 2 days after vaccine resident did not get out of bed all day and refused to eat. She had small amounts of orange juice as her blood sugar level was low due to not eating. Resident was diagnosed with a UTI and began an oral antibiotic. 3 days after and on day 5 after vaccine resident began feeling weak and had a fall on each day. The following day again resident spent the day in bed. The next day she was quite restless, was on the edge of her bed attempting to self transfer often throughout the day. Resident continued to be restless on the 10th of Feb, had further decline on the 11th of Feb. Resident passed away early the AM of Feb. 12th.

No prior vaccinations for this event.

URINARY TRACT INFECTION

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

PATIENT WAS ADMITTED TO ER FOR ALTERED MENTAL STATUS / UTI SEPSIS WITH SEPTIC SHOCK / COVID AND COVID PNA PATIENT WAS ADMITTED TO ICU AND DIED . POA WISH TO WITHDRAWL EXTRME MEASURES

No prior vaccinations for this event.

URINARY TRACT INFECTION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.

URINARY TRACT INFECTION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
92 year-old male with PMHx of vascular dementia, BPH, MDD, sleep disturbance , basal cell carcinoma of neck, osteoarthritis, BLE edema, Guillain-Barre syndrome 30 years prior, s/p COVID positive on 1/11/21 and received IV Bamlanivimab. Sent to hospital on 2/2/21 for altered mental status, generalized weakness with inability to lift bilateral UE and difficulty moving his BLE. He was treated for UTI with 7 days of Cefepime for Morganella Morganii. He was followed by neurology with MRI of the brain and CT of the spine without acute findings. Lumbar puncture unable to be obtained. He received 5 day course of IVIG for presumed Guillain-Barre . EMG showed generalized sensory motor polyneuropathy both axon loss and demyelinating type severe in degree. However, he did not recover from his GBS symptoms, was transferred back to the nursing home and died on 2/15/2021.	Influenza Vaccine

URINARY TRACT INFECTION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Day After - severe headache, 2 days after headache continues, itchy scalp, day 3 rash visible at hair line headache continues, more confusion than normal, day 4 on site nurses check rash and think it is dermatitis,	No prior vaccinations

day 5 continues to get work nurse practitioner was to visit next day, day 6 NP thinks that she has UTI and sends her to hospital (2/11/21). Hospital determines - Rash is Shingles, UTI present, - MRSA is now present in shingles which is on right back of head and right neck and face. Next Sepsis is diagnosed. Since 2/11/21 patient was not conscious. 2/20/21 famiy is notified that she should be moved to Hospice. Moved to hospice on 2/20/21. The patient, my mother, died on 2/23/21 official cause of death is UTI.

for this event.

URINE ABNORMALITY

COVID19 (COVID19 (MODERNA)) (1201)

"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."

No prior vaccinations for this event.

URINE ABNORMALITY

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be

No prior vaccinations for this event.

pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

URINE ANALYSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.	No prior vaccinations for this event.

URINE ANALYSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
ON 1/14/2021 TYPICAL UTI SYMPTOMS FOR RESIDENT DEVELOPED INCLUDING FEVER AND RIGIDITY. RESIDENT IS NON-VERBAL. IV ANTIBIOTICS WERE STARTED. FREQUENT UTI'S ARE COMMON FOR THIS RESIDENT.	No prior vaccinations for this event.

	URINE ANALYSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Had acute respiratory failure, dysuria NSTEMI after Dose #1 Lot # 025L20A (Moderna) hospitalized same day 12/31/20 administered @ 1040 back to baseline. 2nd Dose on 1/27/21 0950 Lot as above. Unknown exact onset same day, ED by EMS @ 1745, respiratory distress, febrile 39.4 degrees C BP 150/105 RR 29		No prior vaccinations for this event.
	URINE ANALYSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
2/2/21-1000-patient presented to the local emergency room with complains of fever, shortness of breath and decreased oxygen sats. temp 101.7, pulse 102, respirations 36, BP 141/92, oxygen 94%. Lung sounds crackles bilaterally with rhonchi on the left. patient worked up for sepsis, CXR shows mild atelectasis. blood pressure dropped, and continued to drop through treatment requiring levophed drop to be initiated. Patient POA determined that this would not be her sister's wishes and made the decision to make patient comfort care status. 2/3/21- patient lethargic throughout night. 0640-patient demise.		No prior vaccinations for this event.
	URINE ANALYSIS	**COVID19 (COVID19 (MODERNA)) (1201)**
Passed away; UTI; Abnormal bleeding; A spontaneous report was received from a healthcare professional concerning a patient who received the Moderna COVID-19 Vaccine (mRNA-1273) and experienced abnormal bleeding, UTI, and passed away. The patient's medical history included a long term history of anticoagulation therapy. Concomitant product use included anticoagulation therapy. On 31Jan2021 prior to the onset of the events the patient recieved their first dose of mRNA-1273 (Lot number:not reported) intramuscularly for prophylaxis of COVID-19 infection. On 07Feb2021, the patient complained of abnormal bleeding. Patient was seen at clinic on 10Feb2021 and was diagnosed with a UTI and given antibiotics. An INR was also completed that day due to patient having a long term history of anticoagulation therapy. Results of that showed the INR to be 12. Prior to vaccination, patient's INR was normal and no changes to		No prior vaccinations for this event.

medications and diet were made after vaccination and prior to complaint starting. On 12Feb2021 the patient passed away. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12Feb2021. The cause of death was unknown. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns an 82 year old male patient, with history of long term anticoagulation therapy (unknown indication), who experienced a fatal event of death and abnormal hemorrhage, 13 days after receiving second dose of mRNA- 1273 (Lot# Unknown). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

	URINE ANALYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Fever, Malaise	No prior vaccinations for this event.	

URINE ANALYSIS COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

See initial report	No prior vaccinations for this event.

URINE ANALYSIS COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

1-12-21 Resident is complaining of heart pain. Resident blood pressure is 228/105. 1-22-21 Dx UTI 1-13-21 His nurse called MD at approximately 0645, reported to him that it was reported to this nurse that resident has not slept in 2 days and night, has an increased blood pressure, reports severe pain in lower back, and appears to be uncomfortable Resident is able to verbalize his pain and where it is at, but is unable to explain the quality of the pain or give a number on the 0/10 pain scale.	No prior vaccinations for this event.

URINE ANALYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Began with vomiting and diarrhea. C/O chest pain. Bradycardia. Hypotension. 2 seizures in 45 minutes after not having one in years. We gave fluids. Gave Zofran. Comfort measures. Pt passed at midnight. Was completely fine one day before. Had minimal issues with COVID though did have a pneumonia that was treated w ATB early on and resolved.	No prior vaccinations for this event.
URINE ANALYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began feeling nauseated on 1/18/21 around 6pm, and had uncontrolled diarrhea, reported that she did not feel right. Staff reported to this writer, that her skin tone was gray in tone and she just didn't look good. She was transferred to the HOSPITAL ER VIA AMBULANCE.	No prior vaccinations for this event.
URINE ANALYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and	No prior vaccinations for this event.

pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib

fractures on the right at ribs 2 through

URINE ANALYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was found with no pulse no heart rate by a staff member around 11 pm. Earlier that day seen by myself for fatigue, sorethroat, nausea.	No prior vaccinations for this event.

URINE ANALYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Emergency room 1/11/21 Patient is a 72 year old female who presents with decreased level of consciousness. The patient is a nursing home patient and had an episode of choking yesterday that was treated with a Heimlich maneuver. Nursing staff at the nursing home reports that she seems to be a bit less responsive today. However, the patient has been for the most part unresponsive for 3-4 months time following a COVID-19 infection. Of note, her oxygen saturation on room air is 72%. The patient is also febrile to 100.8¦. She was unable to provide any information and the aforementioned information is gathered from nursing home staff report.	No prior vaccinations for this event.

URINE ANALYSIS	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/24/21 Patient Died. 02/23/21. Patient came to ED for weakness/falls. Patient had fallen on 02/21 and 02/23. UA was done in LTC, and he was started on ciprofloxacin 02/22/21. Treatment was to put patient on comfort cares (morphine + lorazepam)	No prior vaccinations for this event.

URINE ANALYSIS ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**	
"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended (although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."		No prior vaccinations for this event.
URINE ANALYSIS ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**	
Patient received the vaccine on 1/31/2021. Patient complained of bleeding 2/7/2021. Went to clinic where labs were conducted. Patient had an INR of 12. Previous INR results were normal prior to vaccination. Patient was also diagnosed with UTI and given antibiotics. Patient was encouraged to go to ER. Patient died on 2/12/2021.		No prior vaccinations for this event.
URINE ANALYSIS ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	
Has underlying dementia and often with difficulty eating. 1 week after immunization she developed a stroke with left sided weakness and difficulty swallowing. Comfort measures instituted. Not sure if this is related to the vaccine, but thought I should report		No prior vaccinations for this event.
URINE ANALYSIS ABNORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**	

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status:

No prior vaccinations for this event.

SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

URINE ANALYSIS NORMAL **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

emesis bright yellow in color, liquid BM, increased respirations No prior vaccinations for this event.

URINE ANALYSIS NORMAL **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized

No prior vaccinations for this event.

further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib

fractures on the right at ribs 2 through

URINE ANALYSIS NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
URINE ELECTROLYTES NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospital course 1/31 ? 2/20/21 1/31 in ED pt was at home when children noticed his lips were blue, ems arrived and found him to be 50% on RA, on Non-rebreather pt got to 78%, covid on 01/26 Shortness of Breath 61-year-old male presents with EMS for evaluation of shortness of breath hypoxia. History is limited due to the patient's current clinical condition and so is primarily obtained from EMS. EMS reports that he tested positive for COVID-19 5 days ago. He began developing shortness of breath yesterday and his family called because his lips and fingers were blue today and he appeared short of breath. On EMS arrival he had a room air saturation of less than 50% so he was placed on nonrebreather with improvement in his saturation to 70% and he was transported to the emergency department. Patient does admit to shortness of breath. He denies any chest pain. He is noted to have a cast on his left ankle and said that he broke his left ankle on 23 December but has not had surgery. He denies any new pain or swelling of the leg. In the ED he was placed on 15L nasal cannula and NRB mask with improvement in SPO2 to low 90s. Additional work up revealed troponin of 1.35, lactic acid 5.8, and d-dimer 14.4. He received dexamethasone and was placed on heparin gtt. 1/31 admitted to ICU Acute hypoxic respiratory failure due to COVID-19 vs heart failure vs	No prior vaccinations for this event.

PE. CXR with bilateral hazy infiltrates more pronounced in the bases and left periphery and suspected multifocal pneumonia. At risk for PE given LLE immobility in the setting of COVID-19 with significantly elevated d-dimer. RISK of CTA outweighs benefit given AKI and iodine allergy. Continue with empiric treatment with heparin gtt. Admitted to ICU with SO2 in 60s-70s on 15L and NRB. Attempted 50L 95% FIO2 high flow and nasal cannula. Given lasix 40mg IV with good diuresis however SPO2 still remained low 80s with RR 40s and PO2 42 so the decision was made to intubate. Oxygenation improved following intubation, with further improvement following recruitment maneuver and increase in PEEP. FIO2 weaned to 90% with SPO2 remaining in mid 90s. Will continue to wean FIO2 as able. ARDS net protocol as much as possible. Consider prone ventilation and/or epoprostenol if unable to improve . VAP Bundle: HOB >30 degrees; Oral care per nursing standard and on DVT/PPI prophylaxis Sedation: Target Richmond Agitation and Sedation Scale (RASS) of 0 to -2 with propofol and fentanyl. Check baseline TG levels. COVID - 19: Convalescent plasma: Not indicated Steroids: Dexamethasone 6 mg / day for 10 days Remdesivir: Not indicated d/t AKI IL-6 inhibitor: Meets criteria for tocilizumab Systemic AC: Heparin gtt. No signs of bleeding (Platelets and Hb stable). Antibiotics: Start 3 and 7 day course of azithromycin and ceftriaxone, respectively. Elevated troponin Suspect demand ischemia d/t hypoxia; EKG does not show any ischemic changes AKI: Suspect d/t hypoxia in the setting of COVID infection. Urine output and electrolytes acceptable. Closed fracture of left ankle Suffered fracture following a fall on ice in December. Cast was placed on 12/30 by SOS. He was due to be re-evaluated this week for possible cast removal. Inhaled epoprostenol started Considered for ECMO but not initiated due to not a candidate Vasopressors required at times Antihypertensive infusion required at times severe hypoxia with position changes switched from heparin drip to enoxaparin prophylaxis 2/20 discharge summary 61 y/o male admitted to Hospital on 1/31 with hypoxia. He was diagnosed with COVID 19 5 days prior to admission, and had worsening respiratory status. He was intubated after arrival, and was on ventilator for the entire intervening time, until he was extubated on 2/20 at the time of transition to Comfort measures only. Prior to developing COVID 19, he had received his first dose of the Pfizer vaccine, as a member of the school system. He had a fractured L ankle after a fall on 12/31/20, and had a cast in place at the time of admission. He received Tocilizumab on 1/31, and underwent several cycles of prone positioning, beginning on 2/2. He completed a course of Decadron, he received Ceftriaxone and azithromycin beginning on admission, and completed a course of these.

Anticoagulation with enoxaparin was utilized due to coagulopathy associated with COVID 19. Vasopressor support was required at times, as well as diuresis for fluid management. He required high levels of sedation to maintain ventilator synchrony, and high levels of ventilator support with high oxygen levels throughout his stay. Tracheostomy was being considered, but family decided that since he was not going to have good recovery, withdrawal of support, and allowing death was the appropriate choice for the patient and for them. He was extubated at 2100 on 2/20/2021. Death was pronounced at 2123 on 2/20/2021. Children were at bedside.

URINE KETONE BODY ABSENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care	No prior vaccinations for this event.

center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

URINE KETONE BODY PRESENT

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

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URINE LEUKOCYTE ESTERASE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they

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started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

URINE LEUKOCYTE ESTERASE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up.

No prior vaccinations for this event.

CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

URINE OUTPUT DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Per granddaughter's report, pt became very weak within hours of receiving the first dose of the Moderna COVID-19 vaccine and could not get out of bed the next morning without assistance, reported difficulty seeing, and did not recognize some family members. By Sunday, 1/31, pt was unable to be awakened, would not eat, and had low urinary output. Granddaughter reports that the morning of 2/1 he was awake and ate a small amount and seemed to be improving although still weak and unable to get out of bed. Granddaughter reported he died 2/1 around 10am in the morning.

No prior vaccinations for this event.

URINE OUTPUT DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

presented to ED 1/9/21 with abdominal pain, progressive worsening weakness and fatigue and new onset A fib with RVR likely due to hypertensive urgency . Patient progressed clinically with severe hypoxia and transferred to ICU and started on BiPAP; progressive decline with decreased urinary output with uremia likely secondary to sepsis. Concern with patient worsening clinical decline, palliative care had been consulted on end of life care. Patient expired 1/17/21

No prior vaccinations for this event.

URINE OUTPUT DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pale, not eating, no urine output After 1st covid vaccine

URINE OUTPUT DECREASED COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient

No prior vaccinations for this event.

passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.

UROBILINOGEN URINE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas

No prior vaccinations for this event.

which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

UROBILINOGEN URINE DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff,

No prior vaccinations for this event.

gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."

USE OF ACCESSORY RESPIRATORY MUSCLES

COVID19 (COVID19 (MODERNA)) (1201)

This is a hospice patient under the care of Hospice at an affiliated nursing home. Pt received the vaccination around noon on 2-16-21 by a representative from Pharmacy. The following afternoon 2-17-21 at 14:45 the pt started to experience severe SOB resp rate 36, audible wheezing and use of respiratory accessory muscles. BP180/80, 113 pulse temp 98. Pt was given morphine and ativan. The respiratory distress was eased however pt never returned to baseline and died 2-22-21 around 4am.

No prior vaccinations for this event.

VACCINATION COMPLICATION

COVID19 (COVID19 (MODERNA)) (1201)

On January 1, 2021, patient was admitted to Medical Center with COVID. Tested positive on January 2, 2021. Spent 10 days in hospital. Once recovered from pneumonia and fever gone, on January 10, 2021, she was transferred to Rehabilitation Center for continued treatment. She spent 16 days there. She developed UTI and CDIF infections and was on/off oxygen. She started physical therapy. She was

No prior vaccinations for this event.

scheduled to be released to go home on January 27, 2021. On January 26, 2021, the day before going home, Rehabilitation Center gave her the Moderna vaccine. On January 27, the day she went home, she started feeling very weak and couldn't walk. My dad tried lifting her and they both fell to the ground. My dad called 911 and she was taken to Medical Center, with high fever and possible stroke symptoms (which later was negative). Two days later, she had difficulty breathing and was put on a ventilator. She was on a ventilator for about three days. They took it off and she slowly started recovering. The doctors did all kinds of tests (blood clot in lung, heart, etc.) and all was negative. The only thing they could trace it to was an adverse reaction to the vaccine. After spending 11 days at hospital and treating her for various infections, her heart stopped and she passed away suddenly.

VACCINATION COMPLICATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the	No prior vaccinations for this event.

night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was okay, but he was very agitated; reported as not like this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away

VACCINATION COMPLICATION	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Daughter call in for VAERS report to file for father whom committed suicide 1/16/2021 in the AM after reportable ae of COVID 19 vaccine administered 1/14/2021. Patient sought care twice at ER; first visit by ambulance around 5PM and Friday 1/15/2021 Medical Center: Emergency Room. 1st Discharge summary diagnosis: adverse reaction to COVID shot; 2nd Discharge summary diagnosis: adverse reaction to COVID shot, fever, Panic Disorder-- ER. Medical Center Discharge summary diagnosis: Adverse reaction to the vaccine, acute anxiety. Reportable patient symptoms at, 1st visit : fever, shaking stomach cramps, breathing issues. Medical Center -- No fever, confusion and dementia type, patient would not stay in patient bed; patient would get up and sit down again repeatedly, agitated and anxious. Attempted to urinated	No prior vaccinations for this event.

hospital bed. Patient committed suicide in home.

