COVID Vaccine VAERS Reports for Sepsis - May 7th, 2021

Notes	Vaccine Type	Vaccine Manufacturer	VAERS ID	Age	Onset Interval	Adverse Event Description
	COVID19 VACCINE	JANSSEN	1094062-1	18-29 years	0 days	Janssen COVID-19 Vaccine EUA G1P0 at 33w5d by LMP, presented to L&D the evening of 3/10/2021 after experiencing fevers, chills, diaphoresis, and muscle aches beginning approximately 8 hours after vaccination. She has chronic headaches which is also present on presentation. She denies any cough, sputum production, nausea, vomiting, diarrhea, dysuria, hematuria, flank pain, abdominal pain, vaginal bleeding, rash or skin changes, no leg swelling or pain. On presentation she was noted to have a fever of almost 103F, was tachycardiac to 160s, BPs 90s/50s, and had fetal tachycardia in the 170s. Her exam was non focal with no evidence of infection. Sepsis workup was initiated which was negative. COVID-19 test was negative Discharged home in stable condition
	COVID19 VACCINE	JANSSEN	1142078-1	65+ years	15-30 days	Patient was a high functioning 97-year-old female with a history of CLL diagnosed 1 year ago on no treatment prior to arrival, chronic stable thrombocytopenia, chronic kidney disease, past history of breast cancer and bladder cancer in remission, transfusion dependent anemia of chronic disease, covid 19 vaccination on 3/5/2021, who presented to the emergency room on 3/25/2021 unresponsive found by the family and emergency services was called. The paramedics found her temperature to be 101.6 and her room air sat was 87%. In the ER CT of the head revealed acute subarachnoid hemorrhage. There was no trauma. CT the abdomen and pelvis showed lymphadenopathy and splenomegaly consistent with her known CLL and new bilateral lung infiltrates. Patient's white blood cell count was 124,000 consistent with her known CLL. Patient prior was high functioning and still drove herself to her doctor's appointments. The day prior she told her son she was feeling slightly nauseous and ill and went to bed early. She was admitted with a subarachnoid hemorrhage which was felt to be spontaneous and not traumatic. She was not on any anticoagulation prior to arrival. She was also admitted with severe sepsis felt possibly due to aspiration pneumonia or pneumonia in general and she did have fever and bilateral infiltrates on imaging. covid 19 and influenza neg. The decision was made to place her on comfort care after discussion with family. She ultimately expired on 3/28 At 14:48 PM in the presence of her family
	COVID19 VACCINE	JANSSEN	1144220-1	65+ years	15-30 days	Bacteremia - strep epidermidis, developed respiratory distress required intubation for hypercapnic respiratory failure. Developed PEA on 3/28 died.
	COVID19 VACCINE	JANSSEN	1147888-1	65+ years	1 day	No appetite for days. The smell of food made patient sick. On week two after vaccine, oxygen stayed at 84%, patient couldn?t stand as he had no energy. Patient began to eat after lots of convincing and seemed to be doing at least 20% by week 3, but oxygen was still in mid 80%. On day 20 after vaccine patient had to be rushed to the ER due to sepsis. All vital organs began to fail and on transport patient suffered a mild heart attack. Patient was a healthy 78 year old male that lived alone and drove and had no major health issues before the date of the vaccine.
	COVID19 VACCINE	JANSSEN	1177103-1	40-49 years	1 day	Transferred from Hospital on 4/1/21 for fever and altered mental status, suspecting adverse reaction from Janssen COVID vaccine given 3/30/21, symptom onset 3/31/21 morning. Sepsis with unknown source of infection: This is evidenced by leukopenia, tachycardia and fever. Acute metabolic encephalopathy, likely secondary to possible sepsis versus effects of COVID vaccine. Encephalitis and meningitis ruled out. Acute nontraumatic rhabdomyolysis: evidenced by elevated CK levels 1700 on admission, likely secondary to sepsis. Acute renal failure, hypothyroidism, transaminitis, elevated troponin likely associated with rhabdo. On sepsis protocol (vancomycin, meropenem and acyclovir) Disc
	COVID19 VACCINE	JANSSEN	1193000-1	40-49 years	1 day	High heart rate, low blood pressure, high fever, nausea, fatigue, weakness, headache

COVID19 VACCINE	JANSSEN	1198107-1	Unknown	Over 120 days	53 y.o. female with a PMhx of asthma, CHF, CKD (not on HD), DM, HTN, hypothyroidism, methadone dependence for back pain, chronic bilateral foot ulcers presents with c/o one day of fever and admitted for sepsis of unknown origin on 3/9. Patient tested negative for SARSCOV2 on admission on 3/9. She was deemed a candidate for the vaccine and it was administered on 3/10 (Janssen Lot 1805031). On 3/19, she tested positive for SARSCOV2. She developed worsening respiratory failure and required oxygen supplementation with gradual escalation until she was intubated on 3/29. She received 5 days of remdesivir and steroid therapy. She developed DIC for which she received supportive care (vitamin K, transfusions, etc) and an HLH-type picture for which the steroids treatment was prolonged. She was not a candidate for tocilizumab given the elevated LFTs > 5x the upper limit of normal. During the ICU course patient was started on hemodialysis. Patient gradually started improving around 4/5 with planning for spontaneous breathing trials in attempts to extubate after weaning of sedatives. On 4/8, during a dialysis session patient became hypotensive and bradycardic. After this episode, patient's mental status worsened and developed worsening metabolic acidosis and worsening shock refractory to vasopressors. Family decided for DNR and transition to comfort care. Patient expired on 4/12.
COVID19 VACCINE	JANSSEN	1205267-1	65+ years	15-30 days	bilateral ovarian vein thrombus, thrombocytopenia - Fever, sepsis, altered mental status, nausea, vomiting
COVID19 VACCINE	JANSSEN	1207090-1	65+ years	9 days	Patient presented to clinic 9 days after vaccination in acute distress, shivering, tachypneic and having difficulty with speech. Heart rate at 130 beats per minute, Spo2 91% on room air, temp 99.9f oral. Initial difficulty obtaining blood pressure due to shaking. Patient was treated with 500mL NS and 2L O2 via nasal cannula, which immediately improved symptoms. Due to elevated glucose and minimal austere conditions, patient was evacuated from camp to hospital. There, patient diagnosed with COVID-19 infection, bilateral basilar and right apical pneumonia, diabetes and sepsis.
COVID19 VACCINE	JANSSEN	1212596-1	65+ years	1 day	Patient woke up at 3am not feeling good and confused. Became increasingly confused and uncomfortable. Not very responsive to caregivers. Called an ambulance at 7:30am. ER ran tests that showed Sepsis with n o underlying infection. Patient had to be intubated. Admitted to ICU in hospital. Spent 3 days there and 4 days in regular room at hospital. Then transferred to a rehabilitation clinic where she is currently.
COVID19 VACCINE	JANSSEN	1228230-1	50-59 years	15-30 days	Patient with extensive PMH- rectal adenocarcinoma with colostomy, sacral ulcers, cardiomyopathy, from Nursing Home. Sent from nursing home due to persistent hypotension for 2 days which did not respond to IV fluids, sepsis since patient was tachycardic and hypotensive. Urinalysis positive, sepsis possibly due to urinary tract infection, patient also with bacteremia- gram-negative. Patient still hospitalized on antibiotics.
COVID19 VACCINE	JANSSEN	1239214-1	65+ years	7 days	Left upper extremity DVT in brachial vein. Left upper extremity SVT in basilic vein. Started on xarelto, plan for 3 month course. Sepsis - no source
COVID19 VACCINE	JANSSEN	1242936-1	50-59 years	0 days	Patient presented on 4/21 with 2 weeks of generalized fatigue, abdominal pain, and weight loss with multiple lab derangements concerning for acute liver failure. Patient on 4/22 is tachycardic and change in mental status. Acute liver failure likely due alcoholic hepatitis. Cholestatic etiologies will be considered. Acetaminophen toxicity treated with acetylcysteine. Started on methylprednisolone 32 mg daily. RUQ: biliary sludge within gallbladder. No sonographic evidence of acute cholecystitis. Acute respiratory failure secondary to COVID pneumonia. Chest pain and elevated troponins. Alcohol withdrawal on treatment protocol. Sepsis and Community acquired pneumonia. Thrombocytopenia and elevated INR. Macrocytic anemia and AKI.
COVID19 VACCINE	JANSSEN	1243175-1	60-64 years	0 days	Had Janssen vaccine on 4/9 and within a day developed subjective fevers and dyspnea which progressed until admitted to Hospital on 4/11 and promptly intubated for respiratory distress. Found to be in sepsis and ARDS with multiple negative COVID tests including an extensive respiratory viral panel, we have failed to culture any bacteria from multiple sputum cultures, Legionella antigen and HIV negative. Have been treating as ARDS 2/2 atypical pneumonia, possible aspiration (although no aspiration event reported) with hospital course complicated by VAP. Concern remains for possible reaction to Janssen vaccine. Still admitted to ICU at Hospital.

COVID19 VACCINE	JANSSEN	1248595-1	40-49 years	10-14 days	Patient had severe lower quadrant abdominal pain and fever to 38.2 C at home. Fever starting on 4/20, abdominal pain starting on 4/21. Presented to ED and was found to have bilateral ovarian vein thromboses. Was found to be septic with WBC 23.1, blood culture growing GPC in pairs and chains (anaerobic bottle) and GPC in chains (aerobic bottle). Further speciation pending.
COVID19 VACCINE	JANSSEN	1274411-1	40-49 years	0 days	Started with a fever, on day 3 fever was higher and I was short of breath as well as wheezing. On Thursday the 15th I went to the dr. The x-ray didn't show anything however my cbc was of concern and she also did a d timer. It came back elevated, so she sent me over for a CAT scan with contrast. It showed pneumonia in my upper and lower right lung and also my lower left lung. She sent me home to try and treat it there. Over the weekend I felt worse and my husband took me to the ER. Upon arrival my blood pressure was 160 over 120 and heart rate was 140. They admitted me to the hospital for treatment of sepsis and pneumonia and pain management. I was there for 4 days. I was released on the 22nd of April and I am still feeling all of these effects on my body. Headache that I have not been able to get rid of even with the help of prescription medication.
COVID19 VACCINE	JANSSEN	1276491-1	Unknown	Unknown	UNUSUAL SOUNDS FROM LEFT LUNG BOTTOM; IRRITATED LUNGS AND BLEEDING; SEPSIS; COUGHING UP BLOOD AND PHLEGM; FEVER; DRY COUGHING; This spontaneous report received from a patient concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1805029, and expiry: 25-MAY-2021) dose was not reported, administered on 27-MAR-2021 for prophylactic vaccination. No concomitant medications were reported. On 27-MAR-2021 Patient temperature was 102.5-103 under arm, 103.5-104 orally. The temperature stayed that way for four days. Four days later Patient started dry coughing. Patient went to the clinic, patient's doctor listened to patient lungs, and did an x-ray. Patient's doctor said the x-ray is clear, however, patient's doctor hears an unusual sound from the bottom of patient left lung. Patient's doctor said she has been practicing for 15 years, and there are usual sounds that she is used to hear when listening to people's lungs. However, she said this was not one of them. She gave patient flonase, mucinex, tylenol, and sent patient home to rest. Patient also started on Augmentin antibiotics at the same time (which patient took for 7 days) just in case patient might have an infection. Few days later, Patient started to cough up some blood along with minimal phlegm, and visited the Clinic for the second time. Patient's doctor thought perhaps patient having a rare side effect of the vaccine which irritated patient lungs and causes bleeding. She advised patient to go to Hospital Emergency Room (ER) immediately if patient cough up any more blood. Patient's doctor said patient would need a computerized tomography (CT) Scan. The night of 08-APR-2021, patient got much worse, patient was coughing constantly, and mostly coughing up blood. The early morning of 09-APR-2021, patient was at Hospital ER. Patient's doctor said Patient White blood cell (WBC) is 27000, which is almost 3 times the max value, and patient platelets were close to double the max value. Patient's doctor said patient is at risk for sepsis, and had to be admitted immediately. Patient was at Hospital from 09-APR-2021 to 13-APR-2021. Patient was tested for Covid, Influenza A, B, Methicillin-resistant Staphylococcus aureus (MRSA), etc. All came negative. Patient was given azithromycin, rocephin, and at the time patient recently completed a full dose of Augmentin. Patient body did not respond much to all the antibiotics, patient White blood cell (WBC) came down 20000, and the afterward went back up to 25400. Then, the patient's doctor thought patient might have Tuberculosis. 4 tubes of blood were withdrawn and sent to Indianapolis to be incubated for Gold interferon TB test, Patient was also given a purified protein derivative (PPD) test, and patient bloody sputum was sent to Indianapolis for Acid-Fast Bacillus (AFB) Smear and Nucleic Acid test. In the meantime, patient continued to cough up blood at Reid for 3 nights. Patient was then given antibiotics; Vancomycin, Cefepime, Levaquin, and some of patient values partially came back to normal, and patient was released on 13-APR-2021. As of last week, Infectious Disease specialist, patient's doctor told patient all of Tuberculosis (TB) results came negative, hence, they ruled out Tuberculosis (TB). Patient had a swab and a Polymerase chain reaction (PCR) test that day. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was recovering from irritated lungs and bleeding, and had not recovered from fever, dry coughing, unusual sounds from left lung bottom, coughing up

COVID19 VACCINE	JANSSEN	1286545-1	65+ years	15-30 days	Pt received vaccine in her home state, unable to get details of vaccine administration such as date, site, lot #, etc. Per ED MD note : 81-year-old female with reported history of atrial fibrillation found down at hotel room. Patient states she has been on the ground in the room for 3 days, she was found covered in feces. Alert and oriented x4 however intermittently appears confused and has varying history. She does not know how she got on the ground, however denies fall or syncope. No significant current complaints. Slightly tachycardic and febrile, slightly hypertensive, exam without any significant acute findings, no obvious skin source of ulcer or infection, no focal neurological deficits, no pain. Initiated aggressive fluid hydration and sepsis work-up. EKG appears normal with no signs of ischemia or arrhythmia. Labs show slightly elevated troponin, low magnesium, metabolic/lactic acidosis. VBG relatively normal. Urine negative for infection chest x-ray without evidence of pneumonia, no clinical signs or symptoms to identify source of infection. Nothing to suggest meningitis at this time. CT head is negative. Unclear source of fever however empirically treated with antibiotics and fluids. Patient remains hemodynamically stable with no hypotension. She did arrive slightly hypoxic and with increased respiratory rate however clear lung sounds and no indications of heart failure, COPD/asthma. CT chest without evidence of pulmonary embolism, focal pneumonia, or fluid overload. Respiratory status possibly related to compensation for metabolic acidosis that is likely due to lack of fluid intake due to being on the ground. CK is normal and kidney function is normal. Consulted medicine for admission for further evaluation and treatment. Cardiology was also consulted for NSTEMI, agrees with current plan. per H&P 4/28/21: Altered mental status (R41.82): Etiology is not clear. Patient states she had J&J Covid vaccine about 3 weeks ago. Need to rule out cerebral venous sinus thrombosis. Get a CT scan of the brain with contrast. If negative will get CT venogram or MRV and MRI of the head. Neuro checks. Request PT OT and speech therapy evaluation. Check urine drug screen. Check blood alcohol level. Non-STEMI (non-ST elevated myocardial infarction) (I21.4): Start argatroban drip until cerebral vein sinus thrombosis is excluded then we can switch to heparin drip. Start aspirin and statin. Check fasting lipid panel. Monitor on telemetry. Trend troponin. Request echocardiogram. Cardiology to consult. Dr. was consulted from the ER. + Beta-Blocker Ordered: Beta-Blocker Ordered + Aspirin Ordered: Aspirin Ordered + Statin Ordered: Statin Ordered Fall (W19.XXXA): Plan as documented above. Rhabdomyolysis (M62.82): Hydrate and recheck CPK. Elevated liver enzymes (R74.8): Check hepatitis panel. Monitor levels. Fever (R50.9): No clear source of infection. Follow up on blood cultures. CT chest negative for infectious process. Check CT of the abdomen and pelvis.Start empiric antibiotics: Vancomycin and Zosyn. Hypomagnesemia (E83.42): Administer magnesium sulfate. Repeat level in the morning. Diabetes (E11.9): Start sliding scale insulin. Monitor fingersticks. Hypoglycemic protocol. Check hemoglobin A1c. Hypertension (I10): Fortunately patient is hemodynamically stable. We will cautiously start metoprolol. Adjust antihypertensives to optimal blood pressure control. Acidosis, lactic (E87.2): Likely due to profound volume depletion. Rule out sepsis. Hydrate and trend level. VTE: Argatroban. + VTE Prophylaxis Assessment: Risk Level documented as Low Risk Discharge Planning: + Discharge Planning: + Discharge To, Anticipated: Home independently Per Intensivist note 4/30/21: .
COVID19 VACCINE	JANSSEN	1288955-1	50-59 years	10-14 days	Exactly 11 days after receiving the J&J vaccine my husband developed leg pain in his right lower inner leg, he was taken to the hospital on 04/20/2021 which a ultrasound was completed but resulted no blood clots, no other labs or treatment was performed that day, the next day he developed severe diarrhea and flu like symptoms with continued leg pain and difficulty breathing, He was then rushed to the hospital by ambulance where he was suffering from very low BP 41/31 was the lowest, a line was placed and he was put on pressors to increase his BP. He was transferred to the hospital where he was diagnosed with a flesh eating bacteria in the right leg where the pain was at and Sepsis. He was taken to surgery to debride the right leg and was started on CVVHD because his new kidney was now failing, he eventually was started back on Hemodialysis and taken to surgery 2 more times where he cardiac arrested on the table in surgery and died. A private autopsy is being performed but the preliminary results shows he had multi-system organ failure, including his liver which was NEVER a problem in the past.
COVID19 VACCINE	MODERNA	0918839-1	30-39 years	8 days	Gallbladder removed, septic, 11mm axillary lymph node.