VACCINATION SITE PAIN	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient's primary care provider received a death certificate to be signed for this patient. He spoke with the patient's husband and son, who reported that the patient had pain and swelling at the vaccine administration site after receiving the vaccine and was feeling unwell after receiving the vaccine. The patient's family reported that they found her unresponsive on 2/2/21 and called 9-1-1. The patient was pronounced dead upon arrival of emergency responders.	No prior vaccinations for this event.
VACCINATION SITE SWELLING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient's primary care provider received a death certificate to be signed for this patient. He spoke with the patient's husband and son, who reported that the patient had pain and swelling at the vaccine administration site after receiving the vaccine and was feeling unwell after receiving the vaccine. The patient's family reported that they found her unresponsive on 2/2/21 and called 9-1-1. The patient was pronounced dead upon arrival of emergency responders.	No prior vaccinations for this event.
VAGINAL HAEMORRHAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also	No prior vaccinations for this event.

started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.

VARICES OESOPHAGEAL	COVID19 (COVID19 (MODERNA)) (1201)
Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.	No prior vaccinations for this event.

VASCULAR DEMENTIA	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
Narrative: Patient with history advanced vascular dementia, hypertensive cerebrovascular disease and stroke, T2DM. Received her second dose of Pfizer COVID-19 vaccine at approximately 14:00 and was reported to have expired at home at 20:55. Dr. (Medical Director) spoke with patient's son/caregiver 2/4/21. Son reports that patient was in her usual health yesterday morning, deemed well enough by son to travel for vaccination. He reports she had no bothersome symptoms after either first or second vaccinations. Specifically denied rash, wheeze, and difficulty breathing. Son was with patient throughout the day. In the evening, when preparing for bed, he noted she became suddenly unresponsive in a similar fashion as she has done several times in past years. While in all previous such episodes she recovered within minutes, last evening she did not regain consciousness, experiences a brief period of labored breathing, and died. Patient's son called 911 and the patient's body was brought to the medical examiners. The medical examiner declined to proceed with autopsy. Patient's son is not interested in autopsy. Patient's son reports confidence that his mother's underlying hypertensive/diabetic cardiovascular disease is the natural cause of her death. Other Relevant Hx: Symptoms: & Death Treatment:	No prior vaccinations for this event.

VASCULAR DEMENTIA	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
"never woke up after arrival; Suffered with vascular dementia; Death cause: Covid/Tested positive to Covid 31Jan, tested due to increased lethargy; This is a spontaneous report from a contactable consumer. An 85-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Jan2021 at single dose for COVID-19 immunization. The patient received the vaccine at nursing home/senior living facility. Medical history included dementia, hypertension, past strokes. The patient was exposed to asymptotic staff member on or prior to 25Jan2021. The patient had no known allergy. No COVID prior vaccination. Concomitant medication included lisinopril. No other vaccine was received in four weeks. The patient was tested positive to COVID on 31Jan2021, tested due to increased lethargy started from 26Jan2021. The patient suffered with vascular dementia. She was ambulatory up to 31Jan2021. The patient was sent to hospice that evening on 31Jan2021 to quarantine, never woke up after arrival. Palliative Care started 02Feb2021, the patient expired 12Feb2021. Cause of death was COVID. The patient did not receive treatment for events. The autopsy was not performed. The outcome of events ""never woke up, vascular dementia"" was unknown. Information on Lot /Batch Number has been requested.; Reported Cause(s) of Death: Death cause: Covid"	No prior vaccinations for this event.

VASOGENIC CEREBRAL OEDEMA	COVID19 (COVID19 (MODERNA)) (1201)
From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar	No prior vaccinations for this event.

cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021

VASOPRESSIVE THERAPY		**COVID19 (COVID19 (MODERNA)) (1201)**
The patient, who was a pharmacist, developed fatigue and shortness of breath hours after receiving vaccine. Two days later, on 01/28/2021, the patient went to local urgent care for worsening shortness of breath and was referred to Hospital for worsening dyspnea and hypoxia. The patient was admitted to the hospital We was found to have bilateral pulmonary infiltrates and treated for pneumonia with Rocephin and azithromycin. He was tested for COVID-19 multiple times, but each of the results were negative. Despite the negative results, there was high clinical suspicion for COVID-19 and the patient was started on Remdesivir and Decadron. The patient's oxygen requirements continued to worsen and the patient was transferred to another facility for higher level of care. There his hypoxia worsened and he required mechanical ventilation. Patient then developed hypotension and required vasopressors for blood pressure support. Furthermore, patient developed acute renal failure requiring hemodialysis. Despite mechanical ventilation with FiO2 100%, and for vasopressors, patient clinically deteriorated and family decided to palliatively extubate on 02/05/2021.		No prior vaccinations for this event.
VASOPRESSIVE THERAPY		**COVID19 (COVID19 (MODERNA)) (1201)**
pt received vaccine on 2/3. early on 2/4 developed chest pain, dyspnea, and was seen in ED and diagnosed with acute exacerbation of CHF and NSTEMI type 2, and anemia. on 2/5 transfusion was started and pt developed worsening dyspnea and then PEA arrest. Pt achieved ROSC and was transferred to the cardiac intensive care unit where he required vasopressor support. he subsequently declined and died on 2/7		No prior vaccinations for this event.
VEIN DISORDER		**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
L hand edema, hematoma which burst and caused bleeding sending pt to the ER for pressure dressing and 2 stitches. L hand and arm progressively got more edematous and bruised looking (severely black/blue/purple) and the hand continued to bleed and swell on 2/6/21. Severe arterial and venous issues and apparent blood clots. On 2/7/21 there were also lumps noted on left inner thigh. Pt. stopped eating or drinking on 2/8/21 and expired on 2/12/21.	No prior vaccinations for this event.
VENTRICULAR DRAINAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Patient received 2nd dose of the COVID-19 Pfizer vaccine, was observed in office x 15+ minutes, and released home. Pt and his son exited the building and when they got to the car, the pt shouted out ""oh no!"" and collapsed to the ground. The patient was unconscious experiencing agonal respirations, and unresponsive to painful stimuli. There is an Emergency Room at the same location. Their staff came out and helped to transfer the pt to the ED for further evaluation. It was found that the patient had a known Anterior communicating artery aneurysm (7/28/2017) that seemed to have ruptured. The patient was stabilized and transported to our local hospital and upon arrival, he was effectively comatose with a GCS 3. CT Head notated an extensive subarachnoid and intraventricular hemorrhage most probably related to a bleeding anterior communicating artery aneurysm. Neuro-Interventional Radiologist dictation reads ""Hunt Hess 5 Fisher grade 4 extensive subarachnoid hemorrhage with intraventricular hemorrhage and early hydrocephalus secondary to rupture of a known anterior communicating artery aneurysm. Initial ICP after EVD placement noted to be in the 120s now 68 treatment complicated by aneurysm rerupture after admission and increased volume of blood although large volume of hemorrhage was seen on initial scan and no change in the patient's clinical exam on her scale was noted due to this rerupture. Patient's exam and prognosis are poor giving extensor posturing lack of extraocular movements to doll's maneuver and weak pupillary reflex as well as cough and gag. Follows no commands or instructions at this time with no	No prior vaccinations for this event.

spontaneous movement on ventilator set at 12 overbreathing at 14-16 at this time without any sedation."" The family opted to discontinue any further treatment to include surgical intervention given the findings. The patient was given comfort care with son and daughter at the bedside. The patient was extubated and expired at 1545h on 2/13/2021."

VENTRICULAR DRAINAGE	COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)
61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.	No prior vaccinations for this event.

VENTRICULAR DRAINAGE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)	No prior vaccinations for this event.
VENTRICULAR FIBRILLATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Almost immediate headache per wife. Developed fever around 4 pm. Headache all day. Took Tylenol at 4 and 10 pm. Gradual development of SOB and cough. Temp of 101.4 at 10 pm. pulse ox 92% at 10 pm. Went to sleep, woke up at 0050 with increasing SOB. Pulse ox 82%. Used albuterol inhaler, wife called emergency services at 0113. EMS arrived around 0130 to patient's home. pulse ox 86%, coughing, sob, hard time breathing. Walked to stretcher. Became unresponsive. Found to have no pulse, stopped breathing. CPR initiated at about 0140. King airway placed in field, I/O in left tibia. Patient from PEA to asystole, to vfib, to asystole. ACLS followed. Unrecoverable asystole and patient time of death 0213.	No prior vaccinations for this event.
VENTRICULAR FIBRILLATION	**COVID19 (COVID19 (MODERNA)) (1201)**
Received first 1/15/2021 with no adverse reaction. Received 2nd dose 2/9 @ 0846 with no adverse reaction or report of feeling ill. Traveled to store and arrived approx. 2 hours after receiving vaccine. Daughter stated patient felt well and had to go to the restroom to have BM. Collapsed in bathroom. Transported by ambulance to Hospital @ 1439 in cardiac arrest. Was in PEA and went in v fib back to PEA. Resuscitation efforts initiated and patient expired with time noted at hospital records at 15:11.	No prior vaccinations for this event.
VENTRICULAR FIBRILLATION	**COVID19 (COVID19**

(MODERNA)) (1201)

Developed vomiting, seizure and cardiac arrest, V Fib No prior vaccinations for this event.

VENTRICULAR FIBRILLATION **COVID19 (COVID19 (MODERNA)) (1201)**

Patient was at a gym watching his daughter. He slumped over unconscious. EMS was called. He was found to be in fine ventricular fibrillation and resuscitation efforts failed. He was brought to Hospital ED where he was pronounced dead. He had underlying cardiac disease but his family requested I report this event as possibly related to the recent COVID vaccination.	No prior vaccinations for this event.

VENTRICULAR FIBRILLATION **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile stimulus and had fixed unreactive pupils. He was pronounced at 16:13.	No prior vaccinations for this event.

VENTRICULAR FIBRILLATION **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins.	No prior vaccinations for this event.

Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

	VENTRICULAR FIBRILLATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"CC:full arrest HPI:HPI and ROS limited due to patient's condition. History is via EMS, medical record, and son. Per Son patient had Covid vaccine on Saturday morning. Slept all day Sunday. Woke up Sunday night a bit ""like coming out of a deep sleep per son, around 10 pm. Shortly after that patient was having a hard time breathing. Emergency called. Arrested around the time EMS arrived. King airway, I/O and CPR initiated. Patient has been in v fib. Was shocked multiple times, given 4 rounds of epi, bicarb and amiodarone. ACLS continued on arrival. Multiple rounds of epi, and attempted defib. Patient given epi, bicarb. Rhythms included fine v fib, asystole, and PEA. Unrecoverable with no cardiac motion. Time of death 11:50 pm."		No prior vaccinations for this event.

	VENTRICULAR FIBRILLATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received COVID 19 vaccine the morning of 1/18/21 at Public Health COVID-19 vaccine clinic. I (person completing this report) work for PH. Later that night while in bed, patient reported difficulty breathing to his wife, then turned blue, and became unresponsive. Family report pt was without any symptoms prior to event. 911 called; CPR started by family member 15 min. after pt became unresponsive. EMS performed resuscitation for about 30-40 minutes with multiple defibrillation for V-fib. Between EMS and Medical Center ER, pt had 9 rounds of epi, CPR w/ LUCAS machine, given 2 doses of amiodarone (150 mg and 300 mg). Patient had 3 EKGs, which did not show STEMI, but did show nonspecific		No prior vaccinations for this event.

conduction delay and sinus arrest with junctional escape vs sinus bradycardia (HR 50's). Pt had return of spontaneous circulation. Pt intubated, and started on Levophed. Pt transferred to ICU, and had central line placed. Family decided to make patient DNR. Pt went into coarse VFib again, and as per wishes of family, code blue not called. Patient expired at 01:53 on 1/19/21.

VENTRICULAR FIBRILLATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient arrived at ER with complaints of CPR in progress. Per EMS, patient became short of breath while performing yard work on 1/26/2021. At arrival, patient was in fine v fib with a total of 6 shocks delivered along with 300 mg amiodarone followed by 150 mg amiodarone, 1 amp epinephrine and 2 epinephrine drips adminstered en route to ED. CPR initiated at 1755 and EMS reports asystole at 1829. TOD 1909 pronounced by ED DO Dx: Cardiac arrest	No prior vaccinations for this event.
VENTRICULAR FIBRILLATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per EMS, the patient was last seen walking and talking to wife 10 minutes prior to EMS arrival. EMS reports via patients wife, that patient was upstairs to change for his doctor appointment then patient's wife found him down. The patient received his COVID-19 vaccine on 1/25/21. EMS states they gave 5 rounds of EPI then patient moved into vfib then was shocked once but returned to asystole. In ED, the patient initially in asystole CPR was started immediately. The patient was given 3 rounds EPI, 1 round bicarb. The patient stayed in PEA throughout. Patient was given tPA. Patient continued to be in asystole and time of death was called at 11:35 am.	No prior vaccinations for this event.
VENTRICULAR FIBRILLATION	**COVID19 (COVID19 (PFIZER-BIONTECH))**

		(1200)
73-year-old man s/p first dose of Pfizer at 10:20 AM Ambulated comfortably to exit after 20 minutes in observation but 10:45 collapsed while exiting the building 10:47 CPR initiated 10:49 medical team/EMS found no pulse, agonal respirations, ventricular fibrillation Paramedics and team performed ACLS; of note patient was intubated 7.5 ETT with bilateral breath sounds on ventilation; paramedic reported easy intubation with no apparent throat swelling; 11:02 transported to Emergency Department 11:30 Pronounced dead at Emergency Department	No prior vaccinations for this event.	
VENTRICULAR FIBRILLATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/5/2021 resident noted to be azotemic. Creatinine up to 3.8 and BUN in 80's. He was started on NS hydration. On 2/7/2021 he was noted without VS, per MD notes, possible VF arrest, renal failure; death unclear exact cause.	No prior vaccinations for this event.	
VENTRICULAR FIBRILLATION		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient was coded and expired Code Blue: Patient was in dialysis, after 30 minutes his sbp dropped to 60s he was given 4 albumin. Patient who was responsive before that became unresponsive, had seizure like activity, lost pulse and spontaneous breathing. HD stopped. Code called. Cpr started. A few minutes into cpr patient started to profusely bleed - gi bleed and ventilation became very hard., intubation was very difficult and ventilation hard as we suctioned large amounts of aspirated blood. Patient was eventually intubated. More than 8 doses of epi ws given, sodium bicarbonate * 2 given with continuous cpr. It was mostly PEA with one shockable rhythym. And shock delivered for vfib. patient continued to profusely bleed, og insertion was not successful and effective ventilation was very tough due to massive aspiration,.	No prior vaccinations for this event.	

Possible variceal rupture with cpr from his cirrhosis is likely scenario. After 30 minutes of unsuccessful ventilation and acls protocol. Code was stopped.

	VENTRICULAR FIBRILLATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received the vaccine at an outside healthcare facility on 2/11/21. At approximately 1 pm she screamed out and fell out of her chair. EMS was called and patient was found to be in Vfib. ACLS was performed for approximately 42 minutes prior to arrival at ED. At that time the patient had been pulseless for 25 minutes. Patient received 450 mg of amiodarone, epinephrine x7, sodium bicarbonate x2, and 7 AED shocks. In the ED 3 more doses of epinephrine were given, one more dose of sodium bicarbonate, and 5 additional shocks. ROSC was not achieved and time of death was called at 1416.		No prior vaccinations for this event.

	VENTRICULAR FIBRILLATION	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Few minutes post vaccination, after moving to observation area via wheelchair, the patient complained of dizziness. She took glucose tabs she had brought with her. Staff wheeled her to Triage # 1. Her eyes rolled back in her head and she lost consciousness. Staff (paramedics on site) transferred her to gurney and started compressions. AED placed, V- Fib was rhythm, Shock # 1 given, CPR resumed. Shocked again. Fire truck and additional EMT arrived on site and took over care. Epinephrine was given 3 times via intra-osseous route, Amiodarone given intra-osseous route. Additional defibrillation with on site AED for a total of 6-7 times. Patient had good chest rise with ambu-bag, no airway obstruction or peri-oral edema noted. Code called at 12:40 PM.		No prior vaccinations for this event.

	VENTRICULAR FIBRILLATION	**COVID19 (COVID19 (PFIZER-BIONTECH))**

(1200)

Ventricular fibrillation/sudden death No prior vaccinations for this event.

VENTRICULAR HYPOKINESIA COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

No prior vaccinations for this event.

VIRAL TEST

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.

No prior vaccinations for this event.

VIRAL TEST NEGATIVE

COVID19 (COVID19 (MODERNA)) (1201)

Started feeling unwell; Headaches; Body aches; Chest pain; Didn't had wishes to eat; Diarrhea; COVID-19 pneumonia; A spontaneous report was received from a consumer concerning a 69-year-old male patient

No prior vaccinations for

who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced COVID-19 pneumonia, feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea The patient's medical history high blood pressure which was controlled with medication. Concomitant product use included nifedipine and fenofibrate. On 20-JAN-2021, approximately a week and a half or two prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number 030L20A) intramuscularly in the right arm for prophylaxis of COVID-19 infection. A week and a half or two later the patient stated feeling unwell, headaches, body aches, chest pain, decreased appetite and diarrhea for which patient was hospitalized on 06-FEB-2021. Since everything seemed to be fine the patient was discharged on an unknown date in FEB-2021 however, patient's family was not notified that it was a late reaction to the vaccine's first dose. Later, due to shortness of breath he was hospitalized again on 08-FEB-2021 and was diagnosed for pneumonia and was intubated on the same day. Due to COVID-19 situation patient's family could not be in the facilities and that there wasn't any follow up of the patient given to the family, so family did not have much information. During the first hospitalization(06-FEB-2021) the patient had a blood test which showed a normal result and was tested for COVID-19 and Influenza, both were negative. During second hospitalization (08-FEB-2021) the hospital said that the patient was stable. The patient's family did not know the results of the tests conducted at the time. The action taken with the vaccine in response to the events is not applicable. The outcome of COVID-19 pneumonia was fatal. The patient died on 14 Feb 2021 The cause of death was reported as COVID-19 related pneumonia. The autopsy was not done.; Reporter's Comments: Very limited information regarding this event has been provided at this time. The cause of death was reported as COVID-19 related pneumonia. Based on the current available information and the mechanism of action of mRNA-1237 vaccine, the events are assessed as unlikely related. Further information has been requested.; Reported Cause(s) of Death: COVID-19 pneumonia	this event.
VIRAL TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient 101 years old, nursing home resident, received vaccine 1/11, on 1/13 found on floor without obvious	No prior vaccinations for

trauma, unresponsive. Brought to ED and was bradycardic, hypotensive, hypothermic and refractory to aggressive medical management. No obvious cause of death found on exam or labs, cxr. Unknown if event could be related to vaccine or not. Medical Examiner accepted case although initially unknown that patient had recently received vaccine. ME updated with that information today as soon as discovered.		this event.
	VIRAL TEST NEGATIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative. Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.		No prior vaccinations for this event.

	VISUAL IMPAIRMENT	**COVID19 (COVID19 (MODERNA)) (1201)**
Per granddaughter's report, pt became very weak within hours of receiving the first dose of the Moderna COVID-19 vaccine and could not get out of bed the next morning without assistance, reported difficulty seeing, and did not recognize some family members. By Sunday, 1/31, pt was unable to be awakened, would not eat, and had low urinary output. Granddaughter reports that the morning of 2/1 he was awake and ate a small amount and seemed to be improving although still weak and unable to get out of bed. Granddaughter reported he died 2/1 around 10am in the morning.		No prior vaccinations for this event.
	VITAL FUNCTIONS ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days. 12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV		No prior vaccinations for this event.

Antibiotics

VITAL FUNCTIONS ABNORMAL

COVID19 (COVID19 (MODERNA)) (1201)

"On 1/15/2021 at 1800, resident noted to be lethargic and shaking, stating ""I don't care."" repeatedly. C/O head and neck pain. T100.6. Given Tylenol with no relief of pain. Order received for Aleve and administered.. Assisted to bed as usual in evening. Monitored during night shift and noted to be resting comfortably/sleeping.. Noted agonal breathing at 4:10 AM 1/16/2021 , T 99.4, Absence of vital signs at 4:15AM 1/16/21 and death pronounced at 4:40AM 1/16/21."

No prior vaccinations for this event.

VITAL FUNCTIONS ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

little bit of a reaction light headed after 5 minutes. vitals were low, so observed for 30 minutes after being light headed. Patient was found unresponsive and pronounced dead later that day.

No prior vaccinations for this event.

VITAL FUNCTIONS ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

On 1/9/2021 observed with elevated respirations of 38-42 per minute, BP manually 72/50. pulse is jumping rapidly between 110-16 bpm. oxygen sat 76% RA, resident refusing oxygen at first attempt, allowed oxygen to be placed, is now 84% on 4L. resident shaking head yes that he is hurting, and yes that he would take medication for pain. Dr. notified, branch block. Received order for morphine 2mg per hr as needed for elevated respirations and pain. Dr. also gave orders to D/C Tamsulosin and finasteride. Resident continue with decreased O2 sats and elevated respirations. Absence of vital signs on 1/10/21 at 826PM.

No prior vaccinations for this event.

VITAL FUNCTIONS ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Client received the COVID-19 vaccine on 1/5/21 by the Vaccine clinic. Plans were for Hospice services. Client tested positive for COVID-19 by rapid testing on 1/8/21. On 1/10/21 at 0900 Client was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.

No prior vaccinations for this event.

VITAL FUNCTIONS ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Client recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic. Client tested positive for COVID-19 by rapid testing on 1/21/21, with c/o hurting all over and loose stools. She became non-verbal on 1/23/21 with poor intake. On 1/24/21 at 0537 Client was unresponsive and without vital signs. Orders were for DNR, and CPR was not initiated.

No prior vaccinations for this event.

VITAL FUNCTIONS ABNORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient has been under Hospice services for almost a year. She began to demonstrate a large amount of oral secretions on 1/10/21 at 2130. She was suctioned and a Rapid COVID-19 test was performed, which was negative. The COVID-19 Rapid test was repeated on 1/11/21 and was positive. Oxygen saturation was noted to be 78% on 1/12/21, and oxygen was initiated at 1133 at 3L per nasal cannula. Oxygen was increased to 4L at 1635 d/t shortness of breath. On 1/15/21 @ 0645 patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.

No prior vaccinations for this event.

VITAL FUNCTIONS ABNORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient tested positive for COVID-19 by rapid test on 1/6/21. She began to demonstrate a dry cough on 1/11/21. On 1/12/21 at 1723 her oxygen saturation dropped to 79% and oxygen was applied at 4L per nasal cannula. On 1/19/21 at 2130 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.		No prior vaccinations for this event.
VITAL FUNCTIONS ABNORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient recevied the COVID-19 vaccine on 1/5/21 by the Vaccine clinic #1. Patient tested positive for COVID-19 by rapid testing on 1/6/21. She demonstrated poor appetite and fluid/food intake and an IV of Normal Saline was initiated on 1/7/21. Oxygen saturation was initiated on 1/12/21 at 4L per nasal cannula. for shortness of breath. On 1/22/21 at 0310 Patient was unresponsive and without vital signs. Orders were for DNR and CPR was not initiated.		No prior vaccinations for this event.
VITAL FUNCTIONS ABNORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient began to demonstrate a cough the evening of 1/5/2021, after receiving the COVID-19 vaccine earlier in the afternoon. A rapid COVID-19 test was performed and was positive. She began to demonstrate shortness of breath with exertion on 1/7/21, and lethargy on 1/12/21. Appetite and oral intake began to decline on 1/12/21, and Oxygen saturation dropped on 1/16/21 to 82%, and oxygen was initiated at 3L per nasal cannula. On 1/19/21 at 0414 patient was unresponsive and without vital signs. Orders were for DNR,		No prior vaccinations for this event.

and CPR was not initiated.

VITAL SIGNS MEASUREMENT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/5/2021 resident noted to be azotemic. Creatinine up to 3.8 and BUN in 80's. He was started on NS hydration. On 2/7/2021 he was noted without VS, per MD notes, possible VF arrest, renal failure; death unclear exact cause.	No prior vaccinations for this event.
VOMITING	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident had lunch on 01/14/21 and after lunch around 2:00pm, he vomited and stopped breathing. We coded the resident and 911 paramedics came. They pronounced him dead at 2:18pm.	No prior vaccinations for this event.
VOMITING	**COVID19 (COVID19 (MODERNA)) (1201)**
On 1/13/2021, resident had sudden emesis. Immediately following emesis he was noted without a pulse and pronounced deceased. No acute symptoms noted prior to this episode. Resident does have a significant cardiac history.	No prior vaccinations for this event.
VOMITING	**COVID19 (COVID19 (MODERNA)) (1201)**

Headache, pain in the injection site, threw up. A few hours later she died. No prior vaccinations for this event.

VOMITING	**COVID19 (COVID19 (MODERNA)) (1201)**	
My dad got the Moderna Vaccine on Tuesday, January 12, 2021 in his left arm at the Mall injection site for the Health Department. He was told that the side effects could mean his arm hurting, tiredness, headache, and even a low grade fever. Additionally, the site informed us both (as I was with him to get the injection) that this was all normal and not to seek medical attention unless these symptoms last longer than 72 hours. That evening, my dad was experiencing all of those symptoms, and went to bed at 7pm. A little after 10am on Wednesday, January 13, 2021, when he awoke, my dad went to the bathroom vomiting. This was where he collapsed and went into cardiac arrest. Fire/Rescue was dispatched about 10:30am after my mom started CPR. County Fire Rescue EMTs and Paramedics continued CPR and other attempts at reviving him all the way to Hospital Emergency Department. He was pronounced dead at 12:14pm on Wednesday, January 13, 2021. We have no doubt my dad, following the instructions of the injection facility, thought he was just experiencing the side effects of the vaccine. He had no chance. Had this injection been done in the RIGHT arm, perhaps he could have recognized the arm numbness being that of an impending heart attack. We really miss Dad. He served this country with distinction for over 50 years, and we believe his country failed him.		No prior vaccinations for this event.
VOMITING		**COVID19 (COVID19 (MODERNA)) (1201)**
"Pt. woke up the next morning after vaccination and ""didn't feel well"", described by wife as fatigue, no energy. At approximately 2 PM, he vomited. His wife checked on him at 4:20 PM and he wasn't breathing sitting in his chair. EMS squad was called but when they arrived he was asystole and mottling present. Did not start CPR since he was already gone too long. Pronounced by coroner on scene."		No prior vaccinations for this event.
VOMITING		**COVID19 (COVID19 (MODERNA)) (1201)**
on 1/13/2021 at 3:40am Cliff called for assistance. He lost his balance and had fallen. Cliff refused vitals, refused emergency department, denied hitting his head. As the day progressed patient		Influenza vaccine 10/06/2020, age 88, fever, chills, vomiting,

developed a headache, diarrhea, and vomiting. He again declined the offer for the emergency room. At supper time wife and staff found Cliff unresponsive, 911 was called and he was taken to the emergency department. The ER did a CT scan and found an acute subdural hematoma. Patient was placed on comfort cares and expired at 3pm on 01/14/2021. Cliff did not have a history of falls.	malaise	
VOMITING		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.		No prior vaccinations for this event.
VOMITING		**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.
VOMITING		**COVID19 (COVID19 (MODERNA)) (1201)**
Resident c/o nausea evening of 1/29 (nausea common for her post dialysis), had a large emesis at approx		No prior vaccinations

2220, 0030 (unusual for resident to vomit)- received Zofran per order. Skin cool and damp, Blood sugar 147 (checked due to h/o diabetes and poor intake). At approx 230am Blood pressured checked and noted to be 52/29. Resident transferred to ER, intubated and transferred to higher level of care where she passed away on 1/30 at 736pm. Resident's medical notes indicated likely shock, cardiogenic in nature, sepsis (source unknown) along with a multitude of other co-morbidities that resident has.	for this event.	
VOMITING		**COVID19 (COVID19 (MODERNA)) (1201)**
patient passed away 2 days after vaccine. patient had temperature, nausea, and vomiting after vaccine.	No prior vaccinations for this event.	
VOMITING		**COVID19 (COVID19 (MODERNA)) (1201)**
On 2/1/2021, the patients daughter, who claims is a nurse, reported this incident to me. She stated that the evening after the patient received the vaccine, she felt some mild injection site pain. The morning after, the patient reported severe abdominal pain, diarrhea and vomiting. The patients daughter then called her physician to report these symptoms and attributed them as an adverse reaction to the vaccine at that time. These symptoms were intermittent for one week and no other adverse reactions were noted. In the early morning hours of 1/27/2021, the patient was toileting and had expired while doing so. An ambulance was called and cause of death was not found. An autopsy was not performed.	No prior vaccinations for this event.	
VOMITING		**COVID19 (COVID19 (MODERNA)) (1201)**
Moderna Vaccine Lot 029K20A Patient received second dose of vaccine on 2/2/21. Within 30 minutes patient had a near syncopal episode. She felt lightheaded and shortly after had episode of nonbloody vomiting. Hypotensive 81/69 and started on levophed. Alert and orientated. Lungs clear, abdomen benign on	No prior vaccinations for this event.	

admission. Patient had no reaction when received first dose of the vaccine. Patient developed worsening shortness of breath, tachypnea, Afib with RVR, hypotension and required intubation and multiple pressors.

VOMITING

COVID19 (COVID19 (MODERNA)) (1201)

EARLY SUNDAY MORNING THE PATIENT BEGAN VOMITTING AND SHORT OF BREATH AND CHEST AND BACK PAIN. SHE CODED WHEN SHE GOT IN THE ER AND LATER PASSED AWAY THE MONDAY. DIAGNOSIS WAS PNEUMONIA AND HEART FAILURE PER STEP DAUGHTER.

No prior vaccinations for this event.

VOMITING

COVID19 (COVID19 (MODERNA)) (1201)

"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"

No prior vaccinations for this event.

VOMITING

COVID19 (COVID19 (MODERNA)) (1201)

On 1/26 at breakfast table began vomiting. Continued thru am when at noon a caregiver did his O2 saturation and found it was 75%. This was confirmed, and resent sent to ER .

No prior vaccinations for this event.

VOMITING

COVID19 (COVID19

(MODERNA)) (1201)

Resident reviewed for incident. Resident received the second dose of the Moderna Covid-19 vaccine lot# 016M20A Exp 5/2/2021 on 2/5/2021 from clinic through pharmacy. Resident had her temp/O2 taken on AM shift and was 98.6/93%, beginning PM shift 98.4/95%. A few hours later noted that resident to have chills and was shaking RN assessment completed and vitals taken resident noted to have temp of 102.2, oxygen 95%, pulse 110. Resident alert and oriented at that time and talking to staff. Reported findings to APNP with order to send to ER. 911 called, residents brother updated. Upon EMT arrival RN went down to residents room with EMT and resident had an emesis as resident was getting cleaned up resident went unresponsive. Pulse noted to still be present at that time, resident did briefly respond to sternal rub and then went unresponsive again. Resident full code and EMT transferred to gurney and said that if they lost a pulse in route that they would transfer to hospital B instead of hospital A being the closest facility. RN called brother and gave update. Facility notified from Hospital that resident had passed away.

No prior vaccinations for this event.

VOMITING **COVID19 (COVID19 (MODERNA)) (1201)**

Developed vomiting, seizure and cardiac arrest, V Fib No prior vaccinations for this event.

VOMITING **COVID19 (COVID19 (MODERNA)) (1201)**

Nausea, vomiting and generalized weakness. No prior vaccinations for this event.

VOMITING **COVID19 (COVID19 (MODERNA)) (1201)**

Death Narrative: Patient received Covid vaccine on 2/2/21, person reports his legs were more rigid with some sweating the day of the vaccination with leg rigidity that was slowly improving. No other adverse effects reported for following 7 days. Person states he had vomiting episode earlier this week, person states he had no other symptoms before or after the vomiting episodes. On morning of 2/12/21, person reports patient got

No prior vaccinations for this event.

up ready for breakfast with no issues. She says he asked for chorizo and oatmeal but she laughed and said don't you mean chorizo and eggs. He said yes. They got him into W/C and he was rolling himself into dining room got stuck in hallway. She says he took several breaths then 3 very deep breaths and passed away. She called 911 they took his VS but he has passed. She told them to leave him along no resuscitation.

VOMITING **COVID19 (COVID19 (MODERNA)) (1201)**

Patient became nauseated about 10 minutes after vaccine administered, this subsided but returned several hours after the vaccine was given. She continued with intractable nausea and vomiting for about 24 hours. This patient was enrolled in hospice and she continued to decline and refused to eat or drink. She was taking Ibuprofen due to intractable back pain. Her emesis was coffee ground color. After this her condition continued to decline until her death

No prior vaccinations for this event.

VOMITING **COVID19 (COVID19 (MODERNA)) (1201)**

Vomiting, death. No prior vaccinations for this event.

VOMITING **COVID19 (COVID19 (MODERNA)) (1201)**

She had pain in the injection site Tuesday night and then during Tuesday she got worse with nausea and some fever. By Wednesday she was complaining that she could not pee even though she was drinking a lot of fluids. She continued to complain it was the worst she ever felt and then at 0600 Thursday morning she woke us up and said she needed to go to the hospital. We arrived at the hospital just before 0700 and she immediately threw up in the trash can. We went into a treatment room and they took blood and started fluids as she became incoherent. She said she had taken Tylenol so they started a drug to counter that but her liver function was all wrong and they started to look for a hospital that could transplant a liver. She was air evade about 0930 to Medical center and just over 30 hours latter she was dead. There is a pending autopsy. She

No prior vaccinations for this event.

was a healthy 39 year old mother who got the shots because she worked as a surgical tech and she was the single mother of a 9 year old little girl.

	VOMITING	**COVID19 (COVID19 (MODERNA)) (1201)**
Toileting and had expired while doing so; Severe abdominal pain; Diarrhea; Vomiting; Mild injection site pain; A spontaneous report was received from a healthcare professional concerning an 88-year-old , female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced the events, toileting and had expired while doing so (death), mild injection site pain, severe abdominal pain, diarrhea, and vomiting. The patient's medical history was not provided. No relevant concomitant medications were reported. On 20 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (Lot number: 029L20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 20 Jan 2021, the patient felt mild pain at the injection site after receiving the vaccine. On 21 Jan 2021, the patient reported severe abdominal pain, diarrhea and vomiting. These symptoms were intermittent for a week and no other adverse events were noted. On 27 Jan 2021, the patient passed away while toileting. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 27 Jan 2021. The cause of death was unknown. An autopsy was not performed.; Reporter's Comments: The gastrointestinal events were consistent with increased risk associate with elderly age of patient. The cause of death was unknown. Autopsy was not performed. Very limited information regarding the events is available at this time. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Reported Cause(s) of Death: unknown cause of death		No prior vaccinations for this event.