COVID19 VACCINE	MODERNA	0937579-1	60-64 years	0 days	On 12/31/2020, at approximately 00:15, pt developed a fever of 102.9 F and tachycardia with rate of 120. He was treated with acetaminophen. Later in the morning, he complained of nausea, generalized muscle aches, intermittent increase in confusion. At approximately 14:00, he had a fall out of bed and at that time noted to be short of breath, tachypneic. He was taken via ambulance to Emergency Department. From there he was transferred to Hospital for admission with acute respiratory distress, suspected sepsis with lactic acid 7.4 and Bilateral Pulmonary Emboli. He was started on heparin and broad spectrum antibiotics and transitioned to ELIQUIS on 1/3/2021. Infectious etiology of sepsis was unclear. He continued broad spectrum antibiotics with clinical improvement. Abdominal CT scan was obtained due to intermittent nausea, vomiting, abdominal pain, loose stools. His heart rhythm flipped to Atrial Fibrillation with RVR on 1/2 and his rate improved with titration of metoprolol. He was also treated with prednisone for suspected underlying undiagnosed COPD. It is noted in his hospital summary that PEs presumed provoked in the setting of his recent COVID 19 infection. He was discharged from the hospital on 1/8/2021 and readmitted to the Veterans Home. He has been stable.
COVID19 VACCINE	MODERNA	0937774-1	30-39 years	5 days	Fever/Cough/Body Aches. Covid +, Pneumonia and Sepsis
COVID19 VACCINE	MODERNA	0941500-1	65+ years	0 days	Vomiting the night of the vaccine. Low oxygen and high fever next morning. Has been on palliative care Was hospitalized, but section 21 will not let me fill the info. Hospital Admitting Dx: Sepsis, likely biliary cause; Acute on chronic encephalopathy likely sepsis related Returned 1/12 on hospice
COVID19 VACCINE	MODERNA	0941811-1	50-59 years	7 days	Resident began having fever on 1/11/21 @0600. VS= T-102 B/P- 100/57 P- 112 RR- 24 O2 Sat 92% on RA. MD called. Rapid COVID Test was negative. CBC,CMP, U/A were ordered as well as CXR. Resident's condition declined. At 3:00pm resident started having respiratory distress and hypoxia O2 Sat 89%. Supplemental O2/mask @ 5LPM. Neb TX, EKG, and Rocephin 1 GM ordered. Condition worsened. Resident sent to nearest ER for evaluation. Later in the evening the staff AT Medical Center called to inform staff that resident had expired @ 2230 as a result of Respiratory Failure and Sepsis.
COVID19 VACCINE	MODERNA	0942886-1	65+ years	0 days	Admission Note: ? Weakness - Generalized Patient reports feeling weak prior to dialysis, but demanded clinic to perform dialysis. Had full tx done and brought to ER. Reports still feels weak after dialysis. 84 year old male comes in today after completing dialysis for evaluation of generalized weakness x 5 days. He has also lost his voice. He tells me he received his COVID vaccine yesterday, but he is concerned he may have COVID. He denies any fevers, cough, sore throat, NVD, abd pain. Transfer Note: HOSPITAL COURSE: Patient is a 84 y.o. male who presented with shaking chills and was found to have Gram-negative rods in the blood. The source of infection was unclear. Initially it was thought that it could possibly be cholecystitis but imaging was negative for that. There was concern that it could be UTI but the patient is on dialysis and is an uric and therefore no urinalysis could be got. Early this morning when I saw the patient the patient did have significant pain and tenderness in the right knee and is not able to put weight on that. I.e. Consulted Dr. Today with per lumbar from Orthopedics who said that it would be in the best interest of the patient for him to be transferred to hospital where he could decide on aspiration and or washout of the right knee. Transfer center has been called and we are trying to finalize a transfer of the patient hospital at this point of time Please see problem list listed below. REASON FOR ADMISSION/ ADMISSION DIAGNOSES Sepsis cause unclear
COVID19 VACCINE	MODERNA	0952328-1	40-49 years	1 day	Patient received Moderna Covid vaccine on Friday evening 1/8/21. She awoke Saturday am around 2AM with a severe headache. She also developed a fever during the day. She did not seek treatment until Sunday and went to Hospital ED. She was treated and released same day. She went back to hospital on Monday as she felt worse and she was admitted at that time and treated for a bloodstream infection and meningitis. We are not sure it was caused by the vaccine. She consulted her PCP and her PCP feels it may be more coincidental given her medical HX.
COVID19 VACCINE	MODERNA	0955055-1	65+ years	3 days	Pt received dose #1 Moderna COVID Vaccine 1/12/21 Clinic. 1/15/21 presented to ED for left upper arm redness/swelling, fever, body aches, new cough, decreased appetite, and fatigue . Had been treating w/OTC Tylenol. Developed sepsis, leukocytosis from LUE cellulitis, currently admitted to hospital for treatment. Entered by PSS for tracking.
COVID19 VACCINE	MODERNA	0968341-1	65+ years	1 day	24 hours after presentation patient had developed high fevers 104. He presented to the emergency department with symptoms of severe sepsis and respiratory distress. He was intubated, suffered cardiac arrest with return of spontaneous circulation, requiring vasopressors.

COVID19 VACCINE	MODERNA	0971609-1	65+ years	7 days	71 yo M admitted for sepsis from perforated gangrenous cholecystitis c/b E coli bacteremia, s/p lap chole 1/14 then found to have post-op collections now s/p drain placement of medial collection and aspiration of lateral collection. CT evaluation for pulmonary emboli on 1/22/21 discovered, ""Bilateral upper lobe segmental/subsegmental pulmonary emboli. No evidence of pulmonary infarct or right heart strain.""""
COVID19 VACCINE	MODERNA	0974040-1	65+ years	0 days	high fever, severe pain, dizziness, vomitting, internal bleeding, stroke, sepsis
COVID19 VACCINE	MODERNA	0974095-1	65+ years	15-30 days	Inpatient admission for the treatment of sepsis (peptostreptococcus suspected) source of the infection unknown.
COVID19 VACCINE	MODERNA	0975228-1	40-49 years	1 day	The patient did not have any adverse reactions during the 15 minute observation, nor any reported the day of the vaccine. Between his COVID diagnosis and the second vaccine, he had serval documented complaints of nausea, dizziness, body aches. The patient had a virtual visit on 1/21/2021 for dizziness, nausea and fever. At this time, these symptoms had been persistent for one month according to his medical records. Patient later presented to the Urgent Care for with a fever of 103.1, rigors, nausea and cough. Patient admitted to hospital for sepsis.
COVID19 VACCINE	MODERNA	0975997-1	65+ years	2 days	On 1/20/21 the staff observed resident to be more restless constantly moving his legs. He had a decrease in his appetite and fluid intake and required assistance for consumption. His oxygen sats dropped to 89% on room air and was given oxygen at 2L. On 1/21/2021 the Resident observed moving restlessly, opened his eyes when this writer called his name, murmuring incoherent words, words were unclear, was observed taking off his Foley, attempting to grab something, dropped his hands and legs and at the same time restless. This writer was unable to auscultate lungs or heart, resident was moving uncontrollable. Resident positioned safely in bed. VS revealed high BP 147/101. MD ordered transfer to hospital. Resident was treated in the hospital for acute encephalopathy, sepsis with tachycardia and tachypenia and hypoxia.
COVID19 VACCINE	MODERNA	0981928-1	50-59 years	1 day	Sepsis, Acute Pancreatitis, Respiratory Failure on Mechanical Ventilation, Disseminated Intravascular Coagulation, Pneumonia, Acute Kidney Injury. Refractory Hypoglycemia
COVID19 VACCINE	MODERNA	0983040-1	50-59 years	0 days	Developed immediate fever & cills within 2 hours. By next morning had pain & difficulty producing urine. Saw primary care doctor and urgent care center, infection not treated w/PO Macrobid after 2 days. Admitted to Hospital w/sepsis, kidney infection and acute renal injury?creatinine 4.25 (baseline=1.5)
COVID19 VACCINE	MODERNA	0983428-1	65+ years	10-14 days	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.
COVID19 VACCINE	MODERNA	0991465-1	65+ years	Unknown	Patient previously was diagnosed with COVID-19 and recovered in 12/20. Patient received MODERNA COVID-19 vaccine 72 hours PTA. Patient developed soreness and achiness and fevers 48 hours PTA. This was followed by progressive redness of the skin on left upper arm at vaccine injection site. Patient was then admitted with left upper arm cellulitis with sepsis criteria.
COVID19 VACCINE	MODERNA	0991681-1	65+ years	2 days	Patient experienced labored breathing, rails bilaterally, and a temp of 99.2. Labwork showed a critical sodium level of 163. She was started on D5/NS 2 liters and then sent to the hospital when her fever spiked to 101.3. She was also very lethargic. She was diagnosed with pneumonia / sepsis
COVID19 VACCINE	MODERNA	0991997-1	65+ years	2 days	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.

COVID19 VACCINE	MODERNA	0992774-1	65+ years	1 day	On 1/20/2021 the resident experienced hypotension while at dialysis and was not able to complete treatment prior to being transferred to the hospital. He also had congestion in lungs. The hospital notes indicate upon admission to the hospital he was being treated for # Shock - distributive - cover for sepsis, check u/s RLE, possible SIRS response after second COVID vaccine. MAP >55 and # ESRD. While in the hospital resident was treated for hypotension, right lower leg cellulitis and the rate of pacemaker was increased.
COVID19 VACCINE	MODERNA	0995485-1	60-64 years	8 days	Covid positive 1/29/21. 2/1/21, hypoxia, tachycardia. Admitted to hospital 2/1/21. Diagnoses: UTI, Covid-19 infection, hypoxia, sepsis.
COVID19 VACCINE	MODERNA	1002824-1	65+ years	1 day	Resident received 2nd Covid 19 vaccine from Moderna on 1/26 in Rt deltoid. Immediately felt a little lightheaded during the 15 min window afterward but was able to ambulate independently with walker just afterward. After taking a nap, she woke with a headache, chills, a little shaky and feeling very tired. She was able to eat and take Tylenol at the time. For the rest of the day, she felt under the weather. The next morning she was very weak, unable to ambulate and tachycardic prompting nursing staff to send her to the hospital for assessment.
COVID19 VACCINE	MODERNA	1014590-1	65+ years	1 day	Patient is a 66 y/o male with a PMH of adenocarcinoma of the colon s/p sigmoidectomy and colostomy, currently receiving chemotherapy, CKD3, single R. kidney, R. Hydronephrosis, pulmonary hypertension, presented to the ED from clinic due to weakness x 2weeks. Pt reports feeling weak and dizzy when he stands up, which improves with laying down. Denies any head trauma. Pt reports his BP usually ranges from 120-140 in clinic, but it has been consistently less than 120 for the past couple of weeks. Associated with brown colored urine, sometimes with a small amount of blood when initiating urination, general malaise, nausea, and vomiting a small amount of clear fluid every 2-3 days. Pt does endorse decreased PO intake for the past few months since starting this cycle of chemotherapy but is still able to keep food/water down. Pt denies recent changes in colostomy output, last changed yesterday. Denies fever/chils, urinary frequency/urgency, hematemesis. Assessment/Plan: * Sepsis - WBC 1.54, Hypotensive on admit - Likely 2/2 UTI - 1L IVFs in ED - Lactic Acid: wnl - BNP: wnl - CXR: Calcified granuloma left upper to midlung zone. Small nodular opacities questioned right upper lung zone and right midlung zone. Left subclavian Port-A-Cath again noted. - UA: 1.010, 2+ blood, 3+ leuks, 66 RBCs, >100 WBCs, many WBC clumps, 4 Hyaline casts - No urinary complaints on admit - Received an additional 30cc/kg of fluids - Day 3 of Neupogen - BCx pending - Continue broad spectrum abx (Vanc/ Zosyn), will de-escalate pending cx - Urine gram stain pending Anemia - H/H baseline 11-12 - H/H slowly dropping, today 8.8/26.5 - Denies any hematemesis, no bloody output in colostomy - s/p sigmoidectomy - Not symptomatic - Will continue to monitor - Transfuse if hemoglobin <7 or becomes symptomatic Hypotension due to hypovolemia See Sepsis Acute kidney injury superimposed on CKD - Patient presented with Serum Cr 3.5, with a baseline Serum Cr of 2.7 - Resolved. Serum Cr 2.2 today - Most likely due to sepsis - Gabapentin held at admit due to AKI superimposed on CKD3 1. Challenge with gentle IVF's 2. Maintain UOP at 0.5ml/kg/hr 3. Hold nephrotoxic medications 4. Renally dose current meds if applicable 5. Bladder scan if suspicion of retention, followed by retroperitoneal US to evaluate for hydronephrosis hydronephrosis. Foley if retention. 6. Avoid hypotension 7. Stricts I/O's 8. Monitor renal function closely Neutropenia - WBC on admit: 1.54 - Last chemotherapy 1/25 - ANC 494 today, down from 774 yesterday - Day 3 of Neupogen - See Sepsis NSTEMI (non-ST elevated myocardial infarction) - Troponin mildly elevated on admit: 0.052, repeat plateau will not trend - EKG on admit: NSR, no ST changes or evidence of ischemia present - Likely 2/2 sepsis, low concern for ACS - No CP on admit - Will hold off on initiating ACS protocol - Cardiac monitor Adenocarcinoma of colon metastatic to liver - History of Stage IIC (pT4bN0Mx) poorly differentiated adenocarcinoma of the colon in 2016 with recurrent disease in 2018 and 2020, now p T4b N2 Mx- - Followed by CMC Oncology - Last Oncology appt 1/26/2021: Received Irinotecan but leucovorin of Folfiri held - Will continue to monitor Neuropathy VTE Risk Mitigation (From admission, onward) Ordered heparin (porcine) injection 5,000 Units Every 8 hours 02/04/21 2026 IP VTE HIGH RISK PATIENT Once 02/04/21 2026 Place sequential compression device Until discontinued 02/04/21 2026 pt admitted for inpatient stay from ED on 2/4/2021 and discharged to home on 2/8/2021