	VOMITING	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient experienced an episode of emesis and loss of consciousness several hours after vaccine on 2/16/21. He was taken by EMS to the hospital and was noted to be hypoxic and hypotensive. He was admitted to the		No prior vaccinations for this event.

hospital and subsequently intubated. He was also found to have a small bowel obstruction and a nasogastric tube was placed to decompress the bowel. He required pressor support as well. He expired on 2/17/21.

VOMITING

COVID19 (COVID19 (MODERNA)) (1201)

Individual developed severe body aches, severe shoulder discomfort, high fevers (documented max temp. 103.7 F). Daughter reported that she became non-responsive with high fevers, and when the fevers decreased she was more lucid. Her condition rapidly progressed to nausea vomiting, diarrhea and patient died on 2/9/2021.

No prior vaccinations for this event.

VOMITING

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

VOMITING

COVID19 (COVID19 (MODERNA)) (1201)

Patient was transferred from hospital for further evaluation and care by pulmonologist. He started having symptoms a week before with fatigue, emesis, decreased p.o. intake, shortness of breath, vomiting and diarrhea. The two previous takes before death required increasing oxygen and family wanted everything done including intubation. He was transferred to ICU.

No prior vaccinations for this event.

VOMITING

COVID19 (COVID19 (MODERNA)) (1201)

Hypoxia, Decreased responsiveness, Narrative: 86yo male with PMHx HTN, Afib not on AC after head trauma, CVA, and colon cancer who was brought to the ED by his family on 2/17. Per documentation the pt was in his usual state of health until 2/16. Received Moderna covid vaccine #2 on 2/16/21 at 0900, and was monitored for 15 minutes following immunization no noted issues. Later that night, had myalgias and took Tylenol. Per the family he slipped on the ice and fell on his butt. Overnight, had several dark stools and vomitus. was brought to the ED by his family because he was being less responsive. Pt arrived to the emergency department in extremis. No pulse identified. CPR immediately initiated for several rounds lasting about 25-30 minutes. ROSC unable to be achieved. Patient expired on 2/17 at 1941. Of note, per previous documentation had waxing and waning mental status at baseline. No symptoms noted with 1st dose of Moderna vaccine, which was administered on 1/16/21.	No prior vaccinations for this event.
VOMITING	**COVID19 (COVID19 (MODERNA)) (1201)**
My grandpa got his second covid vaccine on Thursday. Saturday he complained of stiff neck. Sunday he had low grade fever, nausea and vomiting, chills, and mild headache. He was feeling bad enough to call squad at 3 pm. The paramedics did evaluation and thought he was just experiencing normal side effects from vaccine and felt no need to transport to hospital so my grandpa decided to stay home and just rest. At 2 am that same night he went into cardiac arrest and was not able to be brought back	No prior vaccinations for this event.
VOMITING	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient had gotten up to the bathroom and collapsed in the hallway after using the restroom. Patient was unresponsive upon EMS arrival with vomitus coming out of the mouth per the report when they rolled patient over onto his side the emesis was pouring out of his mouth. ER course: Examination. Epinephrine 1 mg IO x4 CBC, CMP, cardiac panel MDM: 1447 patient arrival, per EMS report patient had been sick and vomiting all morning. Bradycardia noted at arrival with rates in the 30s, CPR was initiated patient had received 3 rounds	No prior vaccinations for this event.

of epi prior to arrival. 1450 CPR continues via the Lucas device, 1 mg epinephrine given IV push 1451 CPR pause rhythm check. CPR resumes 1453 CPR paused for rhythm check. No central pulses, CPR resumed, glucose of 99 per fingerstick 1454 King tube removed. Oral airway placed respirations by BVM. 1 mg epinephrine IV push 1455 CPR pause for both pulse and rhythm check. No central pulses noted. CPR resumes via Lucas 1456 pupils are fixed and dilated bilaterally 1457 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via Lucas. 1 mg epinephrine IV push 1459 warm blankets applied. CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed 1501 CPR pause for pulse and rhythm check. No central pulses. CPR resumes 1502 1 mg epinephrine given IV push 1503 CPR pause for pulse and rhythm check. No central pulses noted. CPR resumed via the Lucas device 1506 resuscitation is ceased at this time. Time of death recorded at 1506

VOMITING

COVID19 (COVID19 (MODERNA)) (1201)

Within 10 minutes following the second vaccination, patient reported dizziness and nausea, had an episode of vomiting but recovered within 30 minutes. It was reported to our clinic that the patient was found deceased on March 1, 2021 at approximately 10 pm. Cause of death is not determined at this time.

No prior vaccinations for this event.

VOMITING

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

pt received vaccine at covid clinic on 12/30 at approximately 3:30, pt vomited 4 minutes after receiving shot--dark brown vomit, staff reported pt had vomited night before. Per staff report pt became short of breath between 6 and 7 pm that night. Pt had DNR on file. pt passed away at approximately 10pm. Staff reported pt was 14 + days post covid

No prior vaccinations for this event.

VOMITING

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

vomiting later on 01/05/21. Lethargy and hypoxia in pm of 01/06/21. Hypotension am of 01/07/21. Hospitalized, intubated, cardiac arrest, died 01/07/21.

No prior vaccinations for this event.

VOMITING

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

he passed away; not responsive; mind just seemed like it was racing; body was hyper dried; Restless; not feeling well; ate a bit but not much; kind of pale; Agitated; Vomiting; trouble in breathing; This is a spontaneous report from a contactable consumer (brother of the patient). A 54-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 04Jan2021 (at the age of 54-years-old) as a single dose for COVID-19 immunization. Medical history included diabetes and high blood pressure. Concomitant medications included metformin (MANUFACTURER UNKNOWN) taken for diabetes, glimepiride (MANUFACTURER UNKNOWN) taken for diabetes, lisinopril (MANUFACTURER UNKNOWN), and amlodipine (MANUFACTURER UNKNOWN). The patient experienced not feeling well, ate a bit but not much, kind of pale, vomiting, trouble in breathing, and agitated on 04Jan2021; body was hyper dried and restless on 05Jan2021; mind just seemed like it was racing on 06Jan2021; and not responsive and he passed away on 06Jan2021 at 10:15 (reported as: around 10:15 AM). The clinical course was reported as follows: The patient received the vaccine on 04Jan2021, after which he started not feeling well. He went right home and went to bed. He woke up and ate a bit but not much and then was kind of pale. The patient then started to vomit, which continued throughout the night. He was having trouble in breathing. Emergency services were called, and they took his vitals and said that everything was okay, but he was very agitated; reported as not like this prior to the vaccine. The patient was taken to urgent care where they gave him an unspecified steroid shot and unspecified medication for vomiting. The patient was told he was probably having a reaction to the vaccine, but he was just dried up. The patient continued to vomit throughout the day and then he was very agitated again and would fall asleep for may be 15-20 minutes. When the patient woke up, he was very restless (reported as: his body

No prior vaccinations for this event.

was just amped up and could not calm down). The patient calmed down just a little bit in the evening. When the patient was awoken at 6:00 AM in the morning, he was still agitated. The patient stated that he couldn't breathe, and his mind was racing. The patient's other brother went to him and he was not responsive, and he passed away on 06Jan2021 around 10:15 AM. It was reported that none of the symptoms occurred until the patient received the vaccine. Therapeutic measures were taken as a result of vomiting as aforementioned. The clinical outcome of all of the events was unknown; not responsive was not recovered, the patient died on 06Jan2021. The cause of death was unknown (reported as: not known by reporter). An autopsy was not performed. The batch/lot number for the vaccine, BNT162B2, was not provided and has been requested during follow up.; Reported Cause(s) of Death: not responsive and he passed away		
	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Hospice Resident received first Covid 19 vaccine dose on 1/6/21. 1/7/21 resident had decreased appetite noted in am but ate 100% of meal at dinner. 1/9/21 resident had decreased appetite with emesis x 2, loose BM x 2. Call placed to hospice. 1/10/21 5:44 am resident able to take HS meds, ingest 2 cups of shake. No emesis or loose stool noted. 12PM nurse noted resident not eating meals but ingesting milkshake and medications without any problems. Hospice contacted for change in condition. 1:00 pm hospice ordered Phenergan 12.5 mg Q 6 hrs PRN. Labs to be drawn 1/11/21. Hospice notified POA. 1/11/21 12:24am Resident had blood in stool. Resident denies any pain, on 2L of O2 for comfort.		No prior vaccinations for this event.
	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received 1st dose on 1/4/2021. On 1/6/2021 resident having SOB, increased weakness with O2 sats at 91% RA. On 8th resident sustained a fall, O2 sats 88-92, dizzy, weakness. Rapid COVID test		Influenza Virus Vaccines - Unknown date/type or

performed with negative results. Evening of 8th resident was lethargic and diaphoretic with fever of 99.9. Resident transferred to ER, on 5lt of oxygen. Resident returned from the ER on 1/9/2021 with new diagnosis of Leukemia and orders for hospice. Continued with fever, crackles and N/V and loss of appetite from the 9th and 10th of January. Resident expired at 820am on 1/11/2021.	brand	
VOMITING		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Initial pain in back of head and extreme headache. Some vomiting. At emergency, went into coma and was intubated. Hole drilled in skull to relieve pressure. MRI taken. Lot of bleeding in brain - anuerism lead to death approximately 14 hours after initial symptoms.	No prior vaccinations for this event.	
VOMITING		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/11/21 noted with headache, nausea/vomiting, severe melaise. On 1/12/21 resident expired.	No prior vaccinations for this event.	
VOMITING		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE	No prior vaccinations for this event.	

STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.

VOMITING **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

On Saturday, 1/16/2021, Patient went to the grocery store. Upon her return, she indicated she was experiencing N/V and some throat swelling. Patient subsequently collapsed and expired before she could be brought to an emergency room. During investigation by Coroners Office, it has been reported that Patient may have gotten some takeout food while she was out. Labs are pending and the Coroners investigation is ongoing. Spouse believes that her death was caused by the vaccine. No prior vaccinations for this event.

VOMITING **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Fatigue, muscle aches, vomiting, hematoma No prior vaccinations for this event.

VOMITING **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Vomit 30 minutes after administration. approx. 9 hours later, resident has Stroke-like symptoms. He was previously on Hospice before admitting to our facility and planned to be readmitted to hospice upon discharge. No prior vaccinations for this event.

VOMITING **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix No prior vaccinations for

open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.		this event.
	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"vomiting x3 1/8/21 1/9/21 00:34 - called to resident room by CNAs, staff stated resident was ""different"". Vitals taken and 02 sat was low, O2 in room and applied via NC @3L, O2 sat returned to 98 and all other vitals WNL including BS. Resident asked how he felt, stated he felt ""okay"". Resident exhibiting some shakey movements and clearing throat, states he does not have any phlegm or drainage or trouble swallowing. MD called and updated on situation, voicemail left. 1/9/21 11am- resident has been making a ""growling"" noise this shift. resident also has tremors. resident alert and answers questions appropriately. when asked if resident wants to go to hospital, resident firmly states ""no"". vitals wnl. no emesis noted. will continue to monitor resident. 1/9/21 12p- resident not answering questions appropriately. resident only answering yes or no. resident cannot tell me name, or the year, resident cannot state where he is currently or birthdate."		No prior vaccinations for this event.
	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Arm hurting used his oxygen at time of bed appeared vomited. No prior vaccinations for this event.		

VOMITING **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Jan 3 vaccine administered, jan 4 started headaches, vomiting, pain in the back of the neck, Headaches, chills, loss of speech, | No prior vaccinations for this event.

VOMITING **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient with inoperable pancreatic cancer received second Pfizer vaccine approximately 12:30 pm on 1/27/21. At approximataely 16:30, patient complained of abdominal pain and was given Levsin 0.125mg and morphine 5mg orally. At approximately 19:30 patient was found on the floor covered in a large amount of emesis, unresponsive without a pulse. | No prior vaccinations for this event.

VOMITING **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

emesis bright yellow in color, liquid BM, increased respirations No prior vaccinations for this event.

VOMITING **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

After being observed for approximately 20 minutes and patient walked to her car without assistance I was called to assess the patient in the parking lot for troubles breathing. EMS was called as I made my way outside. Upon my arrival patient was leaning out of the car and stating that she could not breath. She was able to tell me that she was allergic to penicillin. Oxygen was immediately placed on the patient with minimal relief. Lung sounds were coarse throughout. She then began to vomit about every 20-30 seconds. Epipen was administered in the right leg with no relief. Patient continued to complain of troubles breathing and vomiting. A second epipen was administered in the patients right arm again with no relief. A few minutes later patient was given racemic epinephrine through the oxygen mask. There appeared to be mild | No prior vaccinations for this event.

improvement in her breathing as she appeared more comfortable, but still complaining of shortness of breath and vomiting. When EMS arrived patient was unable to transport herself to the stretcher. When EMS and clinical staff transferred patient to the stretcher she became unresponsive. She appeared to still be breathing. She did not respond to verbal stimuli. Per ED report large amount of fluid was suctioned from the patients lungs following intubation in the ambulance. When patient arrived to the ED she was extubated and re-intubated without difficulty and further fluid was suctioned. At that time patient was found to be in PEA, shock was delivered. Shortly thereafter no cardiac activity was found and patient pronounced dead.

	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The next morning after vaccine, patient ran a fever, vomited, and was very tired. Mom laid her down to sleep and when she checked later, patient had passed away.		No prior vaccinations for this event.

	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Began with vomiting and diarrhea. C/O chest pain. Bradycardia. Hypotension. 2 seizures in 45 minutes after not having one in years. We gave fluids. Gave Zofran. Comfort measures. Pt passed at midnight. Was completely fine one day before. Had minimal issues with COVID though did have a pneumonia that was treated w ATB early on and resolved.		No prior vaccinations for this event.

	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute		No prior vaccinations for this

MD visit-basilar crackles right and coughing. Increased confusion.

event.

VOMITING

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar

No prior vaccinations for this event.

opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Received Pfizer Covid Vaccine in the AM on 2/9/21. Arrived to emergency department later the same day complaining of nausea, weakness, fatigue, Vomiting, Diarrhea. Post operative diagnosis, Ischemic colon/toxic megacolon.		No prior vaccinations for this event.
	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Was contacted by the person's daughter on 2/5/21. Patient started vomiting 2 days after vaccination. She aspirated and passed away 1/16/21. Patient had history of stroke and swallowing problems.	No prior vaccinations for this event.	
VOMITING		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 2/7/21 resident complainted of not feeling well, nausea, vomiting and weakness sent to ER passed away.	No prior vaccinations for this event.	
VOMITING		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On December 17, 2020, my husband, received his first BioNTech BNT162b2 COVID-19 vaccination. On Thursday January 7, 2021, he received this second COVID-19 vaccination. The following three days after his second vaccination, he felt fine. The fourth day, on Sunday January 10, my husband felt extremely fatigued. On Monday the 11th and Tuesday the 12th, he worked a full shift but complained of extreme fatigue and extreme chills to the point that his teeth were chattering while on the phone with me. He decided to work through it. When he got home on Monday night, he started vomiting. On Wednesday January 13, he woke up and had swollen eyes. Once again, he felt extremely fatigued, even after a full nights rest. He had the day off but had an early meeting. After his meeting, he was still tired so he went back to sleep. I left to get lunch, and drop off our kids, and upon my return, I found him on the walk in closet floor, face up, having passed away. He felt as cold as ice. The rapid test done after they called the paramedics resulted in a negative COVID-19 test for him.	No prior vaccinations for this event.	
VOMITING		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient had no energy in the first 24 hours and then began a steady decline that started with	No prior vaccinations for this	

vomiting after 48 hours, then an inability to swallow and ultimately the patients death on 2/5/21. event.

VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Death; Passed out; Stomach was bothering; Constipated; Difficulty breathing; Weakness/Event: Weakness was reported as worsened; a temperature of 99.4 degrees; Sweaty; Cold; Muscle ache; Body Aches; Diarrhea; Nausea; Vomiting; Fatigue/Tiredness; His raspy throat felt like he had mucus stuck in his throat; Cough; Raspy throat/worsened; This is a spontaneous report from a contactable consumer reporting her husband. A 75-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM9810, Expiry Date: Jun2021) at the age of 74- year-old via an unspecified route of administration on 04Feb2021 09:15 at single dose in Arm, Right for COVID-19 immunisation. Medical history included type 2 diabetes mellitus for about 20-25 years, ongoing kidney disease from 2005, ongoing chronic kidney disease, cardiac pacemaker insertion. The patient was diagnosed with kidney disease in 2005, but it was about 1 to 1-1/2 years ago that his kidney disease progressed to Stage 4 Kidney Disease. She said the Veterans Administration diagnosed her husband with his kidney disease, but her husband saw a private doctor, as well as, a VA doctor for his care. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (Lot Number: EL3248; Expiration Date: Apr2021) at the age of 74- year-old Intramuscularly at approximately 08:45AM on 15Jan2021 in right arm for COVID-19 immunisation and had no reaction. There were no additional vaccines administered on same date of the Pfizer suspect. There were no Prior Vaccinations within 4 weeks. The patient had symptoms start earlier in the day of Tuesday, 09Feb2021, after his second COVID-19 Vaccine shot (04Feb2021). The reporter said she and her husband didn't think anything of his symptoms at first. The patient had a temperature of 99.4 degrees on 09Feb2021. She didn't check her husband's temperature again after that time because the nurse at her husband's doctor's office said her husband's temperature was not at an area of concern. The patient was sweaty, off and on, starting 09Feb2021. She clarified he would be sweaty and the cold, but nothing extreme. The patient developed muscle aches, body aches, diarrhea, nausea, and vomiting on 09Feb2021. She clarified her husband had fatigue, tiredness, and had	No prior vaccinations for this event.

trouble with a raspy throat. His raspy throat started Tuesday evening (09Feb2021). His raspy throat felt like he had mucus stuck in his throat, and he was unable to clear the mucus from his throat. The reporter called her husband's primary care doctor on the morning of 10Feb2021 because her husband was having trouble with a raspy throat, and difficulty breathing. She said on Tuesday night (09Feb2021) her husband had to sleep sitting up because he couldn't lay down with his breathing. He was able to eat breakfast (clarified as oatmeal and an orange), lunch (clarified as soup and a salad), and dinner (clarified as soup and half a sandwich. She said her husband ate all the meat and half of the bread on the sandwich) on 10Feb2021. Her husband's primary care doctor wasn't available to speak to on Wednesday morning (10Feb2021), but the doctor's nurse said it sounded like her husband was having a reaction to his second COVID-19 Vaccine shot. The reporter said her husband's doctor instructed her later in the day to take her husband to the Emergency Room or Urgent Care if he didn't feel any better. Her husband's throat raspiness got worse in the evening of 10Feb2021. His breathing also became worse after dinner in the evening of 10Feb2021. The patient leaned forward over a couple pillows while sitting on their couch as it was easier for him to breath by doing that. They decided at 11:00PM that her husband should go to the Emergency Room. She said her husband was getting very weak, so she and her husband debated if she should call # for an ambulance, or if she should drive him to the Emergency Room. She said her husband was able to dress himself, but with some difficulty, and she assisted walking him from their house to their car. She said she had turned to walk away from her husband while he was at the side of their car, and then she heard her husband make a noise. He had appeared to have passed out. She clarified in the past, her husband had passed out prior to his pacemaker. She said she dialed #, and the # operator told her how to tell if her husband was still breathing. She said she couldn't tell if her husband was still breathing. She said when the ambulance arrived at her house, the ambulance staff worked on her husband for a long time. The reporter thought her husband had died at the time he had collapsed at the side of their car. The patient took a sugar free cough syrup Tuesday night (09Feb2021), and then again a couple times on Wednesday (10Feb2021) as treatment. The patient had thrown up a couple times, but found that the sugar free cough syrup soothed his cough the night before (09Feb2021). She said her husband had taken 2 TUMS early on Wednesday morning at approximately 2:00AM (10Feb2021). He had said his stomach was bothering him on 10Feb2021. He said he thought he may be constipated, so he took 1 Senokot (Clarified as GeriCare

Senna-Plus Natural Vegetable Laxative with Stool Softener) on 10Feb2021. She clarified her husband had diarrhea on 09Feb2021, but felt on 10Feb2021 he may have been constipated. There were no adverse events required a visit to Emergency Room since Patient's wife stated she was getting her husband to their car, so she could drive him to the Emergency Room, when her husband collapsed and died or to Physician Office as they spoke with the nurse at her husband's primary care doctor's office. Weakness was reported as worsened. The outcome of events Sweaty, Cold, Muscle ache, Body Aches, Fatigue/Tiredness, Raspy throat/worsened, Difficulty breathing, Weakness was not recovered; and of the remaining events was unknown. The patient died on 11Feb2021. The patient's official time of death was Thursday, 11Feb2021, at 12:08AM. Cause of death was unknown. An autopsy was not performed and it would take 3 weeks for a death certificate to be issued. The reporter stated she thought it was important to notify Pfizer of her husband's passing because his side effects fell within the expected time period after receiving his second COVID-19 Vaccine.; Reported Cause(s) of Death: Death		
	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
patient was not vaccinated at hospital. Caregiver reports that patient was vaccinated with second dose on Monday 2/15/21. Tuesday patient experienced n/v/d. Went to an ED on Wednesday and was cleared and sent home. Thursday reported shortness of breath to her caregiver and then collapsed. Patient was brought to as PEA arrest and ultimately died.		No prior vaccinations for this event.
	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident received the 2nd dose of the Covid vaccine approximately around 1105 by pharmacy through the pharmacy LTC partnership vaccination program. Resident had no adverse effects until around 8:00 pm she		No prior vaccinations for this event.

began complaining of body aches, and chills, Tylenol was given at this time. Around 9:30pm resident was sleeping in bed. Around 12:00 am the CNA called nurse into room to assess resident as the resident stated she did not feel good. Temperature at that time was 102.2, and vomiting. RN came to assess @ 1220 am She was noted to be vomiting, diaphoretic, pale and having trouble breathing. Temp was 97.3 after vomting, Pulse 53, Resp 20, o2 sats were 40-45%, unable to obtain Blood pressure, Applied 5 L of oxygen at this time and had LPN call 911 immediately. Resident was repsonsive and able to follow staff members instructions but was only answering yes or no simple questions at the time time of assessment. Paramedics arrived at 0040 and resident was sent to Hospital. @ 0130 ER nurse called to nursing facility to notify resident had coded in the ER and passed away @ 0110.

VOMITING

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21- N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P

No prior vaccinations for this event.

130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.

	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident is a Hospice patient. On 1-23-2021 am shift resident was observed by nursing have chest congestion and had a emesis times 1 with SOB, Zofran 4 mg was given. HOB (02 sats 88%) was elevated resident on 02 via nasal canula with 02 sat now @ 90% . no respiratory distress noted. MD was called with response pending for orders. @ 1400 resident with no signs of life. vs 90%-24-97/71-97.6. Hospice on site and time of death 1436		No prior vaccinations for this event.

	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Elevated heart rate, flushing of the face and ears, vomiting, trouble breathing, pulmonary edema		No prior vaccinations for this event.

	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Pt admitted to Hospital on 2/8/21 with 2-3 days of SOA and cough. His wife was diagnosed with COVID-19 at approximately the same time when the patient received 1st COVID-19 vaccine. Pt had not felt well since receiving the vaccine and had some changes in taste or smell. He became acutely worse 2-3 days p/t		No prior vaccinations for this event.

admission with DOE, productive cough, H/A, N/V, profound weakness and bilateral infiltrates on CXR. He was hypoxic on room air. During hospitalization, has gone back and forth from BiPAP to HFNC. Unable to prone. Pt and wife discussed goals of care and decided on comfort measure approach. Pt expired on 2/19/21.

VOMITING **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Severe headache, nausea and vomiting No prior vaccinations for this event.

VOMITING **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion; On 21Feb he went to the ER after vomiting and passing out; On 21Feb he went to the ER after vomiting and passing out; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; On 19Feb, he began to feel ill again with a fever. He felt worse on 20Feb; fever; headache; stomach upset; This is a spontaneous report from a contactable consumer reporting for the father: A 75-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EL3428) at single dose at left arm on 03Feb2021 for Covid-19 immunisation. Medical history included type 2 diabetes mellitus. No known allergies. The patient had not experienced Covid-19 prior vaccination. Concomitant medication in 2 weeks included amitriptyline hydrochloride (manufacturer unknown) 10 mg, atorvastatin (manufacturer unknown) 20 mg, dutasteride (manufacturer unknown) 0.5 mg, linaclotide (LINZESS) 290 mcg, gabapentin (manufacturer unknown) 300 mg, montelukast (manufacturer unknown) 10 mg, ramipril (manufacturer unknown) 5 mg, insulin degludec (TRESIBA) 100 unit/ml, liraglutide (VICTOZA) 18 mg/3ml solution. No other vaccine in 4 weeks. The patient experienced cardiac arrest due to pericardial effusion on 21Feb2021 14:15, fever on 13Feb2021, headache on 13Feb2021, stomach upset on 13Feb2021, on 19feb, he began to feel ill again with a fever, he felt worse on 20feb on 19Feb2021, on 21feb he went to the ER after vomiting and passing out on 21Feb2021. Events resulted in

No prior vaccinations for this event.

Emergency room/department or urgent care. Therapeutic measures were taken as a result of cardiac arrest due to pericardial effusion. Course of events: In Feb2021, 10 days after his 1st injection, the patient developed fever, headache, and stomach upset. He went for a rapid Covid-19 test (nasal swab) and it was negative on 11Feb2021. The doctor told him he might be having a delayed reaction to the vaccination. After a couple of days, he improved. On 19Feb2021, he began to feel ill again with a fever. He felt worse on 20Feb2021. On 21Feb2021 he went to the ER after vomiting and passing out and received treatment: IV fluids, diagnostic testing at ER. Rapid Covid test (nasal swab) at ER came back negative again on 21Feb2021. His heart arrested suddenly and he could not be resuscitated. CT scan results, that came back after death, showed Covid like pneumonia and pericardial effusion. The patient died on 21Feb2021 14:15. Cause of death was cardiac arrest due to pericardial effusion. An autopsy was not performed. The outcome of cardiac arrest due to pericardial effusion was fatal, of fever, headache, stomach upset was recovering, of he began to feel ill again with a fever, he felt worse was not recovered, of he went to the ER after vomiting and passing out was unknown.; Reported Cause(s) of Death: cardiac arrest due to pericardial effusion; cardiac arrest due to pericardial effusion		
	VOMITING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
He started vomiting 2 days later. we suspect he was having stool issues as well. he vomited blood at some point over the weekend. there was black vomit right before he passed. from 2am-6am he was wheezing and rattling and then he passed at approximately 6am 3/1/2021 at home. EMS did come and try to revive him and were unsuccessful.		No prior vaccinations for this event.
	VOMITING	**COVID19 (COVID19 (UNKNOWN)) (1202)**
Patient was admitted to hospital from home in cardiac arrest. Hx of hypertension, hyperlipidemia, type 2		No prior vaccinations

diabetes (not on insulin) and bilateral carotid artery stenosis. The patient was reportedly at his baseline health on 2/2/21. He received the 2nd dose of COVID vaccine around 1000AM on 2/2/21. Reportedly started running fever of 100.1 and chills the afternoon of 2/2/21. Around 7:00PM he started having dry cough and was complaining of breathing difficulties. He subsequently vomited multiple times (was eating pizza and aspirated) then lost consciousness. His wife called 911, did CPR and EMS reported he in PEA at scene and was intubated. Transported to hospital. SARS CoV-2 and influenza negative.

for this event.

VOMITING PROJECTILE

COVID19 (COVID19 (MODERNA)) (1201)

Low Grade Temp, Persistent low back pain, Projectile Vomiting. No prior vaccinations for this event.

VOMITING PROJECTILE

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

approximately 3 hours prior to expiring the patient was experiencing forceful emesis. later was found to have expired, patient was comfort care only.

No prior vaccinations for this event.

WALKING AID USER

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"death Narrative: 92 yo male seen in clinic on 12/30/2020 for transfusion, hbg 6.9. PMH includes HLD, CKD, myelodysplastic syndrome, DM, prostate cancer, HTN. Pt also received COVID19 Pfizer vaccine the same day. The patient denied any prior severereaction to this vaccine or its components. Post-transfusion, patient had a mechanical fall (per patient he was seated and used the cane to help him stand. However the cane slipped on the floor causing the patient to fall, patient hit his head and injured his right hip, no loss of consciousness at the time). Rapid response team was called and patient was admitted to the ED. Pt was found to have subcapital right femoral neck fracture, scalp contusion, and TBI (per ED provider's note). Ortho evaluated and said patient wasn't a surgical candidate. During his hospitalization, patient tested positive for COVID19 on 1/12/2021, pt was asymptomatic at the time. On 1/13/2021, pt exhibited mild URI

No prior vaccinations for this event.

symptoms, no respiratory distress. He was started on cetirizine, Montelukast, albuterol, and inhaled steroids to manage his symptoms. Dexamethasone was started on 1/14/2021. Chest Xray was ordered on 1/17/2021, pt's respiratory was slowly getting worse, resting O2 sats were in the high 80s and low 90s with IS. On 1/18/2021, CXR shows patchy bilateral airspace opacities suspious for pneumonia of bacterial or viral etiology. Pt was started on remdesivir 01/18/2021 (5 doses, from 1/18-1/22/2021). Pt required 5-6 LPM of oxygen at rest. Pt was then transferred to the ICU. His oxygen demand continued to increase and his condition worsened. On 2/14/2021, pt started to desat into the 70s on max high flow. Patient/family agree to comfort care. Medical cause of death was listed as ""acute hypoxic respiratory failure due to COVID19."" Patient expired 1/24/2021."

WALKING AID USER	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Resident had slight/slow decline in health prior to vaccine but continued to be able to walk around with walker at community. The day of the vaccine she had a fever. 2 days after vaccine resident did not get out of bed all day and refused to eat. She had small amounts of orange juice as her blood sugar level was low due to not eating. Resident was diagnosed with a UTI and began an oral antibiotic. 3 days after and on day 5 after vaccine resident began feeling weak and had a fall on each day. The following day again resident spent the day in bed. The next day she was quite restless, was on the edge of her bed attempting to self transfer often throughout the day. Resident continued to be restless on the 10th of Feb, had further decline on the 11th of Feb. Resident passed away early the AM of Feb. 12th.	No prior vaccinations for this event.
WEIGHT DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Staff walked into resident's room around 10:00am and noted resident's left side of his face was flaccid. Nurse was called and upon assessment resident noted to have an unequal hand grasp with left worse. He was able	No prior vaccinations for this event.

to talk but was mumbled and hard to understand. Physician, hospice, and family were notified. Resident had a stroke at 10:06 am on 1/8/2020. He lost all ability to use his left side. Resident passed away on 1/11/2020.

WEIGHT DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

On monitoring for weight loss . No prior vaccinations for this event.

WEIGHT DECREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Patient tested positive for COVID-19 on 1/8/21. She demonstrated a decline in appetite and the ability to feed herself d/t this illness, but no respiratory or other symptoms. She received COVID-19 vaccine #2 on 1/26/21. She demonstrated an SDTI wound to the Lt. heel on 1/27/21. On 1/31/21 she was noted to have a significant weight loss. She was admitted to services on 2/1/21 with comfort care orders. On 2/2/21 she was observed to be without vital signs. Orders were for DNR, and CPR was not initiated in accordance with that order. She was pronounced dead at 0112 on 2/1/21.

No prior vaccinations for this event.

WEIGHT DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Called PCP, from the note: I got my shot on Jan 19. But last Friday I have been down with a horrible flu. I'm wearing diapers because of uncontrollable diarrhea. I can't leave my sofa to walk over to my desk because I'll be so out of breath. I have a cough that produces a pink or gold Phelm I have dry mouth. I have no appetite I'm so weak and have lost 15 pounds. Don't know what to do. My next Covid is shot is feb 11 Called employer on 2/3/21 but hung up. Tried calling multiple times to follow up. In triage she stated she had a COVID test scheduled and had spoken with her PCP. COVID test through PCP: 2/4/21 She passed away the night of 2/4/21

No prior vaccinations for this event.

WEIGHT DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

My mom received the Covid 19 vaccine on Jan 5, 2021 and became very about a week later. I was informed that she tested positive for Covid 19 on January 14th. One January 17th she became very tired and weak and would not eat. Hospice called me and told me that she was in a decline state. I saw her on January 25 and 26 and she was just sleeping and could not open her eyes. Her vitals were good and she seemed to understand when I talked to her - she would squeeze my hand and moan but she could not talk or open her eyes. My mom passed away on January 27, 2021 just 22 days after receiving the Covid 19 vaccine. She was very think to begin with and being to weak and tired to eat resulted in her losing even more weight. Some of the other residents were given fluids to help and they recovered. My mom was not given fluids. I believe there were 20 deaths in her care home for the month of January when they vaccinated. This was an alarming number of deaths for the home. The facility had very few Covid deaths in 2019 and 2020. I asked every week if they had any Covid and or Covid deaths and this amount was shocking to me and the workers there.

No prior vaccinations for this event.

WEIGHT DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

"The day after the 2nd shot, patient developed blisters on his lips and mouth. The care facility said that he had a nut allergy -- but he had never been allergic to nuts. He stopped eating and drinking and his BP had dropped to 60/40. By Jan 16th they called to say he was dying and he passed away on 1/18/21. Patient had COVID19 from Oct 29th - early November. By Nov 21st he had lost 40 lbs. He was 6'3"" and had gone from 189lbs to 149 lbs with COVID. By Nov 21st when we could visit, he had recovered from COVID, but was very thin and weak. He could not bathroom alone and kept falling. He didn't seem to have a bad reaction to the 1st COVID shot, But he immediately reacted to the 2nd shot

Shingles - Glaxo 8/22/2020, resulted in hospitalization and LTC.

and passed away within 6 days."