COVID19 VACCINE	MODERNA	1016605-1	Unknown	Unknown	Sepsis; A spontaneous report was received from a consumer post , concerning an approximately 55-year-old, male physician who received Moderna's COVID-19 vaccine (mRNA-1273) and developed sepsis, resulting in death. There was no medical history provided. There were no concomitant medications provided. On an unknown date (Thursday), the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. According to the post, two days after vaccine administration, the patient died of sepsis on Saturday. Action taken with mRNA-1273 in response to the event was not applicable. The event, sepsis, was considered fatal. The patient's date of death was not provided. The cause of death was reported as sepsis.; Reporter's Comments: This case concerns a 55-year-old, male subject, who experienced a serious unexpected event of Sepsis. Sepsis occurred after first dose of mRNA-1273 vaccine administration. On an unknown date, two days after vaccine administration, the patient died of sepsis. Treatment for the event was not provided. The patient's medical history was not provided. The patient is a physician. Concomitant product use was not reported. Very limited information regarding this event has been provided at this time and no definite diagnosis or autopsy report have been provided. Based on the current available information and temporal association between the use of the product and the start date of the event of Sepsis, a causal relationship cannot be excluded.; Reported Cause(s) of Death: Sepsis
COVID19 VACCINE	MODERNA	1017937-1	65+ years	8 days	Fever, confusion, sepsis, hospitalized
COVID19 VACCINE	MODERNA	1024882-1	65+ years	1 day	02/03/2021 The next day after the Covid 19 (Moderna) injection my dad felt chills thru out his body around 7:00 pm he took a Tylenol we assumed it was just a side effect from vaccine. At on or around 8:45 PM my dad called my sister that he was having trouble breathing and felt very short of breath. My sister was there in about 7min by the time she got to him my dad was gasping for air he would lift his head up trying to breath. They got him to the hospital shorty after about a 7 min drive. My dad was taken into hospital we were not able to go in due to restrictions.
COVID19 VACCINE	MODERNA	1035997-1	50-59 years	15-30 days	Patient presented to hospital with altered mental status after being found on floor by family. last known normal was day before at 0900. Combative and non-verbal upon arrival to ED. Taken directly to CT. Daughter at bedside in ED, answering all questions on behalf of patient. Reports patient received second dose of COVID vaccine approx 2 weeks prior and had complained of persistent fatigue for 2 weeks since vaccination. Patient combative and uncooperative. Refused to follow instruction, only laying on left side. Febrile upon arrival to ED. Lips dry and cracked, emesis dried to nose. Pupils equal bil and reactive. Patient unable to keep airway secured, ultimately intubated and lumbar puncture done. Many critical lab values including lactic acid, troponin, sodium, glucose, potassium, bilirubin, pH, and WBC. CSF positive for streptococcus pneumoniae. Blood cultures positive for same pathogen. Transferred to a higher level of care.
COVID19 VACCINE	MODERNA	1038595-1	65+ years	1 day	fever 101.2 at 2pm took 2 tylenol and it broke Went to the urgent care Feb 8, on 14th ER treated her as a sepsis pt. and did a whole check up and was negative (WBC and platelets returned back normal) WBC on the 8th was 2.4 now WBC 02/14 5.82 platelets 1750, now 26200 02/14 Recommended: please see a doctor just to confirm otherwise I would still recommend you get the second dose of the vaccine benefits outweight the risk
COVID19 VACCINE	MODERNA	1041595-1	65+ years	15-30 days	Received 2nd dose of Moderna on 1/26/21 and was admitted to the hospital (IVCH) for septic right knee on 2/17/2021
COVID19 VACCINE	MODERNA	1046215-1	60-64 years	5 days	Fever and diaphoresis 2/12/21, followed by neck pain starting 2/13/21. Hospital admission with sepsis with right-sided cervical lymphadenitis without abscess 2/17/21. Treated with Unasyn.
COVID19 VACCINE	MODERNA	1046641-1	65+ years	6 days	Patient hospitalized for sepsis due to UTI. Patient was treated with antibiotics and discharged
COVID19 VACCINE	MODERNA	1050368-1	65+ years	15-30 days	Patient presented with three weeks of progressive back pain and bilateral lower extremity radiculopathy, associated with night sweats (no fevers, no leukocytosis), found to have extensive T9-S1 spinal epidural abscess due to MSSA. Symptoms started at around the time the patient received her first COVID-19 vaccination on 1/26/2021. No other obvious source of infection (she does have an ear wound but this did not appear infected). She was admitted to the Hospital on 2/17/2021. Adverse event reported on 2/23/2021. She remains hospitalized as of this report.
COVID19 VACCINE	MODERNA	1054403-1	Unknown	Unknown	Fever 102.8, chills, uncontrollably shaking, loss of appetite, nausea, vomiting, loss of bladder and bowel I.V. fluid given at hospital

COVID19 VACCINE	MODERNA	1056453-1	Unknown	15-30 days	sepsis regarding to a cancer; A spontaneous report was received from a consumer concerning an unknown aged female patient. Medical history included unspecified cancer No relevant concomitant medication was reported. On 11Jan2021, the patient received the first of their first planned doses of mRNA-1273 (lot number unknown) for prophylaxis of COVID-19 infection. On 10 Feb2021, the patient was hospitalized due to sepsis regarding a cancer. No treatment was reported. Action taken with the mRNA-1273 was not reported. The outcome of the event, sepsis, was unknown.; Reporter's Comments: Very limited information regarding this event has been provided at this time. However, patient's medical history of unspecified cancer is a confounding factor that may play a possible contributory role. Further information has been requested.
COVID19 VACCINE	MODERNA	1058594-1	65+ years	4 days	Total Kidney failure, Sepsis
COVID19 VACCINE	MODERNA	1066942-1	50-59 years	7 days	2/22/21 positive for covid and flu b 2/23/21 requested bamlanivimab infusion d/t not eating and weakness 2/24/21 emergency room after infusion: HPI 59 y.o. male who presents with left-sided posterolateral chest pain. Pain has been present 4-5 days time. It is worsened by deep inspiration or coughing. The patient has also had nausea and vomiting. Fever has been as high as 101.6¶. He was tested and found to be positive for both influenza and COVID-19. He denies anterior or central chest pain dyspnea or orthopnea palpitations sputum production. 3/1/21 emergency room for worsening condition: 59 y.o. male presented to the emergency room with a several day history of intractable nausea vomiting and severe weakness. The patient does have a known history of recent coronavirus (COVID-19) infection. He was diagnosed on February 22nd and did receive Bamlanivimab. He started feeling a little bit better after this, but a few days ago started having increasing weakness and nausea/vomiting. He called me this morning and stated he had been unable will keep anything down for several days and was extremely weak and I asked that he go to the emergency room. In the emergency room is lactic acid was found to be elevated. His CT scan of his chest with contrast showed severe coronavirus (COVID-19) pneumonia. This was run after he was found to have an elevated D-dimer. He was found to be extremely weak and deconditioned. His oxygen saturations at times or found to be in the low 90s. Because of all of this he will be admitted and treated for sepsis from coronavirus (COVID-19).. 3/2/21 currently remains hospitalized
COVID19 VACCINE	MODERNA	1067937-1	Unknown	Unknown	Sepsis; A spontaneous report was received from a consumer of unknown age and gender, who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sepsis. The patient's medical history was not provided. Concomitant product use was not provided by the reporter. On an unknown date, the patient received a dose (first or second dose not specified) of mRNA-1273 (Batch number not provided) for prophylaxis of COVID-19 infection. On an unknown date, the patient was reportedly rushed to the hospital for sepsis (details not provided). Treatment information was not provided. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the event, sepsis was not reported.; Reporter's Comments: Very limited information regarding the events has been provided at this time and is insufficient for causality assessment.
COVID19 VACCINE	MODERNA	1069052-1	65+ years	1 day	sepsis; UTI; shingles; severe headaches; A spontaneous report was received from a 90-year old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced UTI, sepsis, shingles, and headaches. The patient's medical history was not provided. No relevant concomitant medications were reported. On 04 Feb 2021, the patient received their second of two planned doses of mRNA-1273 (Batch number not provided) for prophylaxis of COVID-19 infection. On 05 Feb 2021, the patient began experiencing severe headaches. On 11 Feb 2021, the patient developed a severe urinary tract infection and had to be hospitalized. The patient broke out with shingles and now has sepsis. The patient is reported as being conscious, but not responding. No treatment information was provided. The patient received both scheduled doses of mRNA-1273; therefore, action taken with the drug in response to the event is not applicable. The outcomes of the events, UTI, sepsis, shingles, and headaches, were not provided.; Reporter's Comments: 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.

COVID19 VACCINE	MODERNA	1071136-1	Unknown	7 days	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
COVID19 VACCINE	MODERNA	1073225-1	65+ years	15-30 days	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.
COVID19 VACCINE	MODERNA	1074833-1	65+ years	8 days	Office visit - NP Chief Complaint: seen today, 3/4/2021, complaining of or following up for Fever (started today), Nausea (has nausea today), Abdominal Pain (c\o upper and lower abd pain has been constant for the last 3 days started on monday), Diarrhea (states she had diarrhea all day yesterday but has had no bm today), and Fatigue (pt states she is feeling very week today) . HPI Patient comes in to the office complaining of severe abdominal pain. States the pain started on Monday and was less severe, stating the pain has escalated to a 9/10 today and ""unbearable."" Pt. States she had diarrhea for a 24 hour period yesterday, but denies any bowel movement today. Patient also complains of severe fatigue and states nausea with emesis a ""few times over the last 4 days."" Patient states that on Tuesday her pain became ""a little better,"" but states since that time it has worsened and is severe at approximately 1230 this morning."" Patient states she did not go to the ER because she ""knew she had an appointment today."" BP 134/84 Pulse 104 Temp 101.6 ¶F (38.7 ¶C) Resp 20 SpO2 94% Abdominal: General: There is distension. Palpations: Abdomen is rigid. Tenderness: There is generalized abdominal tenderness. There is guarding and rebound. Comments: Tinkling bowel sounds noted to RLQ and RUQ with hypoactive bowel sounds to LUQ and LLQ. Abdomen is rigid and guarding and rebound pain are noted with examination. triaged to Emergency room: HPI 75 y.o. female who presents with complaints of right upper quadrant pain since Monday reports is moderate to severe sharp better right upper quadrant without radiation better with rest and worse with movement FINAL IMPRESSION ICD-10-CM ICD-9-CM 1. Calculus of gallbladder and bile duct with acute cholecystitis without obstruction K80.62 574.60 2. Sepsis, due to unspecified organism, unspecified whether acute organ dysfunction present (HCC) A41.9 038.9 995.91 Final Disposition Transfer to Another Facility current inpatient at Hospital""

COVID19 VACCINE	MODERNA	1074926-1	Unknown	Unknown	sepsis; surgery to put stent in; Blood pressure dropped to 70/20; kidney stone; A spontaneous report was received from a consumer who is an 80-years-old, female patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and who experienced sepsis, kidney stone, stent replacement and ended up in ICU and blood pressure dropped to 70/20. The patient's medical history included 6 months of chemo and cataracts surgery in both eyes (not specified). The concomitant product was not provided . On an unknown date prior to the onset of the symptoms, the patient received their first of two planned doses of mRNA-1273 (Batch number: Unknown) in the right arm and patients second dose was scheduled on 25-Feb-2021 for prophylaxis of COVID-19 infection. On an unknown date, after vaccination patient experienced sepsis, put the stent in and ended up in ICU and blood pressure dropped to 70/20/ blood pressure low (18-Jan-2021) and kidney stone. The patient was hospitalized for sepsis, stent replacement and ended up in ICU and blood pressure dropped to 70/20/ blood pressure low. On 04-Mar-2021, she was going to have surgery to have kidney stone which was 9cm long removed and to have stent replaced. Treatment information was not provided. Action taken with respect to mRNA-1273 in response to the events. The outcome of the events was not reported for all events.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested. However, the events of kidney stone and stent replacement are unlikely because the kidney stone was preexisting and the procedure of stent replacement was planned for a later date.
COVID19 VACCINE	MODERNA	1082086-1	65+ years	15-30 days	Patient was vaccinated at pharmacy on 2/9/2021, first dose of Moderna COVID-19 vaccine. Per medical records from hospital: patient developed fever, diarrhea, nausea and abdominal pain on 2/25/2021 and presented to the hospital E.R. on 3/1/2021. Patient was diagnosed with Sepsis and Pneumonia. Cardiac arrest on 3/6/21, renal failure, seizures. Patient tested negative for COVID-19 on 3/1/2021 and 3/8/2021. Patient has declined, was placed intubated and placed on a ventilator. Patient admitted to hospice services on 3/8/2021 and plan is for compassionate removal of life support at hospice. Prognosis is poor.
COVID19 VACCINE	MODERNA	1084793-1	60-64 years	1 day	Hypotension in the 70s/40s despite IV fluid replenishment. Per our MD DC/transfer note: PEG displacement, ongoing sepsis, hypoglycemia. Assess for other reason for hypotension including sepsis, cardiogenic shock, acute abdominal processes. patient was transferred to the Hospital ER where she expired
COVID19 VACCINE	MODERNA	1087764-1	65+ years	0 days	Two hours after receiving the vaccine on 3/4/21, he started feeling very tired and had a 100.2 temp. By evening he was feeling very cold and not eating much. On 3/5/21 he was sleeping alot, had headache, chills and fever, no appetite, diaphoretic. At 8pm he could not get up out of his chair and was disoriented. Wife call an ambulance. He was admitted for altered mental status. Blood cultures showed streptococcus pneumoniae. He was hypoxic at 89%. BP 171/96, pulse 85, temp 37.3C. Chest xray showed bilteral infiltrates and a masslike density in the right lung apex. Encephalopathy, pneumonia and sepsis diagnosed. Ct of head normal.WBC count 19 and amonia 24. Wife told me he had a spinal tap on 3/9/21 and that it showed bacterial meningitis. I do not have the lab reports on that yet. THe infection control doctor told wife he is critical.
COVID19 VACCINE	MODERNA	1093838-1	30-39 years	0 days	7pm fever 103.4¶ chills, tremors, vomiting. Fever remained for 2 days, low back and abdominal pain became increasingly worse. Finally went to ER 2/26 was septic hospitalized for 13 days
COVID19 VACCINE	MODERNA	1094975-1	65+ years	3 days	Patient received covid vaccine at local health department clinic on 02/25/2021 and presented to this reporters facility ED on 03/01/2021. Patient with multiple comorbidities and newly diagnosed COPD presented after SOB not relieved by new rescue inhaler. Admitted to hospital with pneumonia/sepsis. Treated, improved and discharged to home
COVID19 VACCINE	MODERNA	1098473-1	65+ years	5 days	My mother had the shot on January 25. On the 30th, she became confused and was having trouble swallowing. I took her to the hospital on the 31st (Sunday). She was admitted with pancreatitis and was unable to drink water. She was then admitted to the ICU. She became septic and her mental status declined. By Tuesday, she was placed on a ventilator. She then had renal failure and died on February 18th.

COVID19 VACCINE	MODERNA	1100257-1	65+ years	15-30 days	23 days after receiving the vaccine was hospitalized because of an urosepsis; A spontaneous report was received from a other healthcare professional concerning a 70-year-old male patient experienced urosepsis 23 days after receiving the vaccine. The patient's medical history was not provided. No relevant concomitant medications were reported. The patient received the first of the two planned doses of mRNA-1273 on 01-FEB-2021 in unknown arm (Batch: 004M20A) intramuscularly for prophylaxis of COVID-19 infection. On 03-MAR-2021, 23 days after receiving the vaccine was hospitalized because of an urosepsis. No treatment information was provided. Action taken with mRNA-1273 in response to the event was unknown. The outcome of the event was unknown. The assessment was not provided for the event.; Reporter's Comments: The event was consistent with increased risk of complications associated with elderly age of patient. Company assessed the event to be unlikely related to company product.
COVID19 VACCINE	MODERNA	1100262-1	Unknown	Unknown	Kidney stone; patient was also treated for sepsisduring her admission; This spontaneous report from was received from a consumer concerning a 79-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and was found to have a kidney stone and was treated for sepsis. The patient was diagnosed with urinary tract infection (UTI) before receiving the first dose of the vaccine. Products known to have been used by patient, within two weeks prior to the event, included antibiotics. On 08-Feb-2021 the patient received her first dose of mRNA-1273 (Lot number: 011M20A) intramuscularly in her left arm for prophylaxis of COVID-19 infection. The patient continued having the UTI after receiving the first dose and was started on antibiotics. The patient was found to have a kidney stone and was admitted to the hospital for kidney stone removal surgery on 24-Feb- 2021. Patient was also treated for sepsis during her admission at the hospital. Patient was scheduled for second dose on 08-Mar-2021 and would like to know if it was okay for her to receive the second dose. Action taken with mRNA-1273 in response to the event was not reported. The outcome of the events kidney stones and sepsis were considered unknown.; Reporter's Comments: 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. Further information has been requested.
COVID19 VACCINE	MODERNA	1100719-1	60-64 years	0 days	Chills started within five minutes then within an hour fever of 104. Patient taken by ambulance to Hospital and patient diagnosed with sepsis and cellulitis and shortness of breath