	WEIGHT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/7/21 Increased difficulty chewing, swallowing, evaluated by SLP and dietician. Diet texture down-graded x 2 with poor appetite and recent 6lb weight loss. 2/8/21-APRN updated regarding poor appetite and difficulty chewing as well as downgraded texture of diet. Also informed of increased s/s of discomfort and increased use of PRN Oxycodone for pain. 2/9/21- elevated temp 100.7. 2/9/21 Covid pcr test negative. 2/9/21-N.O.?s APRN BMP, Albumin and Pre-albumin Level in am. 2/11/21-elevated temp 100.4. Covid rapid test negative. 2/12/21- CBG recorded at 517 at 5:20 am. Resident also has an elevated temp of 100.9. Tylenol administered per order. Vital signs include resp 24, radial pulse 134, O2 sat 83%. Supplemental oxygen administered via nasal cannula. Head of bed elevated. DR. notified at time via telephone. Order given for sliding scale for CBG. Guardian updated regarding changes in residents condition, poor prognosis. Guardian requests Hospice eval and admit. Guardian requests comfort care no hospitalization, no IV's, no G-tubes, no labs etc, D/C of Palliative services. ARNP informed. 2/12/21 Acute Telehealth visit with APRN due to increased lethargy, elevated CBG?s despite poor appetite and insulin administration. Resident unresponsive to verbal and noxious stimuli at time of visit. N.O. Morphine sulfate 20mg/ml, give 2.5mg PO/SL Q4hr PRN pain/shortness of breath. 2/12/2021-Admitted to Hospice, Lethargic, diaphoretic, T 98.1 P 130's R 18 O2 high 80's to low 90's via O2 mask at 3L. 2/12/2021- Resident legs and arms noted to feel cool this afternoon, 02 sat was 97% with 02 on @ 3L with mask Noted resident with sob and increased pulse. Prn morphine 0.25ml sl. given with good effect. Resident was less restless and quiet in her bed. Checked on resident several times this shift for needs. Resident noted to not move in her bed @ 8:15pm and noted she was not breathing. Supervisor called and pronounced resident deceased.		No prior vaccinations for this event.
	WEIGHT INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**

Hx dementia, CVA, CAD. 2-3 year history of only consuming 25% of 1-2 meals daily. All meds d/c early 2020 because of refusing to eat or drink anything. Suddenly began drinking april/may, gained weight back. Vaccinated on 1/7/21 & 2/4/21. On 2/22/21 had significant changes in respiratory status. Passed away 2/23/21.	No prior vaccinations for this event.	
WEIGHT INCREASED		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient received the vaccine around 11 am. He hadn't been feeling well (headache, dizziness) per report and initially called in to work. He then decided to come to work and was found down in a patient bathroom during his shift on our Facility while taking care of a patient (he was a nurse aid). Patient was coded and the team and was transferred to our Facility ED. He expired 3/3 2112	No prior vaccinations for this event.	
WHEELCHAIR USER		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Decedent had unwitnessed fall out of wheelchair 1/25/21 around 9:43am, denied head strike, pain, discomfort. Around 10:02pm, 1/25/21, decedent noted to have slurred speech and fluctuating HR, transported to Hospital and made cmo.	No prior vaccinations for this event.	
WHEELCHAIR USER		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Per Patients Wife - Same day - Flu like symptoms, Nausea, Headache. Restless that night. Next day - Weak, shortness of breath. Wife called squad to get him out of his wheelchair but patient refused hospital as it gets	No prior vaccinations for this event.	

him agitated. Patient passed away around 11 AM the day after vaccination.

	WHEEZING	**COVID19 (COVID19 (MODERNA)) (1201)**
He had rigors starting 6 pm the day after the vaccination. He was treated with one 500 mg tylenol. He had increased wheezing but did not complain of SOB. At 0400 the next morning, he died.		No prior vaccinations for this event.
	WHEEZING	**COVID19 (COVID19 (MODERNA)) (1201)**
This is a hospice patient under the care of Hospice at an affiliated nursing home. Pt received the vaccination around noon on 2-16-21 by a representative from Pharmacy. The following afternoon 2-17-21 at 14:45 the pt started to experience severe SOB resp rate 36, audible wheezing and use of respiratory accessory muscles. BP180/80, 113 pulse temp 98. Pt was given morphine and ativan. The respiratory distress was eased however pt never returned to baseline and died 2-22-21 around 4am.		No prior vaccinations for this event.
	WHEEZING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
On 1/9/21-Diaphoresis, O2 90%, respirations 22, increased weakness, wheezing bilaterally. Send to ER for evaluation and treatment. She was sent to ER, where she was admitted for 2 days, then expired there on 1/11/21		No prior vaccinations for this event.
	WHEEZING	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

He started vomiting 2 days later. we suspect he was having stool issues as well. he vomited blood at some point over the weekend. there was black vomit right before he passed. from 2am-6am he was wheezing and rattling and then he passed at approximately 6am 3/1/2021 at home. EMS did come and try to revive him and were unsuccessful.		No prior vaccinations for this event.
	WHITE BLOOD CELL COUNT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Narrative: Patient received COVID/Pfizer #1 2/10/21 in L deltoid. (Patient home bound). On 2/12/21 reported left flank rash. 2/13 rash spread to entire abdomen/chest and UEs. Continued with fluctuations in BP/HR, fluid retention. On 2/16 labs ordered and Medrol dose pack. seen in home on 2/19 by MD - RUE swelling; diffuse rash over entire body; additional labs ordered (order to home infusion company). Patient passed in AM of 2/20/21. Reported no urine output the prior evening. Additional labs not performed due to death of patient prior to lab company arrival.		No prior vaccinations for this event.
	WHITE BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
started having generalized weakness on 1/21/21, fatigued., nausea/vomiting. went to doctor on 1/25/21 with complaint of sore throat, cough, and felt congested. Went to ER on 1/25/21 with complaints of increased shortness of breath, worsening nausea and vomiting. started on oxygen for sats of 87%. admitted on 1/25/21. On 1/26/21 needed intubated, CXR showed worsening consolidative change right lung at right hilar level. Echocardiogram showed ejection fraction 35-40%, left atrium is moderately dilated.		No prior vaccinations for this event.
	WHITE BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (MODERNA)) (1201)**

Pt. presented to the ER with abd pain and septic shock. Pt. reported to feel ill shortly after receiving the vaccine.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT DECREASED

COVID19 (COVID19 (MODERNA)) (1201)

Abdominal pain, nausea and vomiting, shortness of breath, acidosis, hypoglycemia, death. Onset of abdominal pain was 30 minutes after administration of the vaccine followed by 20+ episodes of vomiting and dry heaving.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT DECREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient was vaccinated for SARS-CoV-2 on 6-Jan-21 at his site of employment, a Nursing Home. Patient presented to Urgent Care on 15-Jan-21 complaining of left sided chest pain that started the evening before with an associated slight cough. Pt was afebrile with a heart rate of 88 and an O2 sat on room air of 98% in triage. His EKG showed a sinus tachycardia of 114 with a slightly prolonged QTc of 463 ms. Physical exam was significant for bibasilar crackles and X-ray showed bibasilar infiltrates consistent with COVID pneumonia but bacterial pneumonia could not be excluded. The patients BP was documented as 97/64. He was treated with Zofran for nausea and tylenol. He was prescribed a five day course of Azithromycin, an Albuterol inhaler, guaifenessin with codeine cough syrup, and Zofran. Labs were drawn and he was discharged. His lab results were reported after his departure and were significant for a white blood cell count of 1.33, platelet count of 73, 2% myelocytes, 1% metamyelocytes, an absolute neutrophil count of 0.75 K/ul, a creatinine of 1.83, total bilirubin of 1.3, with direct bilirubin of 0.8, alkaline phosphatase of 294 and AST of 112 with ALT noted to be within normal limit. His COVID nasopharyngeal swab from the visit was reported as negative and a swab performed at his employment on 13-Jan-21 was also reported to be negative. Patient could not be reached by phone after discharge from Urgent Care about these labs. On the

No prior vaccinations for this event.

evening of 16-Jan-21, Police Department received a 911 call about an adult at the patient's address who was found unresponsive. Upon arrival on scene, the patient was found to be deceased and a decision was made not to attempt to resuscitate. The death was deemed to be non-suspicious and the patient's body was transported to a funeral home. On 19-Jan-21, I contacted the State Medical Examiner's Office. They have decided to perform an autopsy and have recovered the CBC and chemistry specimens obtained for further testing.

WHITE BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Temp of 100.1 and unproductive cough on 1/17; temp of 100.4 1/28; O2 desaturation 88% on RA 1/28; Diagnosed with Covid-19 on 1/18/2021 Patient passed away on 1/29/2021	No prior vaccinations for this event.
WHITE BLOOD CELL COUNT DECREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/12/2021 Vaccine 2/13/2021 Weakness, oral ulcers 2/17/2021 Brought to ER for loss of consciousness, altered mental status, rectal bleeding; work up showed sepsis, UTI, anemia, pneumonia, pleural effusion, pancytopenia, hypotension; persistent hypotension and respiratory failure 2/18/2021 Passed away at 5:54AM	No prior vaccinations for this event.
WHITE BLOOD CELL COUNT INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
12/30/2020 07:02 AM Resident noted to have some redness in face and respiration were fast. Resident vital signs were abnormal except blood pressure. Temp at the time was 102.0 F taken temporal. Resident respirations were 22 labored at times. Pulse is 105 and pulse ox 94% on room air. Resident is made comfortable in bed. Notified triage of change in condition also made triage aware of resident receiving Covid vaccination yesterday morning. Resident appetite and fluid consumption has been poor for few days.	No prior vaccinations for this event.

12/30/2020 07:32 AM Received order from agency to administer Acetaminophen 650mg suppos rectally due to resident not wanting to swallow anything including fluids, medications and food. This writer administered medication as NP ordered. Will monitor for effectiveness and adverse effects if any. 12/30/2020 08:41 AM Received new orders to obtain Flu swab, obtain CBC and BMP, and Chest Xray all to be obtained today. Notified family of resident having temperature and vital signs excluding b/p that was abnormal. Family was thankful for call and inierated to nurse that family does not want resident sent to hospital. Did educate family on benefits of Hospice services, but family persistant on continued daily care provided by nursing staff. Requests visits if decline continues. Family assured if resident continues to decline, facility will accomandate resident family to be able to be at bedside when time comes to do so. NP ordered IVF and IV Levaquin on 12/31/20. Family chose at that time to sign for Hospice services and not have resident provided with IVF or IV Antibiotics

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

No adverse effects noted after vaccination. Patient with cardiac history was found unresponsive at 16:45 on 1/6/21. Abnormal breathing patterns, eyes partially closed SPO2 was 41%, pulseless with no cardiac sounds upon auscultation. CPR and pulse was regained and patient was breathing. Patient sent to Hospital ER were she remained in an unstable condition had multiple cardiac arrest and severe bradycardia and in the end the hospital was unable to bring her back.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Resident has increase weakness and lethargy with abnormal labs. He was transferred to the ER. He was admitted to the hospital and treated for worsening AKI and hypotension.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19

	(MODERNA)) (1201)
Patient presented to Vaccine clinic 1/12/21 to receive COVID vaccination. Patient denied any ill feeling, no fever, cleared for vaccination. Is chronically SOB due to COPD, but patient reported no different than usual. Presented to the ED the next day c/o SOB and weakness for the last week. Patients condition ultimately declined over the next few days and died 01/21/21 from pneumonia (not COVID). Patient did admit she lied about her symptoms on the day of vaccination to get the shot.	No prior vaccinations for this event.
WHITE BLOOD CELL COUNT INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
1/24/21 0445- patient presents to the ED with complaints of neck pain, chest pain, and back pain for about a week. States also feels SOB, intermittent fever with temperature 100.3 on arrival. Patient was worked up for his cardiac type symptoms, found to have elevated WBC and CRP with no explanation. D-Dimer was elevated with CT showing no sign of PE. Patient was sent home from the ED with instructions to follow up with primary care and/or return if s/s worsen. 1/24/21 1705- patient is returned to the ED via ambulance after becoming unresponsive and some seizure like activity. Patient was intubated. Head CT showed large brain bleed that was irreparable and not compatible with life. Patient was also found with positive blood cultures x2 with gram positive cocci in clusters growing after 9 hours.	No prior vaccinations for this event.
WHITE BLOOD CELL COUNT INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presented to ER via EMS at 1556 3 days after receiving vaccine. pt was breathing approximately 50 times a minutes and o2 sats in the 70's upon arrival. NP decided to intubate, Rocuronium and Versed given. Pt became bradycardic and 1 amp of Atropine was given without improvement. No pulse felt, CPR started per ACLS protocol. 7 Epi's given. Time of death- 1632. After TOD pt was swabbed for COVID-19 and the results were positive.	No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Pt. was admitted to hospital on 1/6/21 with fatigue, weakness. Pt. was Covid positive in November of 2020. Impression upon admission was fatigue may be due to her aortic stenosis and some hypertensive issues with blood pressure changes. She was anemic. WBC was elevated to 19.2, HBG 10.5, NA-131, K+ - 3.1, Rule out bacterial infection. Potential source could be her heart valve. Also noted to have acute renal failure with BUN of 47 and Creatinine of 2.2 noted. Pt. was transferred to Hospital on 1/8/2021 with dx of aortic stenosis, bacteremia, ARF, Dehydration and anemia. Discharged with dx. of sepsis. Pt. expired on 1/18/21 with dx. of severe sepsis, complete heart block, staphylococcus epidermidis bacteremia.		No prior vaccinations for this event.
WHITE BLOOD CELL COUNT INCREASED		**COVID19 (COVID19 (MODERNA)) (1201)**
Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient's medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face, increased respirations (reported as 22 and labored at times), pulse of 105, and 94 percent oxygen saturation on room air. The patient had a fever of 102 degrees Fahrenheit. Laboratory tests revealed a negative influenza swab, elevated white blood cell count of 14.1, elevated BUN at 113, and creatinine 2.7. Chest x-ray showed mild, left lower lung infiltrate. On 31 Dec 2020, the patient went under hospice care per her family request.. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01		No prior vaccinations for this event.

Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Resident c/o nausea evening of 1/29 (nausea common for her post dialysis), had a large emesis at approx 2220, 0030 (unusual for resident to vomit)- received Zofran per order. Skin cool and damp, Blood sugar 147 (checked due to h/o diabetes and poor intake). At approx 230am Blood pressured checked and noted to be 52/29. Resident transferred to ER, intubated and transferred to higher level of care where she passed away on 1/30 at 736pm. Resident's medical notes indicated likely shock, cardiogenic in nature, sepsis (source unknown) along with a multitude of other co-morbidities that resident has.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

"This is a 73 year old female that received her 1st dose with Moderna vaccine on 1/8/21 at approximately 1600. Within one hour, the patient developed altered mental status and increasing weakness. She was transported to the hospital by the staff at her Assisted Living Facility for concern of a vaccine reaction. On admission, oxygen saturation was found to be 89% on room air, BP=137/86, HR=94. Labs were normal, with

No prior vaccinations for this event.

the exception of WBC=15 (leukocytes normal, chest xray clear, COVID test negative), and a detectable troponin=63. Head CT negative. Physical exam was only notable for 'slight superficial erythema over distal right forearm and dorsal hand. No significant edema.' The patient was treated for a possible allergic reaction to vaccine with NS bolus, methylprednisolone 125mg, famotidine 20mg, and aspirin 300mg PR. She was admitted for monitoring given continued altered mental status/weakness. The next day, she continued to show no improvement, so a head MRI was ordered. MRI showed "" 1. Numerous acute cerebral and cerebellar infarcts involving both anterior and posterior circulations consistent with a central embolic source. 2. Minimal right parietal petechial hemorrhage. 3. Moderate atrophy and moderate nonspecific white matter signal abnormalities compatible with chronic microvascular ischemia "" Neurology was consulted, who approved the start of aspirin and to continue DVT prophylaxis. The patient's advanced dementia and timeline preclude other intervention. The patient's status was DNR/DNI. The patient was discharged on hospice to her assisted living facility on 1/11/21 (with reports of continued somnolence). It was reported that date of death was 1/24/21."

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Patient presented to emergency room on 2/1/2021 with a chief complaint of having a chronic headache and fatigue following receipt of the Moderna vaccine 10 days prior. Following examination by the physician, the patient was diagnosed with an acute subdural hematoma. The patient subsequently underwent decompressive surgery, however demonstrated worsening neurologic status over the next several days and ultimately expired on 2/4/2021.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

"02/08/21--2 days after vaccine--Resident stated that she ""didn't feel good"" (She is developmentally delayed and less able to communicate how she feels than those in the community) and stopped eating most foods; also had fatigue. Vitals, coloring, & behavior were normal. 02/09/21--Belly was firm and mildly distended

No prior vaccinations for this event.

(although she stated it didn't hurt); she coded this evening and CPR was performed before EMT could transport her to the hospital. 02/10/21--Resident passed."

	WHITE BLOOD CELL COUNT INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Pt presents to ER with increased weakness, hypoxia, history of COPD, but not oxygen dependent., hypotension. Acute Kidney failure noted in labs, not previously diagnosed , new hyperkalemia. BP 73/39, HR 67. dopamine initiated, and switched to Levophed. Oxygen Sat 86%, requiring 10 L O2. Transferred from this critical access hospital to another Hospital. Expires later 2-13-2021		No prior vaccinations for this event.
	WHITE BLOOD CELL COUNT INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident getting rehab therapy in the facility and has a long history of Parkinson's Disease. On 01/29/21, he received the COVID vaccine on left deltoid, resident was recently hospitalized due to Pneumonia and was on antibiotic IV and was recently placed on GT feeding due to severe dysphagia from his Parkinson's disease. On 01/31/21, started having increased congestion. On 02/02/21, started having increased temperature and WBC went up >20,000 on 02/03/21, started on Vancomycin IV on 02/04/21 but was transferred to the hospital. Facility was notified today (02/18/21) that resident expired in the hospital.		No prior vaccinations for this event.
	WHITE BLOOD CELL COUNT INCREASED	**COVID19 (COVID19 (MODERNA)) (1201)**
Received vaccine on 2/6/2021. was a bit off all week per caregivers - low grade temp and reporting pain which they treated with Tylenol. She was pretty much herself on morning of 2/13/2021 - got up, had shower. caregivers noted her extremities were cool and face was red. temp was 97.4. She was placed in wheelchair with book in the living room. caregivers noted she was not turning pages of the book as she usually would. She was tracking, so they don't think she had a seizure. Caregiver moved her back to bed with blanket and		No prior vaccinations for this event.

noted that her lips were blue and at that point called 911. She was found with agonal breathing, CPR started, intubated by EMS, taken to the ER and diagnosed with cardiac arrest upon arrival. CPR was continued until family could be reached and decision was made to stop resuscitation.