COVID19 VACCINE	MODERNA	1102518-1	50-59 years	8 days	Per MD Clinical Note 3/14/21, ""Further discussion with his daughter today-patient has not been able to walk and has had unclear mentation for approximately 8 years after an alcohol related decline. Was in a nursing home until he moved into his parent's house. His mother actually passed away and December and his stepfather has been trying to take care of him since. Patient may periodically stand but is a house where he is pretty much confined to his bedroom and bathroom. Patient received his COVID-19 vaccine at the prescription shop 03/04/2021 and since then he has had a steady decline starting with aches and pains to increased weakness and confusion and then collapse which brought him to the emergency room. Assessment and plan Syncope with altered mental status/toxic metabolic encephalopathy Acute on chronic respiratory failure with hypercapnia Sepsis Supratherapeutic Coumadin level INR greater than 9 Anemia Small hemoperitoneum Hypotension Chronic pain syndrome COPD UTI Enteritis Subsegmental atelectatic changes with nodule left lower lobe the-recheck 3 months Cirrhosis Nicotine dependence CHF-chronic diastolic Functional quadriplegia One week post COVID-19 vaccination Agitation Other: GI bleed, PAD, hypothyroidism, history of DVT left leg, neuropathy, depression, BPH, CAD, subdural hematoma, acquired thyroid disease, GERD, Wernicke -continue to trend the LFTs downward. Is on Precedex currently to allow him to further recover. He was using accessory muscles and poor inspiratory effort today but maintaining his oxygenation. BiPAP was reinstituted to avoid CO2 retention. One possibility is that the patient consumed a significant amount of Tylenol due to the discomfort exacerbated with the cirrhosis. LFTs are trending upward still. -hypercapnia patient consume both the benzodiazepine and morphine supported initially for the 1st 36 hours with BiPAP. Has had periods where he is off and answers appropriately. -consider rescanning in a.m. To further evaluate the hemoperitoneum. Continue broad-spectrum antibiotics and hemoglobins. Patient is NPO until further delineation Patient is a functional quadriplegic year and at home is fairly dependent on his stepfather for a total care family seeking long-term care which may mentally benefit the patient with broadening his activities -blood cultures pending. "" Per Clinical note 3/13/21, ""Assessment and plan Syncope with altered mental status/toxic metabolic encephalopathy Acute on chronic respiratory failure with hypercapnia Sepsis Supratherapeutic Coumadin level INR greater than 9 Anemia Small hemoperitoneum Hypotension Chronic pain syndrome COPD UTI Enteritis Subsegmental atelectatic changes with nodule left lower lobe the-recheck 3 months Cirrhosis Nicotine dependence CHF-chronic diastolic Functional quadriplegia Other: GI bleed, PAD, hypothyroidism, history of DVT left leg, neuropathy, depression, BPH, CAD, subdural hematoma, acquired thyroid disease, GERD -patient is more awake and wakening a hourly on BiPAP will remove 1 fully alert and functioning will use BiPAP overnight. Nicoderm avoid tobacco. NPO unless ammonia level is elevated. Continue empiric antibiotics. Last evening required to units packed RBC. If hypotensive and or increase in anemia will rescanned. Monitor for DTs and withdraws. Was advised by the nursing staff patient is following orders. Functional quadriplegic rotation every 2 hours had bed at 20-30 degrees to avoid aspiration. Patient and his family confirm DNR status. Long-term placement required as his stepfather is unable to care for him without assistance. Anticipate restarting diet

COVID19 VACCINE	MODERNA	1105820-1	65+ years	2 days	Patient seen and evaluated by PA-C. with myself. We agreed on the clinical findings and implemented our plan together. Please see PA's note for details. All relevant procedures supervised. Patient arrived to the emergency department due to respiratory symptoms, hypoxic, reported that Wednesday he received his 2nd dose of COVID vaccine. His initial workup was concern for NSTEMI with elevated troponin and peaked T-waves, his chest x-ray concerning for COVID/pneumonia. Patient initially tolerated oxygen by nasal cannula and sepsis protocol was started including IV fluid resuscitation that was done cautiously due to the concern of COVID with respiratory failure. The biotics were given. PA-C readdressed code status with patient who confirmed that his DNR DNI, she so contacted his daughter. Patient had multiorgan failure including acute kidney injury, and pneumonia with respiratory failure +/- respiratory failure. Due to the concern of NSTEMI patient was initially going to be transfer to was hospital and transfer was started. Patient respiratory status started deteriorating and his blood pressure dropped slightly but improved after 500 cubic centimeters of IV fluid and he was also placed on a NIPPV. Around 6:00 p.m. patient has significantly desaturation and he discontinued himself NIPPV. Due to inability to intubate patient, he was ventilated with BVM, patient is slowly improved saturation levels and was opening his eyes, he was placed on a non-rebreather. At this point there is high concern of ARDS and due to inability to intubate or give for the respiratory support His daughter was at bedside and updated of current medical status and poor prognosis. Patient continued deteriorating and at this point he had agonal breathing. His daughter was at bedside and she was made aware of the futile prognosis of patient due to his respiratory failure. Patient rapidly became bradycardic and went into cardiac arrest. No CPR was done due to the DNI DNR status of the patient. Critical Care Procedure Note Authorized and Performed by: MD Total critical care time: Approximately 30 minutes Due to a high probability of clinically significant, life threatening deterioration, the patient required my highest level of preparedness to intervene emergently and I personally spent this critical care time directly and personally managing the patient. This critical care time included obtaining a history; examining the patient; pulse oximetry; ordering and review of studies; arranging urgent treatment with development of a management plan; evaluation of patient's response to treatment; frequent reassessment; and, discussions with other providers. This critical care time was performed to assess and manage the high probability of imminent, life-threatening deterioration that could result in multi-organ failure. It was exclusive of separately billable procedures and treating other patients and teaching time. Please see MDM section and the rest of the note for further information on patient assessment and treatment. PE: VITAL SIGNS: BP: 126/75 Pulse: (!) 122 Resp: (!) 40 SpO2: (!) 82 % Temp: 98.1 ¶F (36.7 ¶C) Height: 5' 8"" (172.7 cm) Weight: 152 lb (68.9 kg) General: Alert, nontoxic, in no acute distress. Lungs: Clear to auscultation bilaterally. CLINICAL IMPRESSION: 1. Sepsis with acute hypoxic respiratory failure and septic shock, due to unspecified organism (HCC) 2. Suspected COVID-19 virus infection 3. NSTEMI (non-ST elevated myocardial infarction) (HCC) 4. Multifocal pneumonia 5. ARDS (adult respiratory distress syndrome) (HCC) 6. Acute kidney injury (HCC) Further care and disposition otherwise as outlined by PA. ED on 2/14/2021 Revision & Routing History Detailed

COVID19 VACCINE	MODERNA	1107196-1	65+ years	Unknown	Urinary tract infection that was septic; Renal failure; Positive for covid; Confused; Losing her balance; Had no control of her bladder and urinated on the bed; Wasn't feeling well; Tired and didn't want to get up; A spontaneous report was received from a consumer concerning a 77-year-old female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced vaccination related malaise, urinary incontinence, fatigue, confusion, loss of balance, renal failure, severe urinary tract infection that was septic, and Covid 19. The patient's medical history, as provided by the reporter, stated she was sneezing and coughing few days before receiving her first dose vaccine. Concomitant medications reported included iron, metolazone, nicardipine, simvastatin, torsemide, levothyroxine, glimepiride, apixaban, potassium chloride, acetyl salicylic acid, and donepezil 5mg. On 22 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: 032L20A) for prophylaxis of COVID-19 infection. The route of administration was not provided. On an unspecified date in Jan 2021 after receiving the first dose vaccine, the patient experienced not feeling well, urinary incontinence, tiredness, and didn't want to get up. On 25 Jan 2021, the patient was losing her balance and confused. She was hospitalized and diagnosed with renal failure, as well as, severe urinary tract infection that was septic. On an unknown date post hospitalization, the patient tested positive for Covid-19. Treatment drug administered included Tylenol, Azithromycin, Promethazine, 325mg aspirin, and Vitamin D. Action taken with mRNA-1273 in response to the events was not reported. The outcome of events, like not feeling well, urinary incontinence, tiredness, confusion, loss of balance, renal failure, severe urinary tract infection that was septic, and Covid-19 positive test were considered unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded except for the event of COVID-19. The event of COVID-19 is unlikely related to mRNA-1273 since the vaccine does not contain virus capable of causing infection.; Sender's Comments: US-MODERNATX, INC.-MOD-2021-033912:
COVID19 VACCINE	MODERNA	1122391-1	65+ years	2 days	Pt. presented to ER on 3/19/2021. Family reports that pt. received her Covid vaccination on 3/17/2021. Since then her stomach started hurting and pt. is lethargic. Pt. did not open eyes when asked questions and was quite pale. Son reports increased confusion last day or two. Pt. reports that she started feeling ill immediately after receiving the injection. Complains of generalized weakness and fatigue. Denies dizziness or lightheaded. C/o abd. pain. Denies nausea, vomiting, but admits to diarrhea. Denies fevers, cough congestion. She is alert to place and name, but unsure of date at time seen in ER. When seen in ER she was afebrile, but hypoxic and hypotensive. Initial saturations were in mid 80's, but dropped to low 60's. With a non-rebreather mask she maintained at 90%. BP 60's systolic but with fluids increased to 90's . No rectal bleed or hematemeis. Diagnosis of septic shock, anemia, elevated LFT's, pneumonia, and UTI.
COVID19 VACCINE	MODERNA	1124017-1	65+ years	15-30 days	Shortness of breath fever sepsis abdominal mass
COVID19 VACCINE	MODERNA	1125632-1	65+ years	15-30 days	shortness of breath Elevated troponin Acute respiratory failure with hypoxia Acute hypoxemic respiratory failure due to COVID-19 Pneumonia due to COVID-19 virus sepsis
COVID19 VACCINE	MODERNA	1126015-1	40-49 years	4 days	Unknown adverse event from vaccination. 3/14/21 Informed by caregiver that client was sent by ambulance to ER and diagnosed with bilat pneumonia. She developed difficulty breathing on 3/13/21. She was seen at Walk In on 3/12/21 for toenail eviscerated and INR, and had been giving tylenol for pain control for toe. 3/15/21 Informed by caregiver client was in ICU, septic, bilat pneumonia, and low oxygen levels. 3/16/21 Informed by caregiver client not doing well authorized indwelling cath due to low blood pressure and ventilator. Client transfered by med flight to ICU. 3/17/21 Informed by caregiver client death last night.
COVID19 VACCINE	MODERNA	1126687-1	65+ years	2 days	L shoulder abscess/septic joint. Underwent debridement. Started antibiotics, plan for 4-6 weeks
COVID19 VACCINE	MODERNA	1127847-1	65+ years	1 day	Participant felt flushed, feverish, fatigued with general aches and dry cough over the weekend after receiving injection, took acetaminophen and cough syrup on Monday. He became short of breath on 1/20/2021 and was hypoxic on oximeter check, was sent to the ER. He was intubated in ER and went into respiratory failure with sepsis due to COVID19. He was treated with tocilzumab, became paralyzed and DVT in left lower extremity was found. HE required pressors and diuresis, he developed AKI and hyperkalemia. On 2/21 he was in multi-organ failure. His level of cognition decreased until he was no longer responsive and he died on 2/24/2021.

COVID19 VACCINE	MODERNA	1127860-1	65+ years	2 days	Not sure if covid vaccine caused this, but this is what happened - Received covid vaccine. two days later had violent shakes in the night. Immediately went to get a covid test out of precaution. Tested negative for covid, but positive for ""flu b"". Went home to treat flu with fluids and rest. Got no better. Went to heart doctor out of precaution, full work up...everything checked out great. Went home, got no better. Went to primary care physician, full work up...found a ""spot"" on left lung. Was given antibiotics and steroids, go home and in a few days will be getting better. 3 days later became incapacitated and had to be rushed to ER. Was admitted into hospital for 6 days to treat ""pneumonia"". Also possible UTI and sepsis. Also while in hospital found out that a mini stroke had happened. Treatment went well, oxygen levels were good. Was released with glowing reports. 24 hours later at home had to be rushed to ER again after becoming incapacitated.. Was admitted again 7 more days. During this time everything took a nose dive in succession. Lungs were failing, multiple unexplained strokes were happening (while on blood thinners, had been on blood thinner 15 years...after first stroke they changed to another blood thinner...only more strokes). After so many strokes and compounding of strokes, his neuro function started failing. He was put on life support. While on life support his organs started failing. He had to be put on comfort mode and was dead within 8 hours. A perfectly healthy 77 year old man who had never been sick a day in his life (literally) got his 2nd covid shot, two days later he fell ill. From that point on his health spiraled out of control until his death on March 19th. Every doctor (pulmonologist, cardiologist, neurologist, and all attending doctors said that it was ""atypical and abnormal"" what was happening. It should not have happened. 180 degrees from normal.""
COVID19 VACCINE	MODERNA	1130690-1	65+ years	15-30 days	shortness of breath Hypokalemia Metabolic acidosis Pneumonia Chronic atrial fibrillation (CMS/HCC) Acute respiratory failure with hypoxia (CMS/HCC) Multiple myeloma not having achieved remission (CMS/HCC) Severe sepsis (CMS/HCC) ST segment depression
COVID19 VACCINE	MODERNA	1137286-1	50-59 years	6 days	Brought in from ED, family concerned for altered mental status, hyperthermia, Tmax in 105. The patient stated that after the covid-19 vaccine on Friday, he experienced acute onset of R shoulder pain, constant, associated with decreased ROM. On PM Monday, he noticed first episode of chills, that lasted a few minutes, accompanied with sweating. This episode recurred 4 times over the week, then the family started noticed the patient was unable to answer questions and was somnolent. Blood Cultures in the ED were positive for MRSA 2:2. He was positive for endocarditis (previous dental work). Acute metabolic encephalopathy due to severe sepsis most likely 2/2 MRSA bacteremia complicated by NSTEMI and AKI in setting of newly diagnosed aortic valve endocarditis complicated by septic emboli to the bilateral cerebral hemispheres
COVID19 VACCINE	MODERNA	1140885-1	65+ years	31-60 days	Having no previous history of ANY indigestion, or GI problems, I had a sudden onset of acute epigastric pain beginning March 15th, 2021, followed by frequent, unrelenting vomiting, eventual fever, and White Blood Cell count of 20,000. Saw internist, she sent me to an emergency room and then had a subsequent admission to a hospital on March 16. Cholecystectomy was done on March 17, 2021 after 24 hours IV antibiotics to control sepsis prior to surgery.
COVID19 VACCINE	MODERNA	1145067-1	65+ years	5 days	Right arm red, swollen, warm, nausea, vomiting, diarrhea, elevated temperature, altered mental status. Sent to ER. Had elevated cardiac enzymes. Admitted to hospital and treated for sepsis and altered mental status.
COVID19 VACCINE	MODERNA	1145275-1	65+ years	15-30 days	fever fatigue Acute kidney injury (CMS/HCC) Sepsis due to urinary tract infection (CMS/HCC) Severe sepsis (CMS/HCC) Hydronephrosis Endometrial cancer (CMS/ Urinary tract infection

COVID19 VACCINE	MODERNA	1148715-1	Unknown	0 days	Pneumonia; Sepsis; Aggravated an infection; Fever (104 ¶ F); Chills very bad; A spontaneous report was received from a consumer concerning her husband, 44-year-old, male patient who developed pneumonia, sepsis, aggravated an infection/infection, fever (104¶F)/pyrexia, chills very bad/chills. The patient's medical history included diabetes type 2, lung infection and blood pressure. Products known to have been used by the patient, within two weeks prior to the event, included Amlodipine. On 13 Jan 2021, the patient received their second of two planned doses of mRNA-1273 (Batch number: unknown) at unknown injection site for prophylaxis of COVID-19 infection. On 13 Mar 2021 the patient five minutes later after received second dose he started to had chills very bad and fever (104 ¶ F). The patient has pneumonia and sepsis. This aggravated an infection that he had in a lung 11 years ago (before receiving the vaccine they were thinking of amputating a leg, because he also has type 2 diabetes). The patient was under treatment, every week to avoid amputation but now they decided to amputate his leg as soon as possible due to the infection. Treatment information of the event was not provided. Action taken with mRNA-1273 in response to the event(s) was not provided. The outcome of the event(s) pneumonia, sepsis, aggravated an infection, fever (104¶F), chills very bad was not reported.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of these event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1153155-1	65+ years	0 days	Close to ""urea sepsis""; severe UTI; A spontaneous report was received from consumer concerning a 82-years old, male patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and experienced severe UTI/urinary tract infection and close to urea sepsis/sepsis. The patient's medical history was not provided. Concomitant medications was not provided by the reporter. On 16-Feb-2021, the patient received second of the two planned doses of mRNA-1273 (lot number: 006M20A) in the left arm for the prophylaxis of COVID-19 infection. On 16 Feb 2021, the patient developed a severe UTI. Close to urea sepsis. Took antibiotics. Treatment medication included antibiotics. No lab tests were mentioned. The events severe UTI and close to urea sepsis were considered to be serious with criteria of important medical event. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore action taken with the drug in response to the events was not applicable. The outcome of the events severe UTI and close to urea sepsis was considered unknown.; Reporter's Comments: 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""
COVID19 VACCINE	MODERNA	1153159-1	Unknown	7 days	Sepsis; Gall bladder stone; the bile was blocked in the gall bladder; A spontaneous report was received from a Consumer concerning a 49 year old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sepsis, bile was blocked in the gall bladder and gall bladder stones. The patient's medical history was included Down's syndrome and he had gall bladder problem from 5 years. No relevant concomitant medications were reported. On 05 Mar 2021, prior to the onset of the events, the patient received their first of the two planned vaccine doses of mRNA-1273 (lot/batch: 012A21A) intramuscularly in an unspecified location for prophylaxis of COVID-19 infection. On 12 Mar 2021, the patient experienced Sepsis, the bile was blocked in the gall bladder with Gall bladder stones with the seriousness criteria hospitalization. Laboratory details were not provided. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events, sepsis, bile was blocked in the gall bladder and gall bladder stones, was recovering, but still in the hospital at the time of report.; Reporter's Comments: Based on the current available information and lack of temporal association between the use of the product and the start date of the events, the events were assessed as Unlikely Related to study drug. The subject's underlying five year history of gall bladder disease can be a confounding factor as gallstones can lead to inflammation of gall bladder and blockage of bile ducts which can then lead to infection and ultimately, any complication can cause sepsis.; Sender's Comments: MOD21-047715:mother case

COVID19 VACCINE	MODERNA	1153997-1	40-49 years	0 days	Diagnosed with cellulitis; Diagnosed with sepsis; Temperature 102 degrees F/104 degrees F; Chills/Shivering; Discomfort; Difficulty breathing; Felt cold; Not feeling good; In a lot of pain; A spontaneous report was received from a pharmacist concerning a 44-year-old, male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and developed cellulitis, sepsis, temperature was 102 and 104 degrees F/fever, dyspnoea/difficulty breathing, feeling cold, malaise/unwell, pain, discomfort and chills. The patient's medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event were not reported. On 11 Mar 2021, the patient consulted wound care for his foot and was told to be fine. On 13 Mar 2021, prior to the onset of the symptoms, the patient received their dose of two planned doses of mRNA-1273 (batch number: unknown) for prophylaxis of COVID-19 infection. On 13 Mar 2021, within eight to ten minutes, after vaccination patient felt cold .The patient's temperature was noted to be 102 degree Fahrenheit. Also, patient reported a lot of pain and discomfort. Patient also complained about chills, cold and shivering and he was given an orange juice and blanket after five to ten minutes by the pharmacist. Pharmacist called patients wife and by that time patient developed breathing difficulty. Patient's temperature was raised to 104-degree Fahrenheit by that time and was taken by the emergency medical service to the hospital. The patient was hospitalised. On 16 Mar 2021, after 2 days, patients wife reported to pharmacist that the patient was diagnosed with sepsis and cellulitis and was given two antibiotics. The events sepsis and cellulitis were considered as serious (medically significant). The patient's wife reported that the patient was about to have an amputation in this past weekend. Treatment for the event included two unknown antibiotics. Action taken with mRNA-1273 in response to the event was unknown. The outcome of the events cellulitis, sepsis, temperature was 102 and 104 degrees F/fever, dyspnea /difficulty breathing, feeling cold, malaise/unwell, pain, discomfort and chills were considered to be unknown.; Reporter's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.
COVID19 VACCINE	MODERNA	1159620-1	65+ years	0 days	Patient admitted to the hospital 3/16/21 2 weeks post #2 Moderna COVID-19 vaccination with sepsis, atypical pulmonary infiltrates, and hypoxia. Patient treated for pneumonia and discharged home 3/19. Patient readmitted to hospital 3/31/21 with dyspnea, CT with worsening miliary appearing pattern.
COVID19 VACCINE	MODERNA	1170996-1	65+ years	4 days	Patient admitted to hospital on 4/5 for neutropenic sepsis, cellulitis shoulder at site of covid vaccine.

COVID19 VACCINE	MODERNA	1171302-1	65+ years	31-60 days	3/23/21 Medical Group note: dx pleuritis Chief Complaint Patient presents with ? URI c/o sob, tired, chills, headache, achey. symptoms started today. 72 y.o. male Pt has had both COVID vaccines. URI :This is a new problem. The current episode started in the past 7 days. The problem has been unchanged. There has been no fever. Associated symptoms include abdominal pain and chest pain. Pertinent negatives include no congestion, coughing, diarrhea, dysuria, ear pain, headaches, joint pain, joint swelling, nausea, neck pain, plugged ear sensation, rash, rhinorrhea, sinus pain, sneezing, sore throat, swollen glands, vomiting or wheezing. He has tried nothing for the symptoms. The treatment provided no relief. Review of Systems HENT: Negative for congestion, ear pain, rhinorrhea, sinus pain, sneezing and sore throat. Respiratory: Negative for cough and wheezing. Cardiovascular: Positive for chest pain. Gastrointestinal: Positive for abdominal pain. Negative for diarrhea, nausea and vomiting. Genitourinary: Negative for dysuria. Musculoskeletal: Negative for joint pain and neck pain. Skin: Negative for rash. Neurological: Negative for headaches. Objective Vitals: 03/23/21 1604 Weight: 120 kg (264 lb) Comment: pt. reported Height: 69"" Body mass index is 38.99 kg/m¶. Diagnoses and all orders for this visit:Pleuritis Chest wall pain Pt was advised to go to ER if symptoms persist or worsen. Pt was advised to come to office tomorrow for CXR and recheck. 3/24 sih med group dx rib pain: Patient presents with ? Chest Pain c/o chest pain/initially had chills, sob. symptoms started yesterday. Patient is a 72 y.o. male. Pt states he has gained 20 lbs in last few months. Pt sleeps in a recliner. He states he has to reach over the arm of the chair to adjust the reclining lever. Pt has pain to right ribs and abd. Abdominal Pain The current episode started in the past 7 days. The onset quality is sudden. The problem occurs intermittently. The problem has been unchanged. The pain is located in the RUQ. The pain is moderate. The quality of the pain is aching and dull. The abdominal pain does not radiate. Pertinent negatives include no anorexia, arthralgias, belching, constipation, diarrhea, dysuria, fever, flatus, frequency, headaches, hematochezia, hematuria, melena, myalgias, nausea, vomiting or weight loss. The pain is aggravated by palpation. The pain is relieved by nothing. He has tried acetaminophen for the symptoms. The treatment provided no relief. There is no history of abdominal surgery, colon cancer, Crohn's disease, pancreatitis or ulcerative colitis. 3/26/21 Admitted to Hospital, dx: elevated troponin, sepsis, acute renal failure, streptococcus bacteremia HPI: 4/5/21 Admitted to Hospital, swing bed status dx sepsis, physical deconditioning""
COVID19 VACCINE	MODERNA	1175621-1	50-59 years	7 days	Followed up with our clinic on 4/1/2021 after hospital admission for sepsis, pancreatitis, and cholycystitis. Admitted to medical center on March 23rd, discharged home March 27th. Was seen at a smaller facility close to home, Medical Center, prior to adimission to . Pt states he was admitted to the ICU. We have not yet received copies of his medical records from admissions for additional information on presenting symptoms or labs. No previous hx of pancreatitis or cholycystitis. Pt was ambulatory and without acute complaints of abd pain, chest pain, or dyspnea at the time of his office follow-up. Reported to our providers that he was advised to have surgical follow-up for cholycystectomy within 1-2 weeks. No surgery while admitted.
COVID19 VACCINE	MODERNA	1190387-1	40-49 years	1 day	Fever, malaise , body aches, headache, foggy memory, fast heart rate lasting more then a week and progress worse each day diagnosis with sepsis in the hospital
COVID19 VACCINE	MODERNA	1196151-1	50-59 years	1 day	Received vaccine #2 04/08/2021. Fell at home 04/09/2021 and was transferred to ER and they admitted her to hospital for Urinary Sepsos.
COVID19 VACCINE	MODERNA	1196864-1	65+ years	1 day	vomiting with fruity odor, BG 417, weakness & SOB, Torsade de pointe & received CPR, DKA, sepsis, lactic acidosis
COVID19 VACCINE	MODERNA	1198939-1	65+ years	0 days	Per Medical Examiner, fourteen hours after receiving vaccine presenting symptoms were fatigue and muscle aches, went to Hospital Emergency Room and was released. Six hours later family stated symptoms had worsened, fever, shortness of breath and fatigue, admitted to Medical Center, diagnosed with sepsis and died within 48 hours of vaccination, deceased 4/7/2021, cause of death neutropenic sepsis with multi-lobar pneumonia, autopsy scheduled 4/13/2021.

COVID19 VACCINE	MODERNA	1204747-1	65+ years	Unknown	dehydration; temperature that I couldn't keep down; weak; difficulty breathing; spots on lungs; low blood pressure; cracked 2 crowns and 3 crowns lost from clinching jaw; cracked 2 crowns and 3 crowns lost from clinching jaw; nausea/vomiting; body aches; muscle aches; rash; vomiting; Started on fluids and lungs filled up with fluid; pancreas was being attacked- pancreatitis; septic; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PULMONARY OEDEMA (Started on fluids and lungs filled up with fluid), PANCREATITIS (pancreas was being attacked- pancreatitis), SEPSIS (septic) and DEHYDRATION (dehydration) in a 70-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 001B21A and 006M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On 12-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 12-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced PULMONARY OEDEMA (Started on fluids and lungs filled up with fluid) (seriousness criterion medically significant), PANCREATITIS (pancreas was being attacked- pancreatitis) (seriousness criterion medically significant), SEPSIS (septic) (seriousness criterion medically significant), DEHYDRATION (dehydration) (seriousness criterion hospitalization), BODY TEMPERATURE INCREASED (temperature that I couldn't keep down), ASTHENIA (weak), DYSPNOEA (difficulty breathing), PULMONARY MASS (spots on lungs), HYPOTENSION (low blood pressure), BRUXISM (cracked 2 crowns and 3 crowns lost from clinching jaw), TOOTH INJURY (cracked 2 crowns and 3 crowns lost from clinching jaw), NAUSEA (nausea/vomiting), PAIN (body aches), MYALGIA (muscle aches), RASH (rash) and VOMITING (vomiting). The patient was hospitalized from 20-Mar-2021 to 26-Mar-2021 due to DEHYDRATION. At the time of the report, PULMONARY OEDEMA (Started on fluids and lungs filled up with fluid), PANCREATITIS (pancreas was being attacked- pancreatitis), SEPSIS (septic), DEHYDRATION (dehydration), BODY TEMPERATURE INCREASED (temperature that I couldn't keep down), ASTHENIA (weak), DYSPNOEA (difficulty breathing), PULMONARY MASS (spots on lungs), HYPOTENSION (low blood pressure), BRUXISM (cracked 2 crowns and 3 crowns lost from clinching jaw), TOOTH INJURY (cracked 2 crowns and 3 crowns lost from clinching jaw), NAUSEA (nausea/vomiting), PAIN (body aches), MYALGIA (muscle aches), RASH (rash) and VOMITING (vomiting) outcome was unknown. No concomitant products included. Patient's treatment information include Advil, trigger point injections in neck, hot and cold packs, Lasix, antibiotics, pain meds, discharged from hospital on oxygen. 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.; Sender's Comments: 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.
COVID19 VACCINE	MODERNA	1204783-1	Unknown	Unknown	Sepsis; Been 52 days for second dose of vaccine; This spontaneous case was reported by a nurse (subsequently medically confirmed) and describes the occurrence of SEPSIS (Sepsis) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No reported medical history). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced SEPSIS (Sepsis) (seriousness criterion hospitalization) and PRODUCT DOSE OMISSION ISSUE (Been 52 days for second dose of vaccine). At the time of the report, SEPSIS (Sepsis) outcome was unknown and PRODUCT DOSE OMISSION ISSUE (Been 52 days for second dose of vaccine) had resolved. Not Provided The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported The patient was hospitalized for almost 3 weeks for sepsis after receiving first dose. At the time of report, the patient was on 52nd day since receiving first dose. Treatment information was not provided. Very limited information regarding these events has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.
COVID19 VACCINE	MODERNA	1209139-1	65+ years	15-30 days	Death Shortness of breath Sepsis

COVID19 VACCINE	MODERNA	1209874-1	60-64 years	4 days	a few days after receiving 2nd dose of maderna vaccine patient became shor.t of breath. was found to be in acute heart failure, was septic with a lactic acid of 5.6, and sustained a NSTEMI with a troponin of >6.0. stabilized on a bipap for respiratory failure and a nitro gtt for heart profusion. now on impella device r/t severe cardiac decompensation during heart cath procedure
COVID19 VACCINE	MODERNA	1209906-1	65+ years	15-30 days	On March 4 patient experienced vomiting. Early morning March 5 he fell and landed on his hip after being disoriented and experienced aches, weakness, and nausea without vomiting throughout the day. On March 6 he experienced excruciating pain in his left hip and went to the local emergency room following guidance from his primary care physician. He was diagnosed with fluid near his hip joint at the hospital and was discharged the same day. The next day, March 7 he was still in pain but able to walk with assistance. On March 8 he got an x-ray from an orthopedic physician and severe arthritis was found. March 10 the severe pain persisted, but he was able to walk with a walker. On March 12 he received a cortisone shot and required emergency medical assistance to get into a personal vehicle with a family member who drove to the appointment. The next few days, the pain persisted, became worse, and spread throughout his body. On March 16 he was transported by emergency medical services to the local emergency room for treatment and was diagnosed with sepsis and pneumonia. On March 18 he was still being treated when he experienced cardiac arrest while being intubated. He was resuscitated and was on a ventilator being treated for a few more days but ultimately succumbed to sepsis on March 30.
COVID19 VACCINE	MODERNA	1211262-1	50-59 years	10-14 days	Patient had her 2nd dose of Moderna COVID vaccine on 3/29. Starting 4/8, she was having shortness of breath on exertion with a mild cough. On 4/11, her husband states that he saw her sitting down watching TV, then he heard a thud in the next room and went in to see her on the floor and she started crying for help which led to him calling the paramedics. The paramedics noticed the patient was in PEA and resuscitated her and brought her to the ER. The patient appeared to have an NSTEMI and she was diagnosed with a pulmonary embolism that led to the cardiac arrest event. Patient was taking to cath lab and was found to have normal coronary arteries with no evidence of coronary artery disease. Patient was also in sepsis and had an extensive bilateral pneumonia. Patient is currently inpatient and intubated.
COVID19 VACCINE	MODERNA	1213568-1	65+ years	15-30 days	death Narrative: Patient received Moderna covid vaccine # 1 on 2/26/21. Per scanned records on 3/18/21, he presented to the ER with reports of shortness of breath and was subsequently admitted and treated for acute CHF, NSTEMI and sepsis (ceftriaxone and azithromycin). He later developed AKI and surgery was consulted for placement of a Trialysis catheter. After placement of this catheter, he developed increasing respiratory distress and confusion and was transferred to the ICU where he received vasopressors, intubation and unsuccessful resuscitation after a code blue. Autopsy reports not available. 22 days from date of vaccine to date of death.
COVID19 VACCINE	MODERNA	1214163-1	65+ years	3 days	E83.42 - Hypomagnesemia R77.8 - Elevated troponin A41.9, R65.20 - Severe sepsis (CMS/HCC) R50.9 - Fever, unspecified fever cause A41.9 - Sepsis, due to unspecified organism, unspecified whether acute organ dysfunction present (CMS/HCC) R41.0 - Delirium N39.0 - Urinary tract infection A41.9 - Sepsis (CMS/HCC)
COVID19 VACCINE	MODERNA	1214594-1	18-29 years	10-14 days	pt developed peri rectal abscess 4/1 requiring inpatient management due to sepsis and I&D also noted to have incidental finding of pseudocyst pt has no h/o etoh use or any abd pain or diarrhea has had abd cramps on and off in the past will be getting referred to GI for IBD work up
COVID19 VACCINE	MODERNA	1218467-1	65+ years	0 days	Patient hospitalized Hospital Admission Diagnoses: Severe sepsis (CMS/HCC) [A41.9, R65.20] Discharge Diagnosis: Patient Active Problem List Diagnosis Date Noted *Elevated troponin 03/30/2021 *B12 deficiency 03/30/2021 *Acute systolic heart failure (CMS/HCC) 03/25/2021 Discharge Diagnoses: Patient Active Problem List Diagnosis Date Noted *Elevated troponin 03/30/2021 *B12 deficiency 03/30/2021 *Acute systolic heart failure (CMS/HCC) 03/25/2021 *Acute respiratory failure with hypoxia (CMS/HCC) 03/24/2021 *Acute pulmonary edema (CMS/HCC) 03/24/2021 *IVH (Intraventricular hemorrhage) (CMS/HCC) 06/06/2018 *Brain edema (CMS/HCC) 06/06/2018 *Brain compression (CMS/HCC) 06/06/2018 *Benign essential HTN *Coronary artery disease * Type 2 diabetes mellitus with hemoglobin A1c goal of less than 7.0% (CMS/HCC) *Nontraumatic right thalamic hemorrhage (HCC) 06/05/2018 Consults: IP CONSULT TO PULMONOLOGY IP CONSULT TO CARDIOLOGY INPATIENT CONSULT TO PHARMACY INPATIENT CONSULT TO PHARMACY IP CONSULT TO NUTRITION SERVICES IP CONSULT TO NUTRITION SERVICES Procedures: Intubation Catheterization Significant Diagnostic Studies: Cardiac Catheterization