WHITE BLOOD CELL COUNT INCREASED | **COVID19 (COVID19 (MODERNA)) (1201)**

Resident yelling for assistance in apartment. Nursing personnel found resident on floor at 6:10 AM on 2/18/2021. Resident was transported to Hospital on 2/18/2021. Status update on 2/18/2021 from son, resident CT & X-rays were done all normal. Labs done and WBC count was elevated and awaiting results. Resident stable and admitted to hospital for observation. Resident passed away on 2.21.2021.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED | **COVID19 (COVID19 (MODERNA)) (1201)**

Pt received second Moderna Vaccination on 2/21/21 at 1:00 pm at Pharmacy. Pt present on 2/22/21 to ER via ambulance at 1940. Upon presentation C/C hypotension Post COVID vaccine. Nurse notes states that Home Health nurse sent patient to ER secondary to hypotension and hyperglycemia. Pt states back ached and was holding his head. Nurse noted pt had random petechiae over body and bruising to abdomen following injections received during recent hospitalization. (unknown hospitalization). Patient was treated with IVF bolus in addition to initiating Dopamine for hypotension, patient became agonal and daughter at bedside presented Adv. Directive, pt was DNR. Pt pronounced time of death was 2110pm. (Pt only reported a sore shoulder secondary to vaccine).

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED | **COVID19 (COVID19 (MODERNA)) (1201)**

loss of consciousness;febrile Narrative: Patient received his 2nd vaccine at 10am 2/17. That evening he felt subjectively febrile and then suffered a ground level fall at 0400 on 2/18. He did not lose consciousness or

No prior vaccinations

injure his head. EMS was contacted and assisted him into bed. At 0600, wife noted increased work of breathing, which prompted another EMS call, who found him hypoxic with fever of 106. He was transported to a community hospital, where he was found to have temp 102.9 and blood pressure in 70s-80s systolic. He was transferred to hospital at 1300 on 2/18/21, requiring norepinephrine for pressure support after fluid resuscitation. He c/o stiffness and soreness all over but presenting ROS was otherwise negative. Patient was treated with 4L IV fluids and vancomycin and piperacillin/tazobactam at the outside ER. Here at the hospital he was treated with vancomycin, piperacillin/tazobactam and levofloxacin along with IV fluids and norepinephrine. Despite this he had several fevers with Tmax 103.5F the night of 2/18-2/19 and he required norepinephrine plus vasopressin overnight to maintain blood pressure. Piperacillin/Tazobactam was discontinued in favor of meropenem. His last fever was at 6am on 2/19. ID consult was obtained 2/19/21 and vancomycin and levofloxacin were weaned off. Ultimately his blood pressure improved and he was weaned off of all vasopressors the morning of 2/20. Notably, he never developed severe hypoxemia at rest while in the ICU, but did require BiPAP non-invasive ventilation at night instead of his usual CPAP to keep his oxygen levels > 90% while sleeping and additionally had desaturations into the low 80% range with exertion from which he was slow to recover. His oxygen saturation was >90% on 30-40% FiO2 via aerosol mask overnight and 3L (his current baseline) NC during the day. He was transferred out of the ICU on 2/21 based on hemodynamic improvement, stable oxygenation, and improved mentation and symptoms. Unfortunately, on the morning of 2/22/21, patient had an abrupt change in status and was found to be unresponsive with hypercarbic respiratory failure and hypotension. ABG during this event was 7.16/121/65. BiPAP was initiated as patient's code status was DNR/DNI. CXR with no significant change from 2/18/21. CT of head without contrast was negative for acute processes. Based on lack of rapid improvement, the decision was made by wife to transition to comfort care. Patient died at 1446 on 2/22/21. **Of note: patient was admitted for 1 week for covid 19 pneumonia November 2020. During this hospitalization he was found to have chronic R sided PE, no acute PE.

for this event.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

From CT Scan in ED at 7:40 pm on 1/25/2021 -- There is a large intraparenchymal hemorrhage with Surrounding vasogenic edema within the left occipital lobe. There is additional subdural hemorrhage layering along the left frontal, temporal and parietal convexity which may be decompressing from the area of intraparenchymal hematoma. No visualized intraventricular hemorrhage.There is some trace hemorrhage layering along the left tentorium cerebelli. Severe associated mass effect with left-to-right midline shift of 2.1 cm. There is subfalcine and downward transtentorial herniation with complete effacement of the basilar cisterns. Evaluation of the craniocervical junction is limited due to beam hardening artifact. Near-complete effacement of the left lateral ventricle. No head trauma or fall. Deceased 1/26/2021

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (MODERNA)) (1201)

Vaccine manufacturer and lot number unknown, vaccine given at alternate location. 2/23/21 8:27 PM: The patient is a 68-year-old male comes to the emergency department by paramedic ambulance for altered mental status that, began at around noon in association fever temp 102.9. PMH of myelofibrosis (on Jakafi and hydroxychloroquine), depression, anxiety, OSA, and history of AVR. Given history of myelodysplasia and Jak inhibitor predisposing to some opportunistic infections most notably viral reactivation with history of HSV and possible bacterial endocarditis he was admitted to the ICU for further monitoring and pressors. Patient has a MOS procedure 14 days prior - Status post MOSs procedure with large wound deficit on forehead -- Does not appear to be overtly infected at the time of admission. ED physician indicated mild facial cellulitis. 2/23/21- WBC 16.1 on admission. ECHO 2/26 indicated - no vegetation visualized. Of note second COVID vaccine 2 days prior to admission. Dr. felt incident was possible cardiogenic shock secondary to COVID vaccine. He did not feel the patient has a source of infection upon admission. Questionable given wounds on forehead Dr. (CMO) review of case- his impression was septic shock with and underlying case of chronic cardiac compromise making the hemodynamics worse

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

PATIENT GOT HER FIRST COVID PFIZER VACCINE AT 12/31 IN THE AM. HAD GOTTEN FLU LIKE SYMPTOMS AND HAD BEEN SICK FOR A COUPLE OF DAYS. HAD NAUSEA AND VOMITTING DURING THIS TIME AS WELL. ON 1/3 THE CARE GIVER WENT TO CHECK ON HER PT AT HER LTC FACILITY WHERE SHE LIVES AND SHE WASN'T ACTING RIGHT. SHE WAS UNABLE TO DO A STROKE EXAM. PT HAD NO MOVEMNET IN ARMS OR LEGS AND WAS UNABLE TO SPEAK. PT WAS VITALLY STABLE AT THE TIME. EMS RECORDED THAT THEY THOUGHT DIAGNOSIS WOULD BE STROKE, PNEUMONIA OR SEPSIS. AFTER ARRIVAL AT THE HOSPITIAL DETERMED THAT SHE HAD A STORKE, ACUTE KIDNEY INJURY, ABNORMAL LFTS.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received COVID-19 vaccination on 1/14/2021. On 1/17/2021, patient was transferred to Hospital s/p multiple cardiac arrests. Patient was hyperkalemic and in acute renal failure at time of transfer. Hyperkalemia was treated, but the patient suffered PEA vs VFib. At the time of transfer, patient was on vasopressin, norepinephrine, and epinephrine. The patient had an EF of 40-45% and elevated troponins. Patient was made DNR and placed on comfort care. Patient passed away on 1/18/2021. Ultimately we suspect that the patients condition was a direct result of his underlying disease states, but wanted to make sure reporting was made available.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank

No prior vaccinations for

anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21	this event.
WHITE BLOOD CELL COUNT INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
01/22/20When transferring resident from bed to W/C Resident became unresponsive to voice with eyes fix open and point up to the right. Placed resident back in bed found 82% o2 sats B/P 110/106 pulse 110 resp below 16 placed o2 via non rebreather with 20 l/min 02 up to 90% then stabilized at 89% Resident following all commands encouraged to take do breathing exercises, with some compliance, continues ABT/pneumonia , no s/s adverse 1/23/2021 16:48 Discharge Summary Note Text: Resident found unresponsive with no pulse or respirations in bed with emesis on gown. Time of death verified at 1645 with LPN. Funeral Home called at 1900 and body released at 2000.	No prior vaccinations for this event.
WHITE BLOOD CELL COUNT INCREASED	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: See ""Other Relevant History"" in Section 6 above Symptoms: ElevatedLiverEnzymes & death, pneumonia, afib Treatment:"	No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

1-12-21 Resident is complaining of heart pain. Resident blood pressure is 228/105. 1-22-21 Dx UTI 1-13-21 His nurse called MD at approximately 0645, reported to him that it was reported to this nurse that resident has not slept in 2 days and night, has an increased blood pressure, reports severe pain in lower back, and appears to be uncomfortable Resident is able to verbalize his pain and where it is at, but is unable to explain the quality of the pain or give a number on the 0/10 pain scale.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Lethargic, refusing medications and meals. 1/11/2021- Covid+, poor appetite. No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED **COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"anxious, restless, weak, dizzy, felt ""horrible"". Continued to C/O symptoms,. At 01:15, patient lost consciousness , then stopped breathing and lost pulse. Narrative: Patient was first vaccinated for COVID 19 on 1/8/21. On 1/24/21: 61 year old presents to E.R. with CC of chest pain/sob, with multiple medical conditions including hypertension, atrial fibrillation on apixaban, cardiomyopathy with poor EF, dyslipidemia, COPD, CVA, lung CA s/p radiotherapy, PTSD, depression, Churg Strauss Syndrome, Sjogren's syndrome presented with chief complaint of chest pain or shortness of breath. He has been having worsening shortness of breath the past few days, also complains of cough productive of yellowish sputum, no hemoptysis. He complains of left upper chest pain with no radiation. There is no diaphoresis, palpitations or lightheadedness. He denies fever or chills. He complains of having fallen a few times recently, thus he passed out. Could not say if there were seizures activity. Admitted to 3D Tele. On 1/27, Pt advises he had episode of substernal CP this am. RN advises pt was in afib w/ RVR at a rate >140 at time of CP. Pt CP improved w/ prn NTG. Pt HR improved after daily medications. Pt sts his CP has resolved. Pt admits to

No prior vaccinations for this event.

continued dyspnea. Increased trop, transferred. 1/28, struggling with orthopnea and cough. He has no peripheral edema. He does have intermittent chest pain. Patient having periods of A-Fib RVR with non-sustained rates of 140's-150's 1/29 more chest pain at 04:00, relieved with NTG. HR = AF, with RVR 145. At about 08:00, Cardiology sees patient and signs off, ""shortness of breath and cough not due to heart failure as evidenced by orthostatic hypotension and no improvement in symptoms with diuresis. Consider underlying lung disease vs acute pulmonary disease."" No pulmonary consult noted. 1/29 Patient received 2nd dose COVID19 vaccine at about 3:30-4p. No notes from staff on this event. No notes from MD that this was discussed and still part of the plan. 1/29 nurse's note: At around 2240 Pt was able to rest briefly but is now restless and anxious again. Tachypneic, stating he feels so weak and dizzy and overall just feel horrible. Continuing to get up frequently to have small soft bowel movements with assistance. Pt also stated ever since he got ""that shot"" he hasn't felt well. When asked what shot pt replied ""COVID shot."" Pt did receive 2nd dose of COVID vaccine 1/29 at 1530. Around 2250 Spoke w MOD to relay above information and overall concern for pt, asked for MOD to come to bedside to evaluate pt. MOD states he's handing off to oncoming MOD and they will come to bedside to see pt. Around 2300 oncoming MOD called and all above and previous information discussed Around 2310 MOD came to bedside to see pt. Will continue to monitor closely. 01/30/2021 ADDENDUM Around 0115 pt called for help to use bedside commode to urinate and have BM. Assisted x2 to BSC. While sitting on BSC pt's eyes rolled back and pt made postures consistent with a seizure, body became very rigid. Pt was unresponsive still with pulse. Lifted patient back to bed with 3 staff assist. Pt stopped breathing and lost pulse. Chest compressions started immediately and Code Blue called at 0120. 1/30 Hospitalist note: Called for CODE BLUE AGAIN AT 4:53. While on Vent after s/p Code blue for reasons not clear patient went into Asystole and code called second time. Patient had a prolonged CPR and was actually called off at 5:17 but he started having pulse and agonal resp. he was placed on Levophed and D5NS. He got a total of 9 amps of epi, 3 amps od Bicarb and 1amp of D50. Trope bumped from 0.12 to 0.43 prior to this he already was on ASA, Apixiban for afib. Cards are on board for his CHF for his pulmonary edema Lasix ordered. Hid lactic acid is elevated. Blood cultures pending. Started Zosyn and is on Levophed. Continue to monitor. Updated patients Mom and she requested to do everything at this point. Coded again at 5:40, survived, but AOD writes a death note(?) Coded for the 4th

time at 08:18. Family at beside, Mother asks for code to be stopped."

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Patient received dose #1 of COVID-19 vaccine on 1/16/21. Within 3 days, she developed petechiae up to ankles, later rising up to her knees. Pt admitted to hospital on 2/6/21 for symptomatic anemia 2/2 vaginal bleeding. Patient received 4 units FFP, 4 units PRBC, 1 unit cryoprecipitate, and vitamin K 5 mg IV. Also started on medroxyprogesterone 20 mg PO TID. Alectinib d/ced due to worsening liver function. Evalauted by OB/GYN and Hematology. Diagnosed with DIC. Patient with worsening bilateral lower extremity edema and purpura with pain and weakness. Palliative care consulted. Patient passed away on 2/11.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death on 1/31/2021 multiple comorbidities

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

61 yo F with history of bilateral lung transplant 6/23/17 presented to ED on 2/4/21 with chief complaint of worsening shortness of breath, nausea and diarrhea for past week since receiving since receiving COVID-19 vaccine (Pfizer) on 1/28/21. Upon arrival to triage she was obviously dyspneic with significantly low oxygen saturations. O2 sats on arrival were 65%, improved to mid 90's with O2 6 liters per NC. Admitting diagnosis: hypoxic respiratory failure post COVID vaccine. Lab work shows an elevation of the BUN and creatinine at 31 and 1.71 which is slightly higher than her usual baseline levels. BNP is elevated at 2 448 with a mildly elevated troponin. Procalcitonin is also elevated. Patient's white blood cell count is 11.07. Full viral panel including COVID-19 is not detected. All blood cultures and respiratory cultures were negative.

No prior vaccinations for this event.

Patient chest x-ray shows numerous bilateral patchy opacities which is significantly different from her previous chest x-ray here. Empiric rejection treatment initiated including high dose methylprednisolone, plasmapheresis, IVIG, Thymoglobulin. She continued to decline and ultimately required intubation, proning and paralyzing on 2/8/2021 and then VV ECMO cannulation on 2/13/2021. EGD done 2/14/2021 as unable to pass the TEE probe during cannulation prior day (unable to complete due to abnormal anatomy). Acute pupil exam change in the early am hours of 2/15/2021 prompted urgent head CT which revealed catastrophic brain bleed. Brainstem reflexes were lost soon after. Despite placing an EVD emergently at bedside, brain stem reflexes were not recovered. GOL engaged and patient not an organ donation candidate. Therefore discussion with sister at bedside resulted in decision for cessation of life support. Patient expired shortly after support withdrawn and pronounced dead on 2/15/2021 at 11:11 AM.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Sent to ER 1/14/2021 due to drop in blood pressure with LOC during dialysis. Imaging revealed right lower lobe pneumonia given script for amoxicillin. According to staff patient was on dialysis had pneumonia and was on hospice, dialysis stopped resulting in death.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Death on same day as vaccination

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT INCREASED COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Emergency Room HPI: The patient is a 71 y.o. female with a PMH notable for COPD, hypertension and anxiety and depression who presented on 2/6/2021 for evaluation of shortness of breath. Patient presented

No prior vaccinations for

to our emergency room yesterday morning from local nursing facility rehab nursing staff reported that she had had a increased shortness of breath for the last 3 days she has been diagnosed with COVID-19 on 2-2-2021. Patient has also received both COVID-19 vaccines. Patient presented to the emergency room with labored respirations conscious awake and was on a non-rebreather at 15 L. upon arrival to our emergency room patient's temperature 101.6¦, pulse 169, respirations 40 to blood pressure 142/91 and oxygen saturation 100% on 15 L non-rebreather. Patient received a chest x-ray that showed chronic emphysema and fibrotic changes in the lung no acute processes identified. Patient's white count 12.8, glucose 197, creatinine 1.2, lactic acid 4.6, cardiac enzymes negative, D-dimer 1180, patient has urine culture pending. Patient has received about 3 L normal saline boluses patient was having hypotension 86/52. Patient also received IV acetaminophen a 1000 mg IV in the emergency room along with Decadron 10 mg IV piggyback. Patient was admitted acute care for the need of IV fluids and IV antibiotics for COVID-19 and sepsis 2/12 admit Brief history and initial physical exam: Patient is a 71 year old long-term resident of Rehab and Healthcare. Unfortunately, she contracted coronavirus (COVID-19) at the nursing home. Her respiratory status started to decompensate and so she was brought into the hospital. Initial workup showed significant bilateral pleural effusions and ground-glass opacity of both lungs. She had a significant supplemental oxygen requirement. She was admitted for further evaluation and treatment. á Hospital course: The patient was admitted and started on IV Remdesivir. She was given IV Decadron. She was given immune support vitamins. Despite this, her sepsis worsened. When it became apparent that the patient was not going to recover, her daughter did make her comfort care only and hospice was consulted. The patient was found to be appropriate for general inpatient hospice and was made comfort care. Her requirement for morphine and Ativan did slowly rise. Eventually, the patient did succumb to her respiratory failure. Time of death was called at 10:00 p.m. on February 15, 2021 á Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia á Disposition: Deceased

this event.