COVID19 VACCINE	MODERNA	1220973-1	Unknown	Unknown	kidney stones; kidney stone blocked the tube; Did not get second dose; sepsis; This spontaneous case was reported by a consumer and describes the occurrence of NEPHROLITHIASIS (kidney stones), SEPSIS (sepsis) and URINARY TRACT OBSTRUCTION (kidney stone blocked the tube) in a 79-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 024M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included No adverse event (No medical history was provided.). On 03-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced NEPHROLITHIASIS (kidney stones) (seriousness criterion hospitalization), SEPSIS (sepsis) (seriousness criterion hospitalization prolonged), URINARY TRACT OBSTRUCTION (kidney stone blocked the tube) (seriousness criterion hospitalization) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Did not get second dose). At the time of the report, NEPHROLITHIASIS (kidney stones), SEPSIS (sepsis), URINARY TRACT OBSTRUCTION (kidney stone blocked the tube) and INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION (Did not get second dose) outcome was unknown. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. Treatment information included unspecific transfusion. No concomitant medications provided. The patient reported that due to being hospitalized, she was unable to get the second dose of the Moderna COVID-19 vaccine. This report refers to a case of incomplete course of vaccination (second dose) for mRNA-1273, with associated AEs of Nephrolithiasis, sepsis and Urinary tract obstruction. Further information is requested.; Sender's Comments: This report refers to a case of incomplete course of vaccination (second dose) for mRNA-1273, with associated AEs of Nephrolithiasis, sepsis and Urinary tract obstruction. Further information is requested.
COVID19 VACCINE	MODERNA	1223040-1	65+ years	3 days	Admitted 4/5/2021 with severe cdiff pancolitis, severe sepsis, multi-organ failure. DIscharged to hospice on 4/9/2021.
COVID19 VACCINE	MODERNA	1228019-1	65+ years	10-14 days	Narrative: 2/8/2021 UTI, sepsis, hyperglycemia, staphylococcus, MRSA infection-discharged to hospice care from Medical Center 2/9, passed 2/11.
COVID19 VACCINE	MODERNA	1229034-1	65+ years	1 day	Pt. had hx of SOB prior to vaccination and Dx with hear failure Woke up day after vaccination with being very tired. Admitted to hospital with UTI, Sepsis
COVID19 VACCINE	MODERNA	1232936-1	65+ years	15-30 days	Taken to the Hospital due to a fracture, severe UTI and sepsis. Dies at the Hospital.
COVID19 VACCINE	MODERNA	1234488-1	65+ years	0 days	Patient had an undiagnosed/unknown UTI at the time of her second vaccine on 3/2/21. She was admitted to Hospital on 3/3/21 with organ failure; she passed away on 3/5/21. Her cause of death is listed as Sepsis, and UTI. The vaccine was not listed as a cause of death, but might have been a ""tipping point"" in her inability to recover with antibiotic treatment.""
COVID19 VACCINE	MODERNA	1242118-1	65+ years	10-14 days	Patient presented after being found down next to toilet found to have COVID-pneumonia and sepsis needing intubation for ARDS and CRRT for hyperkalemia and oliguria. Hospitalization complicated by GIB s/p rectal artery embolization by IR and GNR bacteremia requiring cefepime. Due to worsening hypoxia and shock, patient was made comfort care/hospice by family and passed away on 4/9.

COVID19 VACCINE	MODERNA	1261497-1	65+ years	4 days	cellulitis; Sepsis; Elevated heart rate; Rash from the waist down on left side of body; chills; Fever; This spontaneous case was reported by a physician assistant (subsequently medically confirmed) and describes the occurrence of CELLULITIS (cellulitis) and SEPSIS (Sepsis) in a 68-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Heart rate increased (elevated heartrate). On 10-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 14-Apr-2021, the patient experienced CHILLS (chills) and PYREXIA (Fever). On 15-Apr-2021, the patient experienced CELLULITIS (cellulitis) (seriousness criterion hospitalization), SEPSIS (Sepsis) (seriousness criterion hospitalization) and RASH (Rash from the waist down on left side of body). On an unknown date, the patient experienced HEART RATE INCREASED (Elevated heart rate). The patient was hospitalized from sometime in April 2021 to sometime in April 2021 due to CELLULITIS and SEPSIS. At the time of the report, CELLULITIS (cellulitis), SEPSIS (Sepsis), HEART RATE INCREASED (Elevated heart rate), RASH (Rash from the waist down on left side of body), CHILLS (chills) and PYREXIA (Fever) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 15-Apr-2021, Heart rate: 132 (High) 132 beats per minute. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were reported. She was admitted to the hospital and hospitalized for four days. She was diagnosed with cellulitis and sepsis. She was discharged home from the hospital with Augmentin (Amoxicillin / Clavulanic acid) for 10 days. Based on the current available information and temporal association between the use of the product and the start date of the event,s a causal relationship cannot be excluded. However, Further information has been requested This case was linked to MODERNATX, INC.-MOD-2021-081503~, MODERNATX, INC.-MOD-2021-081439, MODERNATX, INC.-MOD-2021-081647 (E2B Linked Report).; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event,s a causal relationship cannot be excluded. However, Further information has been requested MODERNATX, INC.-MOD-2021-081503 :Fourth patient-Same reporter MODERNATX, INC.-MOD-2021-081439:First patient-Same reporter US-MODERNATX, INC.-MOD-2021-081647:Third patient-Same reporter
COVID19 VACCINE	MODERNA	1271737-1	65+ years	15-30 days	Patient presented to the ED and was subsequently hospitalized with sepsis, respiratory failure and pneumonia on 3/2/2021. Patient presented to the ED and was subsequently hospitalized with pneumonia on 3/22/2021. Patient presented to the ED and was subsequently hospitalized with sepsis on 3/31/2021. He died on 4/4/2021.

COVID19 VACCINE	MODERNA	1276742-1	65+ years	7 days	Shortness of breath; COVID-19 pneumonia; COVID-19 infection; Hypoxic respiratory failure; sepsis; This spontaneous case was reported by a health care professional (subsequently medically confirmed) and describes the occurrence of RESPIRATORY FAILURE (Hypoxic respiratory failure), SEPSIS (sepsis), COVID-19 PNEUMONIA (COVID-19 pneumonia), COVID-19 (COVID-19 infection) and DYSPNOEA (Shortness of breath) in a 66-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient's past medical history included Heart failure with preserved ejection fraction. Concurrent medical conditions included COPD exacerbation (On 2 liters of oxygen at baseline), Squamous cell carcinoma of lung, Schizoaffective disorder and oxygen. On 30-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 06-Apr-2021, the patient experienced COVID-19 PNEUMONIA (COVID-19 pneumonia) (seriousness criteria hospitalization and medically significant) and COVID-19 (COVID-19 infection) (seriousness criterion hospitalization). On 16-Apr-2021, the patient experienced DYSPNOEA (Shortness of breath) (seriousness criterion hospitalization). On an unknown date, the patient experienced RESPIRATORY FAILURE (Hypoxic respiratory failure) (seriousness criteria hospitalization and medically significant) and SEPSIS (sepsis) (seriousness criteria hospitalization and medically significant). The patient was hospitalized until 21-Apr-2021 due to COVID-19, COVID-19 PNEUMONIA, DYSPNOEA, RESPIRATORY FAILURE and SEPSIS. At the time of the report, RESPIRATORY FAILURE (Hypoxic respiratory failure), SEPSIS (sepsis), COVID-19 PNEUMONIA (COVID-19 pneumonia) and COVID-19 (COVID-19 infection) had resolved and DYSPNOEA (Shortness of breath) was resolving. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In April 2021, Chest X-ray: abnormal (abnormal) multifocal pneumonia in the setting of chronic Interstitial changes.. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Treatment information provided included 6L O2 Nasal cannula, Remdesivir for 5 days (stop date : 20 - Apr - 2021) ,Decadron for 6 days (stop date : 21 - Apr - 2021) . The patient was discharged on 21 Apr 2021 to rehabilitation on baseline 2L O2 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. Reporter did not allow further contact; Sender's Comments: 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.

COVID19 VACCINE	MODERNA	1276785-1	65+ years	0 days	had the cardiac arrest & was hospitalized for 12 days we still cannot find any reason for the cardiac arrest; was in extreme acidosis; somewhere along the line, I got sepsis; CT scan showed a hematoma in stomach; distended stomach; Still have terrible diarrhea; haven't gotten my second shot yet; following day, I started with extreme chills; Fever; was just miserable for several days; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of CARDIAC ARREST (had the cardiac arrest & was hospitalized for 12 days we still cannot find any reason for the cardiac arrest), ACIDOSIS (was in extreme acidosis), SEPSIS (somewhere along the line, I got sepsis), HAEMATOMA (CT scan showed a hematoma in stomach), GASTRIC DILATATION (distended stomach) and DIARRHOEA (Still have terrible diarrhea) in a 72-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 046A21A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No medical history reported. Concomitant products included OMEPRAZOLE (PROTONIX [OMEPRAZOLE]), ESTROGENS CONJUGATED (PREMARIN), VITAMIN D3, PROBIOTICS NOS and ALPRAZOLAM (XANAX) for an unknown indication. On 18-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 18-Mar-2021, the patient experienced DIARRHOEA (Still have terrible diarrhea) (seriousness criterion hospitalization prolonged), FEELING ABNORMAL (was just miserable for several days), CHILLS (following day, I started with extreme chills) and PYREXIA (Fever). On 24-Mar-2021, the patient experienced CARDIAC ARREST (had the cardiac arrest & was hospitalized for 12 days we still cannot find any reason for the cardiac arrest) (seriousness criteria hospitalization prolonged, medically significant and life threatening), ACIDOSIS (was in extreme acidosis) (seriousness criteria hospitalization prolonged and life threatening), SEPSIS (somewhere along the line, I got sepsis) (seriousness criteria hospitalization prolonged and life threatening), HAEMATOMA (CT scan showed a hematoma in stomach) (seriousness criteria hospitalization prolonged and life threatening) and GASTRIC DILATATION (distended stomach) (seriousness criterion hospitalization prolonged). On an unknown date, the patient experienced PRODUCT DOSE OMISSION ISSUE (haven't gotten my second shot yet). The patient was hospitalized on 24-Mar-2021 due to ACIDOSIS, CARDIAC ARREST, DIARRHOEA, GASTRIC DILATATION, HAEMATOMA and SEPSIS. At the time of the report, CARDIAC ARREST (had the cardiac arrest & was hospitalized for 12 days we still cannot find any reason for the cardiac arrest), ACIDOSIS (was in extreme acidosis), SEPSIS (somewhere along the line, I got sepsis), HAEMATOMA (CT scan showed a hematoma in stomach), GASTRIC DILATATION (distended stomach), DIARRHOEA (Still have terrible diarrhea), FEELING ABNORMAL (was just miserable for several days), PRODUCT DOSE OMISSION ISSUE (haven't gotten my second shot yet), CHILLS (following day, I started with extreme chills) and PYREXIA (Fever) outcome was unknown. Not Provided DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 24-Mar-2021, Computerised tomogram: hematoma in stomach (abnormal) Four CT scans. Showed hematoma in stomach. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) was unknown. On 24th March 21, Patient had multiple x-rays done. The result was not provided. Treatment for the events was not provided. CPR for 10

COVID19 VACCINE	MODERNA	1289333-1	65+ years	1 day	March 2 - second Moderna March 3 - spontaneous bruising appears March 4 - visit with primary care doctor, blood work shows significant drop in platelets March 9 - first visit with oncologist/haematologist & hospitalized March 9-19 - hospitalized for tests, treatment to increase platelets, & many blood panels. No official diagnosis, treat as ITP. Follow up visits with oncologist/haematologist to keep an eye on platelets as they increase. March 30-Apr 4 - ER visit due to swelling of ankles, feet, and left arm. Tests show superficial blood clot, fluid on lungs, and pneumonia. Oncologist said that ""we have no official diagnosis"", that she's being treated for ITP. April 6-14 - follow up visit to oncologist/haematologist show elevated kidney enzymes, then later liver enzymes, low sodium. April 14 - decision to move to short term rehab for regular PT and OT. Continued swelling (fluid in third spaces.) April 21 - visit to cardiologist to perform cardioversion, successful (during first week of hospital stay, heart rhythm med had to stop). April 23 - facility nurse discovered significantly low Hemoglobin and a blood transfusion was ordered. April 24 - returned to short term rehab facility. April 25 - discovered my mother on O2 and state of health was different, extremely weak and not moving, arm hurting badly. I insisted that her oncologist is contacted. Transported to ER. Discovered her blood work abnormal. After stabilizing her, rushed to the hospital ICU. April 26 - Discussed with her ICU doctor the history of what you have read above. He explained that the covid-19 vaccination has a tendency to affect three proteins specifically that clot and thin blood. I begged him to ""get it out of her system."" Her bleeding was significant and platelets dropped, again. Still has her mental facilities. Responding well to aggressive treatment: albumin transfusion, plateletpheresis, and CRRT. Pleural catheter to remove fluid from the lungs. Mention of Sepsis. April 27 - Lifted her head up today, opened her eyes, making doctors very happy. Her cardiologist and the ICU doctor both said they were ""confused"" and everything happening to my mom was ""a mystery."" Though going in to the evening, her nurse expressed to me that she's worried. The ICU oncologist called me at home in the evening. He asked me if she had been having a fever on a regular basis. He said he thought it could be TTP or a rare disease called HTH, but both results wouldn't be back for one week. He planned to consult with a doctor. He explained to me that the blood was attacking itself and ""confused,"" and that her organs were shutting down. He indicated that the blood work wasn't indicating significant infection. He referenced how the vaccination has made her auto immune system ""go crazy."" April 28 - I get a call very early from the nurse that she has been fighting with my mother's blood pressure all night, trying to keep it elevated. She told me to come to the hospital, because she had taken a turn for the worse. I arrive to find my mother's eyes wide open, breathing shallow, and blood pressure steady, but drops without assistance from medication. She continues to have her mental facilities. She passed away, organs shutting down, and blood pressure dropped.""

COVID19 VACCINE	MODERNA	1290764-1	65+ years	0 days	encephalopathy with facial muscle weakness; facial muscle weakness; back pain causing inability to ambulate; dysarthria; Constipation; urinary retention; MSSA; extremity weakness; Severe refractory immune thrombocytopenia; ACUTE EPISTAXIS; DIFFUSE CUTANEOUS PURPURA; This literature-non-study case was reported in a literature article and describes the occurrence of IMMUNE THROMBOCYTOPENIA (Severe refractory immune thrombocytopenia), EPISTAXIS (ACUTE EPISTAXIS), PURPURA (DIFFUSE CUTANEOUS PURPURA), MUSCULAR WEAKNESS (extremity weakness), ENCEPHALOPATHY (encephalopathy with facial muscle weakness), FACIAL PARESIS (facial muscle weakness), BACK PAIN (back pain causing inability to ambulate), DYSARTHRIA (dysarthria), CONSTIPATION (Constipation), URINARY RETENTION (urinary retention) and STAPHYLOCOCCAL SEPSIS (MSSA) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. LITERATURE REFERENCE: Severe, Refractory Immune Thrombocytopenia Occurring After SARS-CoV-2 Vaccine. Journal of Blood Medicine. 2021;12:221-224 Previously administered products included for Influenza immunization: influenza in October 2020; for Pneumococcal immunization: pneumococcal in December 2020. Past adverse reactions to the above products included No adverse event with influenza and pneumococcal. Concurrent medical conditions included Hypertension, Gout, Hyperlipidemia and Cardiomyopathy. On 19-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 19-Jan-2021, the patient experienced EPISTAXIS (ACUTE EPISTAXIS) (seriousness criterion hospitalization) and PURPURA (DIFFUSE CUTANEOUS PURPURA) (seriousness criterion hospitalization). On 20-Jan-2021, the patient experienced IMMUNE THROMBOCYTOPENIA (Severe refractory immune thrombocytopenia) (seriousness criterion hospitalization). On 31-Jan-2021, the patient experienced MUSCULAR WEAKNESS (extremity weakness) (seriousness criterion hospitalization), ENCEPHALOPATHY (encephalopathy with facial muscle weakness) (seriousness criterion hospitalization), FACIAL PARESIS (facial muscle weakness) (seriousness criterion hospitalization), BACK PAIN (back pain causing inability to ambulate) (seriousness criterion hospitalization), DYSARTHRIA (dysarthria) (seriousness criterion hospitalization), CONSTIPATION (Constipation) (seriousness criterion hospitalization), URINARY RETENTION (urinary retention) (seriousness criterion hospitalization) and STAPHYLOCOCCAL SEPSIS (MSSA) (seriousness criterion hospitalization). The patient was hospitalized for 5 days due to EPISTAXIS, IMMUNE THROMBOCYTOPENIA, MUSCULAR WEAKNESS and PURPURA. At the time of the report, IMMUNE THROMBOCYTOPENIA (Severe refractory immune thrombocytopenia), EPISTAXIS (ACUTE EPISTAXIS), PURPURA (DIFFUSE CUTANEOUS PURPURA), MUSCULAR WEAKNESS (extremity weakness) and FACIAL PARESIS (facial muscle weakness) was resolving and ENCEPHALOPATHY (encephalopathy with facial muscle weakness), BACK PAIN (back pain causing inability to ambulate), DYSARTHRIA (dysarthria), CONSTIPATION (Constipation), URINARY RETENTION (urinary retention) and STAPHYLOCOCCAL SEPSIS (MSSA) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 20-Jan-2021, Platelet count: 10 10^9/L (Inconclusive) 10. On 01-Feb-2021, Blood culture: abnormal (abnormal) blood culture grew methicillin-susceptible Staphylococcus aureus (MSSA). On 01-Feb-2021, Culture urine:
COVID19 VACCINE	PFIZER\BIONTECH	0909031-1	65+ years	6 days	Patient presented with signs and symptoms of sepsis, developing over 12 to 24 hours 6 days after vaccination. was hypotensive and confused (beyond baseline)
COVID19 VACCINE	PFIZER\BIONTECH	0920572-1	60-64 years	0 days	Received vaccine in the morning 08:00 am, took acetaminophen 1 GM at 09:00 am due to pain in arm. By 10:30pm, I began having flu like symptoms, (aches, low grade fever, sinus symptoms) took another acetaminophen 1 GM. At 11:00 pm, developed severe rigors that lasted for approximately 2 hours. I am an RN and I have seen many cases of sepsis and felt like I was experiencing similar symptomatology. By 1:45 am, the rigors finally ceased and the body, muscle and joint pain became severe (on a pain scale of 1-10, it was an 8). At 7:00 am, I took another acetaminophen 1 GM, the body pain became much less and I was experiencing a global headache. I do not get headaches, so this was unusual. By 10:00 am, the headache was minimal, body aches were gone, only sinus symptoms persisted.
COVID19 VACCINE	PFIZER\BIONTECH	0929689-1	60-64 years	1 day	Fever to 103.7F, respiratory rate 36. Was transferred from facility to hospital. Since then has been found to have gram-negative rod bacteremia, although urinalysis was negative, urine culture pending. Patient has since defervesced after receiving 1 dose of cefepime. Overall the most likely cause of fever seems to be urosepsis w/ bacteremia, pending confirmation with urine & blood cultures.
COVID19 VACCINE	PFIZER\BIONTECH	0943432-1	65+ years	0 days	RESIDENT BEGAN VOMITING AND BECAME UNRESPONSIVE AT 12PM.

COVID19 VACCINE	PFIZER\BIONTECH	0953333-1	65+ years	0 days	patient began with vomiting and diarrhea the day after administration, leading to bowel and urine incontinence. patient was hospitalized on 01/16/20 with sepsis. no origin discovered yet. still waiting on blood/urine/stool cultures.
COVID19 VACCINE	PFIZER\BIONTECH	0956578-1	65+ years	1 day	At approximately 4pm on Jan 11, 2021, I began to have hard chills and fever that reached 104.9. I was admitted to ICU at the Hospital. My blood pressure dropped to dangerous levels. I was diagnosed with sepsis and the doctors determined it was caused by the vaccine.
COVID19 VACCINE	PFIZER\BIONTECH	0963057-1	65+ years	0 days	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
COVID19 VACCINE	PFIZER\BIONTECH	0970166-1	40-49 years	10-14 days	Acute pancreatitis with sepsis; Acute pancreatitis with sepsis; This is a spontaneous report from a contactable pharmacist, the patient. A 48-year-old non-pregnant female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK5730), via an unspecified route of administration on 17Dec2020 at 15:00 (at the age of 48-years-old) as a single dose for COVID-19 immunization. Medical history included penicillin allergy. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included fexofenadine (MANUFACTURER UNKNOWN). The patient did not receive any other vaccines within four weeks prior to the vaccination. On 28Dec2020, the patient experienced acute pancreatitis with sepsis, which were reported as serious for hospitalization and being life threatening. The patient had gone to the emergency room due to the event and was hospitalized for a total of 6 days. On 29Dec2020 and 31Dec2020, the patient had COVID-19 nasal swabs performed and both results were negative. Therapeutic measures were taken as a result of acute pancreatitis with sepsis and included gall bladder removal. The clinical outcome of acute pancreatitis with sepsis was recovering.; Sender's Comments: Based on the temporal relationship, the association between the events pancreatitis with sepsis with BNT162b2 can not 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.
COVID19 VACCINE	PFIZER\BIONTECH	0972778-1	40-49 years	1 day	On 1/23/21 at approximately 3:30pm I began to develop headaches. Approximately 2-3 hours later I began to feel nauseous and began to vomit. I then was taken to the Emergency Room where I had begun to suffer from an Addisonian Crisis where I was given Stress Dose steroids. The stress does steroids where given through 1/24/21 and medicine for the headaches are still be used to relieve the pain from the headaches. I was released from the hospital the late morning in the late morning of 1/25/21
COVID19 VACCINE	PFIZER\BIONTECH	0975434-1	65+ years	5 days	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.""

COVID19 VACCINE	PFIZER\BIONTECH	0995473-1	65+ years	2 days	Starting on 1/17/21 had fever of 101.6, 1/18/21 fever of 101.2, 1/19/21 fever of 102.6. From 1/19-1/23 she had defervesed to normal temp. Afternoon of 1/23/21 temp 101.4, 1/24/21 fever of 103 and 101. On 1/25/21 the nurses called the doctor and said that she was lethargic. Dr. found her to be hypotensive, lethargic, tacchycardic, They sent her to the ER. She also had during that day they found her with neck pain with movement, chills and fever. From 1/25-today she is still admitted to the hospital. They found her to have staph aureus sepsis - source unknown, encephalopathy related to sepsis, they did rule out meningitis, hyponatremia, UTI with E-coli and some staph, urinary retention, rhabdomyalisis with acute kidney injury and dehydration. They are treating her with antibiotics, getting better but still hospitalized.
COVID19 VACCINE	PFIZER\BIONTECH	0998616-1	50-59 years	4 days	**Pfizer-BioNTech COVID-19 Vaccine EUA** 1/25/2021 - was found unresponsive with left upward gaze deviation at midnight and admitted to hospital (last seen normal around 7 pm 1/24/2021). Intubated in ED, ABG 6.98/17/186 on 40%, Bicarb <5, Scr 1.4, Lactate 1, Wbc 20.3, BP 101/45-- >95/41, Temp 94.3, RR 23-32. Acidotic and initially required norepineprine for hypotension management (stopped 1/26/2021 0400 am) 1/26 to 2/1/2021 - supportive care for encephalopathy (anoxic vs. ischemic brain injury), ARF, HTN, MSSA growth in resp culture (no respiratory distress, on antibiotic) 1/28 GCS:E4VTM4; 1/29 GCS: EV4VTM4 with intact protective reflexes, extubated 2 pm 2/1 arousable, follows very simple commands, non verbal
COVID19 VACCINE	PFIZER\BIONTECH	1000754-1	65+ years	7 days	on 2/1/2021 Resident Reported Back pain given Tylenol Medication orally For Relief. APPRoximately 30 Min Later. complaint of & Noted Diarrhea, Shivering, and vomiting SenT To ER 2/1 And Admitted Diagnosis: Sepsis
COVID19 VACCINE	PFIZER\BIONTECH	1005663-1	65+ years	1 day	Per report from family member illness started with fever, chills and increasingly progressed to needing emergency care
COVID19 VACCINE	PFIZER\BIONTECH	1008547-1	65+ years	0 days	AMS-Fever-UTI-myoclonic jerks-unresponsive <6hrs post 1st covid vaccine. AMS-UTI- post 2nd covid vaccine
COVID19 VACCINE	PFIZER\BIONTECH	1012986-1	65+ years	6 days	Hospitalized for community-acquired pneumonia and sepsis 6 days following administration of COVID-19 vaccine, complicated by acute hypoxemic respiratory failure and acute kidney injury requiring. Admitted to ICU, treated with intravenous antibiotics and initial pressor support. Intubated on hospital day #3, extubated on hospital day #8. Remains in ICU at time of this report.
COVID19 VACCINE	PFIZER\BIONTECH	1019548-1	65+ years	3 days	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>""
COVID19 VACCINE	PFIZER\BIONTECH	1021027-1	65+ years	4 days	Patient was brought in by ambulance on 01/28/2021 with complaints of fever, chills, myalgias, shakiness, and severe hypotension. Patient was treated for severe sepsis and acute kidney injury. Patient was given fluid resuscitation, but unresponsive to treatment; NE+ vasopressin, hydrocortisone IV, along with empiric antibiotic regimen were initiated. Patient later on developed pulmonary edema, Non-ST elevation MI with no chest pain and new onset of cardiomyopathy with EF 40-45% and clean coronary arteries shown on cardiac catheterization. Physician suspected cytokine release syndrome related to the COVID vaccine and congestive heart failure. Naranjo scale score of 2 indicates possible ADR. MD indicated vaccine reaction unlikely.

COVID19 VACCINE	PFIZER\BIONTECH	1022055-1	65+ years	4 days	Had a mild a heart attack and mild stroke; had a mild a heart attack and mild stroke; urinary tract infection; Blood infection; A1C was 6.5; there was a little blood in his urine; he fell out of bed and couldn't get up; he was flushed; he had a fever of 101; This is a spontaneous report from a contactable consumer (patient's wife). A 74-year-old male patient (husband) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number: EL1283) at 0.3 mL single on 20Jan2021 for COVID-19 immunization. Medical history included thyroid; hypertension, was under control with the medication; dementia, taking memantine as a treatment for dementia, no other impairment other than what he normally has from his dementia. Concomitant medications included levothyroxine; memantine for dementia; fish oil tablet; Vitamins. Patient had a mild heart attack and a slight stroke and he did have urinary tract and blood infection on 24Jan2021. They both had the first dose of the Pfizer covid vaccine on 20Jan2021, Saturday night into Sunday. He was a dementia patient, alert to his name. On 24Jan2021, he fell out of bed and couldn't get up, he was flushed, so patient's wife took his temperature, he had a fever of 101. Patient's wife couldn't move him, so called the paramedics and they took him to Hospital. Patient's wife just found out that he had a very mild heart attack and slight stroke, no impairment other than what he normally had from the dementia. Patient's wife was wondering should he get the second shot and what was the timing of the 2nd dose of vaccine. Reporter seriousness for mild heart attack, slight stroke, urinary tract and blood infection was hospitalization. They also have him on some sort of penicillin derivative for a urinary tract infection. Since he had been to the hospital, he had at his doctor's office about 2 weeks ago today, he had a blood test, a urine test. His A1C was 6.5, there was a little blood in his urine. For that since Sunday (24Jan2021) he was having MRI, he had a couple of PET scans, he had an electrocardiogram. The neurologist came in to check on him. He was in hospital now. Hospitalization date was 25Jan2021 early in the morning. The outcome of events was unknown.
COVID19 VACCINE	PFIZER\BIONTECH	1024099-1	65+ years	0 days	I am the discharging physician and did not admit her but based off the information at admit: the patient received her Pfizer vaccine and developed nausea during her observation time but it was not significant enough to cause concern for the family. They took her home in good spirits and she appeared to be doing well until the evening when she became unresponsive. She developed high fevers and came to the ER with low normal O2 saturations and evidence of sepsis. Blood work showed a markedly elevated white count and an elevated lactic acid of 8 along with an elevated renal function and cardiac enzymes without EKG changes (multiorgan failure). Her COVID test was negative. Blood and urine cultures were negative. A CT scan of the abdomen demonstrated no acute findings but likely chronic fecal impaction. CT Head was negative for bleed or stroke. At this time is is unclear as to what was the cause of her symptoms but we believe it was presumed bacterial sepsis but this diagnosis is in question as all her cultures were unremarkable. The family opted on comfort measures rather than aggressive intervention and she was sent home with hospice. Since it occurred so closely after receiving the vaccine I think it was worthwhile to bring it to your attention.
COVID19 VACCINE	PFIZER\BIONTECH	1024451-1	65+ years	1 day	CHF, Resp failure, intubated, on Levophed, suspected septic and cardiogenic shock.
COVID19 VACCINE	PFIZER\BIONTECH	1026952-1	65+ years	8 days	1st dose COVID vaccine 1/30/21; developed shortness of breath 2/7/21; worsening symptoms SOA, falls, chest pain; seen in ED on 2/12/21; Admitted to Hospital for severe sepsis, acute respirator failure.
COVID19 VACCINE	PFIZER\BIONTECH	1033131-1	65+ years	3 days	Patient received initial COVID vaccine on 2/11/2021 at Clinic. Direct observation for 15 minutes and no documentation noting an adverse reaction. On 2/14/2021 was diagnosed with Sepsis secondary to pneumonia, started on antibiotic therapy, cardiac arrested, and expired on 2/14/2021 while at Hospital.
COVID19 VACCINE	PFIZER\BIONTECH	1033218-1	65+ years	3 days	patient presented to ED with weakness, altered mental status. Admitted to the hospital with urosepsis, acute on chronic kidney injury, elevated lactate and BNP
COVID19 VACCINE	PFIZER\BIONTECH	1033447-1	30-39 years	15-30 days	1/21/21 pt started experiencing fever about 3:30 PM, went to Urgent care received rapid COVID test which was negative, 1/22/21 still has fever drive thru at hospital covid drive thru pt had PCR and it was also negative, went back to same drive thru on 1/24/21 and had another PCR which was negative, 1/25/21 urgent care visit, pt was tested for flu-Negative, lab work was done which showed CBC all counts were low resulted in ER visit, admitted 1/25/21 afternoon with panside apnea and sepsis and patient stayed in hospital for 9 days 2/2/21 pt was released to go home. Lots of labs and test were done while patient was inpatient, Pt is still weak and has no energy.

COVID19 VACCINE	PFIZER\BIONTECH	1035539-1	65+ years	Unknown	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
COVID19 VACCINE	PFIZER\BIONTECH	1039597-1	60-64 years	15-30 days	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"""""
COVID19 VACCINE	PFIZER\BIONTECH	1040308-1	65+ years	0 days	Pfizer-BioNTech COVID-19 Vaccine EUA Patient presented to the ER on 2/14/21 after experiencing night sweats, fevers, urinary incontinence, flank pain, and generalized fatigue for 5 days. Admitted and treated empirically for sepsis. No source of infection found, fevers continued on IV antibiotics.
COVID19 VACCINE	PFIZER\BIONTECH	1041983-1	65+ years	15-30 days	Admitted with covid pneumonia, Acute hypoxic respiratory failure, currently in ICU ventilator dependent respiratory failure. Patient tested 1/26 with 1/29 positive results. never symptomatic. presented to receive covid vaccine and received it on 2/1, (reportedly discussed with a physician to make sure getting vaccine was ok) Then hospitalized 2/11 with urosepsis and discharged 2/14. 2/15 presented to oncology office with o2 sats 78% on RA. transported to Hospital.
COVID19 VACCINE	PFIZER\BIONTECH	1041990-1	65+ years	15-30 days	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
COVID19 VACCINE	PFIZER\BIONTECH	1044185-1	50-59 years	6 days	She received 2nd COVID vaccine on 1/7//21. On 1/13/21, she developed sore throat, earache, dizziness, dyspnea, diarrhea, vomiting and fever. She required hospitalization on 1/18/21 for Acute hypoxic respiratory failure secondary to bilateral Pneumonia with left pleural effusion. Sepsis secondary to Gram-Positive bacteremia (strep pneumococcus). UTI. Acute Kidney Injury
COVID19 VACCINE	PFIZER\BIONTECH	1046447-1	30-39 years	1 day	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
COVID19 VACCINE	PFIZER\BIONTECH	1046588-1	65+ years	2 days	Presented to ER with subsequent admission two days after receiving second dose of COVID 19 vaccine with Lactic Acidosis/Sepsis. She was hospitalized for 4 days