WHITE BLOOD CELL COUNT INCREASED

COVID19 (COVID19 (PFIZER-BIONTECH))

(1200)

[COVID-19 mRNA vaccine (Pfizer-BioNtech] treatment under Emergency Use Authorization (EUA)

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Moderna Vaccine Lot 029K20A Patient received second dose of vaccine on 2/2/21. Within 30 minutes patient had a near syncopal episode. She felt lightheaded and shortly after had episode of nonbloody vomiting. Hypotensive 81/69 and started on levophed. Alert and orientated. Lungs clear, abdomen benign on admission. Patient had no reaction when received first dose of the vaccine. Patient developed worsening shortness of breath, tachypnea, Afib with RVR, hypotension and required intubation and multiple pressors.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT NORMAL

COVID19 (COVID19 (MODERNA)) (1201)

Patient awoke on 2/12/21 with altered mental status, confusion, respiratory distress, was taken to hospital by ambulance. Per ED notes from ED attending Pt presented with hypotension and respiratory distress. DNR status, patient given comfort measures and passed away in ED at 11:24 am on 2/12/21.

No prior vaccinations for this event.

WHITE BLOOD CELL COUNT NORMAL

COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)

Pt had witnessed arrest by wife. Pt wife started CPR and called EMS. CPR started at 15:12. Continued by EMS. Pt arrived to medical center asystole with CRP in progress and ventilated via igel device. He was in refractory ventricular fibrillation and continued CPR for a total of 1 hour. At that point, we checked a bedside ultrasound which showed his heart at a standstill. He was unresponsive to verbal and tactile

No prior vaccinations for this event.

stimulus and had fixed unreactive pupils. He was pronounced at 16:13.

WHITE BLOOD CELL COUNT NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Narrative: Patient seen in ED 1-17-21 with c/c of ""bloated with epigastric pain"". Patient with complicated medical history including stage 1B pancreatic cancer (was currently on chemotherapy mFOLFIRINOX), and a leadless permanent pacemaker implantation on 1-11-21 for long episodes of SR with complete heart block following symptoms of syncope (other cardiac history: CAD s/p CABG 2009, PAF, and HTN). Regarding ER visit for epigastric pain, nothing notable was found on workup and patient was to discharge home to rest. There were available doses of COVID-19 Vaccine following a vaccine clinic that same day, and patient was offered and agreed to a dose of vaccine. Patient was monitored for 15 minutes post vaccine with no notable issues. The following day, Monday 1-18-21, patient's caregiver called facility at 22:30 to report he had a fever of 102.8 degrees and that he had been ""feeling kind of bad all day"". Patient was advise to seek urgent medical care and reported back to ED on 1-19-21 at 00:55. Patient wasd admitted for SIRS (tachycardia and febrile) -- patient also reported diffuse myalgia. WBC WNL, CXR unremarkable for infection, UA neg for bacteria, LFTs WNL, blood cultures negative. Procalcitonin elevated at 17.8 -- suggesting inflammatory response. Patient initially reported feeling better on the morning of 1-19-21, but around 13:00 began rapidly declining (confusion, unable to walk) and started experiencing EKG changes (9 beats of SVT). Patient then coded and resuscitation was attempted for approximately 30 minutes. Patient did not survive the code. Coroner has been notified and family is considering autopsy at time of this report."		No prior vaccinations for this event.

WHITE BLOOD CELL COUNT NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

Symptoms of fever (Tmax 102.9), diarrhea, and altered mental status started ~ 24 hours after vaccination. No evidence of septicemia with negative blood cultures Minimal improvement over 3 days, transferred to tertiary care center for MRI brain after which LP was recommended. However family declined as intubation would have been required and was not consistent with patient's goals of care.	No prior vaccinations for this event.	
WHITE BLOOD CELL COUNT NORMAL		**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.	
WHITE BLOOD CELL COUNT NORMAL		**COVID19 (COVID19**

	(PFIZER-BIONTECH)) (1200)
1/18/2021- Tested positive for Covid-19. 1/20 Patient lethargic, unable to swallow. 1/24 Although 90% O2 sat on RA, it has decreased from her baseline ranging at high 90's. 1/27/2021 Patient passed.	No prior vaccinations for this event.
WHITE BLOOD CELL COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
1/14/2021-0545, blood noted left and right ear. 0715, vomited x 1. Covid Antigen positive. Acute MD visit-basilar crackles right and coughing. Increased confusion.	No prior vaccinations for this event.
WHITE BLOOD CELL COUNT NORMAL	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without	No prior vaccinations for this event.

a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5. Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

WHITE BLOOD CELL DISORDER

COVID19 (COVID19 (MODERNA)) (1201)

"Resident complained of feeling ""hot"" at supper time. Had emesis an hour or so later. Became hypoxic

No prior vaccinations for

and was transferred to the hospital emergency room. Her evaluation in the ED revealed continued presence of UTI, leukocytosis (19.8), and renal insufficiency (BUN 22 Cr. 1.3) BP 99/63; P 74; Temp 98.1; RR 16; and O2 sat of 95% with 2 LPNC (she is typically on RA). CXR reported changes most consistent with CHF with cardiomegaly and bilateral pulmonary vascular prominence. Bibasilar pleural effusions greater on the right than left with pulmonary edema. Large hiatal hernia and likely old chronic wedge defromities involving the mid thoracic vertebral body. She was admitted for IV antibiotics. She expired 2/6/2021"	this event.
WHITE BLOOD CELLS URINE POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
Patient is a 90-year-old female. She is a nursing home resident with and ongoing COVID 19 outbreak occurring . She has been diagnosed with corona virus on 1/4/21. She apparently has not eaten or drank anything in about a week. She was being hydrated at the nursing home with normal saline, but has failed to improve. She was sent to the ER and was admitted on 1/8/21 to hospital At no time during the hospital stay has she been more than minimal responsive. She need O2 for Comfort but on CXR and CT cardiopulmonary imagining was clear. Discharge note stated that he was requiring supplemental oxygen, but her chest x-ray on admission actually showed no acute cardiopulmonary disease. She was diagnosed with COVID-19 on 1/4/21. Most likely, this disease set her level of function back to the point that she was no longer eating and drinking, and she just overall rapidly declined after that. There was no evidence of an actual COVID pneumonia or pneumonitis. On 1/12/2021 family made patient a DNR and IVF were stopped and switched to comforted care. Patient expired 1/13/21	No prior vaccinations for this event.
WHITE BLOOD CELLS URINE POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**

"In discussion with Dr., medical director at Detox, she arrived night of 2/3/21 was quite intoxicated so was not going through any withdrawal. She was getting vitals and CIW checked regularly. First dose of chlordiazepoxide 25mg was 2/4 at 1:25pm for CIWA 9. She had repeat vitals at 5:50pm, CIWA 1, vitals: P 67, 118/79, 94% on RA, T 98.3. she had complained of some ""pressure in her head"" and feeling anxious, but otherwise denied other complaints. she was talking with others in the group, then other patients report she suddenly started having seizure like activity around 6:45pm, med techs came to help and found her stiff, gurgling. they tried to get vitals on her, called 911, noticed that at 6:54pm she had lost a pulse and they started CPR. paramedics arrived at 7:08pm and she was brought to ED. Pt BIBA in cardiac arrest. Pt was at Detox Center when she was reported to have seizure-like activity followed by collapse. She was found to be pulseless and CPR initiated by staff members. EMS arrived and performed approx 15 min of CPR and gave pt epi x 3 and bicarb. No shocks administered but they did not report a rhythm. In the emergency room the patient arrived and was found to be pulseless with PEA arrest, CPR was initiated, patient was intubated. ROSC ultimately achieved, patient remained very acidotic despite ventilator adjustment, head CT revealed cerebral edema. Pt also found to be profoundly anemic with a hemoglobin of 5 and platelets of 37, she was thought to be GI bleeding so medications for this were initiated. Patient then became more hypoxemic with bradycardia, consultation with neurosurgery and critical care medicine at tertiary care center deemed ongoing CPR futile. Patient arrested at 2:30AM on 2/5, pronounced dead at 2:48AM."	No prior vaccinations for this event.
WHITE BLOOD CELLS URINE POSITIVE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
2/2/2021- seen in Ed with c/o intermittent fever following 2nd dose. Redness to bilateral upper extremities, c/o some pain with urination, weak. V/S stable, afebrile in ED. Assess for infection. No significant abnormal labs (see below), hydrated and discharged. 2/4/2021- arrived in ED with c/o vomiting, seen earlier by PCP that day labs drawn. Shortly after arriving in the ED copious amouts of emesis noted, the patient went into full cardiac arrest and CPR was started. -Please see HPI above, in addition after intubation the patient coded again. More epinephrine and lidocaine were given. CPR was resumed. We did obtain ROSC and targeted temperature	No prior vaccinations for this event.

management was pursued. He is placed on a lidocaine drip and a right femoral central line was placed by myself. At this time, norepinephrine drip was initiated given his continued hypotension. Post intubation chest x-ray suggests possible abdominal pathology and once the patient was stabilized further, he was sent to the CT scanner where CT head without IV contrast and CT chest, abdomen and pelvis with IV contrast was obtained. He did lose pulses once in the radiology suite. This was brief. IV fluids were initiated and he received over 2 L of crystalloid therapy. He continued to be hypotensive in the emergency department and vasopressin was added. He also had a single dose of Neo-Synephrine and IV push fashion to help bring his blood pressure up. CT scan reveals probable bilateral aspiration pneumonia/pneumonitis and dilated loops of small bowel without a transition point and pneumatosis involving loops in the left upper quadrant. I did try to initiate consult with critical care and possible transfer, however he continued to be unstable and coded requiring CPR multiple times. He was given IV bicarbonate given his prolonged CPR state and pH. Ultimately, the family decided to make the patient comfort measures only given his critical illness. Shortly after making this decision he did pass away in the emergency department. RADIOLOGY DIAGNOSTIC - CHEST PORTABLE 02/04 2051 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2059 IMPRESSION: 1. Findings highly suspicious for portal venous gas which can be seen in the setting of bowel ischemia. Consider CT for further evaluation and/or surgical consultation. 2. Endotracheal tube 3.7 cm above the carina. 3. Low lung volumes with mild patchy perihilar opacities. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 8:55 PM Impression By: MD CT SCAN - CT HEAD WO 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2200 IMPRESSION: Negative for acute intracranial process. No evidence of mass effect, acute hemorrhage or definite acute cortical infarct. Final Report Signed by: M.D., Sign Date/Time: 02/04/2021 9:57 PM Impression By: - MD CT SCAN - CT CHEST/ABD/PELVIS W 02/04 2140 *** Report Impression - Status: SIGNED Entered: 02/04/2021 2214 IMPRESSION: 1. Ill-defined patchy opacities within the bilateral upper lobes, right middle lobe, in consolidative opacities within bilateral lower lobes which could represent aspiration, and/or multifocal pneumonia. 2. Small right trace left pleural effusions. 3. Diffusely dilated small bowel without a transition point and mucosal hyperenhancement involving the colon with areas of pneumatosis involving loops of small bowel within the left upper quadrant and portal venous air consistent with hypoperfusion complex. There is a small caliber appearance of the aorta and a flattened appearance of the IVC is well. 4. Intravascular air within the IVC and bilateral iliac veins could be secondary to right femoral central lying injection. 5.

Somewhat abnormal enhancement pattern of the kidneys with hypoenhancement of the medullary pyramids which may suggest hypoperfusion injury as well. 6. Probable nondisplaced rib fractures on the right at ribs 2 through

WITHDRAWAL OF LIFE SUPPORT	**COVID19 (COVID19 (MODERNA)) (1201)**
We don't know what happened. 25 hours after the shot, he started gagging and stopped breathing. He was pronounced at OSF at 8:07pm after we took him off life support.	No prior vaccinations for this event.
WITHDRAWAL OF LIFE SUPPORT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
The patient had an apparent cardiac arrest on 12/23/20 and was admitted to the ICU. He was taken off of life support on 12/30/20. He had known cardiac disease.	No prior vaccinations for this event.
WITHDRAWAL OF LIFE SUPPORT	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
"Staff member checked on her at 3am and patient stated that she felt like she couldn't breathe. 911 was called and taken to the hospital. While in the ambulance, patient coded. Patient was given CPR and ""brought back"". Once at the hospital, patient was placed on a ventilator and efforts were made to contact the guardian for end of life decisions. Two EEGs were given to determine that patient had no brain activity. Guardian, made the decision to end all life saving measures. Patient was taken off the ventilator on 1/9/2021 and passed away at 1:30am on 1/10/2021. The initial indication from the ICU doctor was the patient had a mucus plug that she couldn't clear."	No prior vaccinations for this event.
WOUND	**COVID19 (COVID19 (PFIZER-BIONTECH))**

	(1200)
Patient tested positive for COVID-19 on 1/8/21. She demonstrated a decline in appetite and the ability to feed herself d/t this illness, but no respiratory or other symptoms. She received COVID-19 vaccine #2 on 1/26/21. She demonstrated an SDTI wound to the Lt. heel on 1/27/21. On 1/31/21 she was noted to have a significant weight loss. She was admitted to services on 2/1/21 with comfort care orders. On 2/2/21 she was observed to be without vital signs. Orders were for DNR, and CPR was not initiated in accordance with that order. She was pronounced dead at 0112 on 2/1/21.	No prior vaccinations for this event.
WOUND CLOSURE	**COVID19 (COVID19 (PFIZER-BIONTECH)) (1200)**
All residents had been in isolation due to multiple cases of COVID in the facility. Resident voiced no health related complaints. He continued to visit with staff and required moderate assist with toileting. Resident had fall 0130 on 1-15-2021, which resulted in laceration with surgical repair. Resident was noted to change in mental status and respirations on morning of 1-16-2021 during morning blood sugar check. Resident had O2 @1.5l/m via n/c and respirations of 10 with periods of apnea and unresponsive to verbal stimuli. Blood sugar was 583. Resident deceased upon re-check after calling PCP to report status change.	No prior vaccinations for this event.
WOUND SECRETION	**COVID19 (COVID19 (MODERNA)) (1201)**
I video chatted with her Thursday after receiving the vaccine. My mom was in poor health but she was talking in complete sentences and responded appropriately. She was upright in bed and made eye contact. She smiled and denied pain. By Sunday, she was extremely weak and unable to sip water with a straw. Her health had changed dramatically and rapidly. She moaned in pain and was very fatigued. Her condition continued to deteriorate over the week and she stopped talking and was constantly sleeping. They started antibiotics for the oozing cancer lesion and then morphine for pain and end of life care. She passed away on January 22nd	No prior vaccinations for this event.

which was 15 days post vaccination.

	X-RAY ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
At approximately, 1855, I was alerted by caregiver, resident was not responding. Per caregiver, she was doing her rounds and found resident in bed, unresponsive, mouth open, observed gurgling noises and tongue hanging out of mouth. This primary caregiver observed resident at baseline and ambulating after dinner at approximately, 1800 less than an hour prior to incident. This PCG called 911 for EMS and gave report of incident. Resident was taken to Medical Center Emergency Department. At ER, CT scan and X-ray was performed. Per report from ER RN, CT scan and x-ray revealed an intracranial aneurysm and fluid in the lungs. Per RN, resident was still unresponsive and was admitted to Medical Center for observation and comfort measures. This primary caregiver reported to RN, resident recently received the first dose of COVID-19 vaccine on 1/2/21. Primary caregiver received a call from Castle RN at 0700, resident expired at 0615.		No prior vaccinations for this event.

	X-RAY ABNORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Per family, patient has been feeling sick since he was vaccinated, patient went to ER on 02/15/2021, and after few hours at ER patient passed away.		No prior vaccinations for this event.

	X-RAY NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Resident yelling for assistance in apartment. Nursing personnel found resident on floor at 6:10 AM on 2/18/2021. Resident was transported to Hospital on 2/18/2021. Status update on 2/18/2021 from son, resident CT & X-rays were done all normal. Labs done and WBC count was elevated and awaiting results. Resident stable and admitted to hospital for observation. Resident passed away on 2.21.2021.		No prior vaccinations for this event.

X-RAY OF PELVIS AND HIP	**COVID19 (COVID19 (MODERNA)) (1201)**
VACCINATION WAS RECEVIED THE MORNING OF 1/5/2021- IN THE EVENING OF THAT DAY RESIDENT SUSTAINED A FALL AND WAS TRASNPORTED TO FACILITY FOR TREATMENT. IT IS NOT UNUSUAL THAT RESIDENT WAS SELF TRANSFERRING AND HAS A HISTORY OF FALLS.	No prior vaccinations for this event.
X-RAY OF PELVIS AND HIP NORMAL	**COVID19 (COVID19 (MODERNA)) (1201)**
Patient recieved vaccine 1 of covid 19 i 1/19/2021. She felt poorly on 1/20/2021. She felt dizzy and fell at 3 AM on 1/23/2021. She felt poorly and did not know her son's name which was not normal. She went to ER on 1/24. She was assessed as not having fractures. She was going to be transferred to a skilled nursing facility. She was not having respiratory complaints. She was awaiting transfer when her O2 levels started dropping substantially. She declined aggressive intervention and she died within a few hours.	No prior vaccinations for this event.
X-RAY WITH CONTRAST	**COVID19 (COVID19 (MODERNA)) (1201)**
Death	No prior vaccinations for this event.

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

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Notes:

VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Caveats:

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more then 1

Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information.

Data contains VAERS reports processed as of 3/5/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information.

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation for more information.

Query Date: Mar 13, 2021 10:13:18 AM

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Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 3/5/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Mar 13, 2021 10:13:18 AM

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Query Criteria:

Date Died:	Nov., 1999 to Mar., 2021
Date of Onset:	Nov., 1999 to Mar., 2021
Date Report Completed:	Nov., 1999 to Mar., 2021

Date Report Received:	Nov., 1999 to Mar., 2021
Date Vaccinated:	Nov., 1999 to Mar., 2021
State / Territory:	The United States/Territories/Unknown
Vaccine Products:	COVID19 VACCINE (COVID19)
VAERS ID:	All
Group By:	Symptoms; Vaccine; VAERS ID
Show Totals:	False
Show Zero Values:	Disabled

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