COVID19 VACCINE	PFIZER\BIONTECH	1048211-1	60-64 years	8 days	a genitourinary infection (UTI)/diagnosed with a gram negative urinary tract infection; iron level was low at 21. He said a normal iron level for a male is 35; couldn't walk afterwards; Tiredness; another soft tissue injury; Headache; left eye was totally blurry/ one eye blurriness; has severe eye dryness; Injection site pain; Injection site redness; injection site puffiness; stated he noticed at around 2:30PM-3:00PM he had a rash on his hip and back; shingles/ shingles pain; a fever of 100.4 Degree F/Fever; This is a spontaneous report from a contactable pharmacist (patient) reported similar events for two patients. This is the first of two reports. A 64-year-old male patient receive first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL3246), at same age intramuscular in arm left on 16Jan2021 11:00 at single dose for COVID-19 immunization. Medical history included fallen at work and landed on his left side, hitting his head and left knee, a knot on the left side of his head, bleeding from above his left eyebrow, had a left black eye, all on Nov2020, subarachnoid hemorrhage, cataract surgery, using crutches when he walks, in the hospital from Nov2020 to 17Nov2020, pacemaker implanted while he was in the hospital on Nov2020, he couldn't walk on 19Nov2020, 6 stents, 3 cardiac stents on Oct2020, and chicken pox as a young adult. Concomitant medication included aspirin [acetylsalicylic acid], clopidogrel bisulfate (PLAVIX) from unspecified date to 27Jan2021 for 6 stents, paracetamol (TYLENOL, 500 mg, caplets, NDC Number: 5058044936, Lot Number: SJA066 and Expiration Date: Jul2024). The patient said he received his first COVID-19 Vaccine dose on 16Jan2021. He said at the time he pre-medicated with 2 paracetamol. He said he had read afterwards that it is not recommended to pre-medicate with Tylenol before receiving the COVID-19 Vaccine. On 24Jan2021 he developed a fever of 100.4 Degree F (body temperature). He stated his fever was 8 days after receiving his first COVID-19 Vaccine dose. On 27Jan2021, he was urinating blood/blood clots and was admitted to the hospital and treated for a UTI. He was diagnosed with a genitourinary infection (UTI). He clarified on the morning of 27Jan2021 his urine looked darker than normal. He said he went to physical therapy (PT) on 27Jan2021. He said when he came back from PT, and went to the bathroom, there was blood and blood clots in his urine. He said he called his urologist, and his urologist saw him on 27Jan2021. He said his urologist took a urine sample, and his urine sample was clear and negative for nitrites. He clarified his urologist did a digital prostate exam, and his prostate was fine. He said his urologist wanted him to make an appointment for a cystoscopy, and a CAT scan of his abdomen and pelvis. He said after he got home from the urologist, he went to the bathroom, and again had blood and blood clots in his urine. He went to emergency room. While he was in the Emergency Room, he was set-up on CBI (Continuous Bladder Irrigation). He said the urologist did not seem concerned about the amount of blood in his urine. He clarified he was admitted to the hospital, and had in place for approximately 16 hours. Next day (28Jan2021) he was diagnosed with a gram negative urinary tract infection. He said he was given a daily dose of IV Ceftriaxone 1gram on 29Jan2021 and 30Jan2021. He said he was also given a daily dose on 29Jan2021 and 30Jan2021 of IV Ferrlecit 125mg because his iron level was low at 21. He said a normal iron level for a male is 35. On 31Jan2021 he had injection site pain in his left arm, he said the COVID-19 Vaccine injection site was red and puffy. He said the COVID-19 Vaccine injection site pain, redness, and puffiness resolved on the same day,
COVID19 VACCINE	PFIZER\BIONTECH	1048686-1	Unknown	Unknown	died just 10 days after being given the vaccine/ put sepsis on her medical records; This is a spontaneous report from a contactable consumer report for Aunt. A 59-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in Jan2021 at single dose for COVID-19 immunization. Medical history included schizophrenia and depression. The patient's concomitant medications were not reported. Consumer's aunt (patient) was housed in a facility. She was being treated for schizophrenia and depression. This was one of the facilities that chose to house Covid patients during the pandemic. Many of the patients here contracted covid19 during this time and they had to do a full facility lockdown and quarantine. The patient tested positive in Nov2020 and was quarantined to her room for 10 days. 3 weeks ago (in Jan2021), she received the Pfizer vaccine. Consumer's family was not given notice of this and we are sad to report that she died just 10 days after being given the vaccine. They put sepsis on her medical records and have not connected this to the vaccine. Consumer stated aunt was just 59 yrs old, though she was being treated for her mental illness, she was physically healthy. Consumer's family gravely concerned that this facility neglected her health by administering the vaccine without considering possible reactions from the medication she was taking, or the fact she had Covid just months prior. Patient died on an unspecified date. it was unknown if an autopsy performed. Information on Lot/Batch number has been requested.; Reported Cause(s) of Death: died just 10 days after being given the vaccine/ put sepsis on her medical records

COVID19 VACCINE	PFIZER\BIONTECH	1054592-1	65+ years	31-60 days	Resident expired on 2/24/21, under hospice care.
COVID19 VACCINE	PFIZER\BIONTECH	1055203-1	65+ years	1 day	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.
COVID19 VACCINE	PFIZER\BIONTECH	1055298-1	65+ years	15-30 days	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. 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 Discharge Condition: expired. Presume cause of death with cardiopulmonary arrest secondary to acute respiratory failure secondary to coronavirus (COVID-19) pneumonia Disposition: Deceased
COVID19 VACCINE	PFIZER\BIONTECH	1057565-1	Unknown	Unknown	He had an infection, a UTI, Sepsis; He had an infection, a UTI, Sepsis; walking to the car when he started shaking; he felt freezing; This is a spontaneous report from a contactable consumer. This consumer reported for a male patient (reporter's husband). A male patient of an unspecified age received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. Report's husband who got his first vaccine at the same time (unknown date reported as two and a half weeks ago) as the reporter, she was walking to the car when the patient started shaking and said he felt freezing on unknown date. Later that night reporter had to call an ambulance. He was rushed to ER (emergency room) and hospitalized for 5 days. The patient had an infection, a UTI, Sepsis. He did not know had a UTI and the doctors believe that between the COVID vaccine and infection the two went crazy and beat up on each other. The patient was in the hospital for five days after his COVID shot. It was a combination of an infection and he didn't know and didn't have any symptoms. The two just clashed. He was very sensitive about it. He was feeling better and clean and clear. He was getting the second one. The outcome of events was recovering. Information about lot/batch number has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1058604-1	65+ years	3 days	Patient was found on bathroom floor by spouse @ approximately 02:30 am (2.5 days after receiving 2nd dose of Covid-19 vaccine). He had fallen and had an obvious head injury & demonstrated altered mentation from usual baseline. Family utilized 911 to transport him to local ED. He was febrile upon arrival to ED and admitted for severe sepsis with unknown etiology. He was found to have positive SIRS criteria and elevated LA. He was admitted to hospital and received IV antibiotics for 11 days (spent 7 days as an inpatient and completed remaining infusions in home environment)
COVID19 VACCINE	PFIZER\BIONTECH	1061380-1	65+ years	0 days	Received the vaccine & the next day became very weak and ill with throwing up. Her sister came to visit and noticed her right face was drooping & her balance was off so she called ambulance. Subsequently has been hospitalized for a month with a heart failure exacerbation that has led to ICU care, sepsis with Klebsiella pneumonia, acute kidney injury now with long term dialysis, hyponatremia, & elevated liver enzymes
COVID19 VACCINE	PFIZER\BIONTECH	1063984-1	65+ years	1 day	Patient had her second COVID vaccine on 2/20/21. The next day she developed diffuse body aches. She went on to develop worsening dyspnea and fever to 103¶F on February 23. She had a fever again on February 24. The patient also experienced a few episodes of vomiting and diarrhea but no abdominal pain and had pain of the legs, right greater than left. Blotchy red patches of the hands and arms developed. She therefore presented to the ER on 2/25/21. See full history below from infectious disease note on 3/1/21: Patient is an 80 year old female who has a past medical history notable for hypertension, dyslipidemia, and hypothyroidism. The patient was diagnosed with a high-grade lymphoma of the retroperitoneum in 2004 and completed 4 cycles of multi-chemotherapy (Cytoxan, Adriamycin, vincristine, methotrexate, and IT chemotherapy (Magrath-like regimen)). She completed 4 cycles with complete remission on PET scan. The biopsy of a left cervical lymph node in 2007 revealed follicular lymphoma and she completed radiation therapy to the neck with complete remission. A left axillary lymph node biopsy in 2016 revealed grade-3 follicular lymphoma with mixed follicular and diffuse histology. Chemotherapy was pursued. The biopsy of a pelvic lymph node in 2019 was consistent with G1-2 follicular lymphoma. ·She completed radiation to the pelvis in May of 2019. ·She developed progressive pelvic adenopathy in April of 2020 and received 5 cycles of chemotherapy. Subsequent CT showed improvement in the adenopathy. ·Her course was complicated by pulmonary emboli (September 2020). ·In November of 2020 she was started on maintenance Rituxan every 2 months. ·She received the 2-dose Pfizer COVID vaccine series on 1/29/21 and 2/20/21. With the above background, the patient presented to the emergency room on February 25, 2021 with complaints of diffuse body aches, which had developed that day after receiving her second dose of COVID-19 (SARS-CoV-2) vaccine. ·She went on to develop worsening dyspnea and fever to 103¶F on February 23. ·She had a fever again on February 24. The patient also experienced a few episodes of vomiting and diarrhea but no abdominal pain and had pain of the legs, right greater than left. Blotchy red patches of the hands and arms developed. ·She called Oncology on February 20 and it was recommended that she go to the emergency room for evaluation. · She was afebrile on presentation to the emergency room. ·She was tachycardic, however, with a pulse rate of 117 bpm. ·She was breathing at 48 breaths per minute. ·Blood pressure was 105/80 mmHg. ·Oxygen saturation by pulse oximetry was 96%. Examination was notable for paraspinous muscle tenderness, tachypnea, mild respiratory distress, and a mildly distended abdomen. ·Mild erythematous patches of the feet and forearm were noted, as well as evidence of edema of the right leg from the knee to the lower leg. The peripheral blood leukocyte count measured 0.8x10e3/¶L. ·ANC was 0.48x10e3/¶L. ·Platelets measured 96x10e3/¶L. ·Creatinine was 0.97 mg/dL. ·AST was 86 and ALT 20 U/L. The lactic acid level of the venous blood was 3.6 mmol/L. The procalcitonin level of the blood measured 28.37 ng/mL. The C-reactive protein level was 313.7 mg/deciliter. The creatine kinase (CK) level was 4023 U/L. ·LDH measured 314 U/L. Troponin was 3.22 ng/mL. ·Urinalysis showed 6-10 wbc?s, 0-2 rbc?s/hpf, 3+ blood, negative nitrites, hyaline and granular casts as well as amorphus crystals. A chest radiograph showed possible, but not definite, mild atelectasis or infiltrate at the left lung base. ·A radiograph of the right tibia/fibula showed circumferential soft tissue edema seen within the
COVID19 VACCINE	PFIZER\BIONTECH	1067143-1	30-39 years	10-14 days	On 02.24.21 in the evening I began experiencing body aches. The following day I had a fever of 100.8 and saw an Urgent Care provider who referred me to the hospital. Upon arrival my fever spiked to 102.3, bloodwork showed elevated lactate at 2.4 and pulse rate was over 119. I was admitted with sepsis symptomatology.

COVID19 VACCINE	PFIZER\BIONTECH	1067251-1	65+ years	3 days	she got the shot on 1/31/2021. Over the next 3 days she developed poor oral intake and diarrhea every 15 minutes; required hospitalization on 2/3/2021. Was hospitalized at Hospital. Hospital course was complicated by sepsis, pressors, intubation, GI bleed with ruptured rectum requiring surgery (ostomy). anticipated discharge 3/3/2021.
COVID19 VACCINE	PFIZER\BIONTECH	1068884-1	65+ years	10-14 days	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
COVID19 VACCINE	PFIZER\BIONTECH	1071814-1	65+ years	0 days	Fevers, sepsis being admitted to the hospital.
COVID19 VACCINE	PFIZER\BIONTECH	1072993-1	65+ years	1 day	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.
COVID19 VACCINE	PFIZER\BIONTECH	1084607-1	65+ years	7 days	Per the EUA, cases of COVID-19 vaccination that result in hospitalization or death are to be reported. This patient received Pfizer vaccine on 2/26/2021. Patient is admitted for sepsis secondary left diabetic foot ulcer.
COVID19 VACCINE	PFIZER\BIONTECH	1094488-1	40-49 years	5 days	patient administered vaccine at another facility and presented to this facilities ED on 2/24. Patient with multiple comorbidities: Bipolar disorder, parkinsons, PD, COPD, DM, PVD, GERD, HTN, Dyslipidemia, sleep apnea. H/O CVA, has sacral decubitus and cellulitis of pannus. presents with sepsis likely secondary to cellulitis of pannus. Admitted for care then discharged on 2/26
COVID19 VACCINE	PFIZER\BIONTECH	1095503-1	65+ years	15-30 days	Adverse reaction was not to the immediate vaccine. The adverse reaction being reported is that patient has tested positive for COVID-19 on 3/10/21, almost 1 month after second vaccination. Pt has been hospitalized since 2/20/21 for 1. Suspected acute toxoplasmosis 2. Severe sepsis with encephalopathy, transaminitis and acute respiratory failure d/t #1. He had tested negative for COVID per NP PCR tests twice prior to testing positive for discharge to SNF with associated chest pains. This has prolonged his existing hospitalization

COVID19 VACCINE	PFIZER\BIONTECH	1095588-1	65+ years	1 day	Pfizer COVID-19 Vaccine EUA 3/2: Pt received Pfizer vaccine 2/26/2021 and started feeling progressively worse - endorsed fever, diarrhea, body aches, trouble breathing, lack of appetite. On 3/2/2021 pt and husband presented to ED. Pt's husband stated that pt had become more and more confused since she received the vaccine and that on 3/2 she could not complete her sentences. Temp 101.6 on arrival, tachycardic in 130s, tachypneic in 120s, but not hypoxic. Patient was given acetaminophen on arrival. IV was inserted and patient was given 1 L intravenous fluid replacement as well as 2 g ceftriaxone for broad-spectrum coverage within 3 hours of arrival. Blood work was drawn that shows no leukocytosis but lactic acidosis to 3.3. There are multiple electrolyte abnormalities, hyponatremia 127, hypokalemia 2.8, creatinine 1.01, ALT 59 AST 53, ALP 136, total bili 1.3, lactic acidosis 3.3, troponin 0.02. Patient was given 40 mEq of oral potassium. Additional L of normal saline was given for total of 2 L normal saline bolus. Chest x-ray shows right basilar pneumonia. Also shows pulmonary nodule of which husband was made aware. LFTs are noted be elevated, so biliary ultrasound was obtained that was negative with limit to body habitus. Husband was updated. Azithromycin was added on. Rapid COVID antigen was negative. 3/3/21: Febrile, SOB overnight. Pt more lethargic, trailing off in the middle of sentences and having difficulties following conversation. Continue sepsis protocol, add vancomycin IV to ceftriaxone and azithromycin. Frequent neuro checks. MRCP. Chest pain-free, serial cardiac enzymes from yesterday to demonstrate nonischemic pattern likely type 2 NSTEMI. 2/2 blood cultures from 3/2 positive for Streptococcus pyogenes (Group A). Vancomycin and azithromycin dc'd. 3/11: Discharged from hospital. Patient admitted for acute hypoxic respiratory failure secondary to right basilar community-acquired pneumonia. Blood culture grew Streptococcus pyogenes, patient was initially treated with ceftriaxone and switched to Ancef . repeat blood culture on 03/04/2021 showed no growth. Patient will complete a total 14 day course of antibiotics with amoxicillin from culture negative date. Patient had right-sided pleural effusion, pulmonary consulted and she underwent thoracentesis x2 culture showed no growth, considered parapneumonic effusion. Patient required 2 L continuous oxygen and deemed stable for discharge. She will follow up with Pulmonary in 3 weeks, outpatient chest CT in 4-6 weeks to be ordered by Pulmonary to assess lung nodule and known thoracic aortic aneurysm. PTOT recommended home discharge with VNA. On discharge patient was a febrile and hemodynamically stable. Remained COVID negative throughout.
COVID19 VACCINE	PFIZER\BIONTECH	1098225-1	65+ years	0 days	On evening of vaccine, he began to run high fever of 101.5. next day 102. 3 with extended chills, Doctor was called and patient was told to take Tylenol, On second time Doctor was called, he was told to alternate Tylenol with ibuphrofen. Fever came down on 2/28 started back up on 3/2 , went to Er ON 3/4 FOR BREATHING ISSUES, a blood infection was found, went back to ER ON 3/8 FOR ANTIBIOTIC,(DOCTOR HAD WANTED HIM ADMITTED,THIS WAS NOT COMMUNICATED) , next day was admitted to Providence Hospital for IV antibiotics, dismissed from Providence on 3/13, with antibiotics infusion to continue at home.
COVID19 VACCINE	PFIZER\BIONTECH	1106311-1	Unknown	Unknown	double pneumonia and sepsis; double pneumonia and sepsis; This is a spontaneous report from a contactable consumer (patient). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration on 30Jan2021 as a single dose for COVID-19 immunisation. The patient's medical history was chronic obstructive pulmonary disease (COPD). The patient previously took prednisone for COPD. She has a history of COPD and prior to getting her first Pfizer vaccine, she was on prednisone and antibiotics and was not feeling well. Concomitant medications were not reported. When she got her first vaccine on 30Jan2021, she started having problems breathing and a high fever and thought it was related to the vaccine. She was admitted to the hospital last Tuesday and was diagnosed with double pneumonia and sepsis. The doctor said it was not related to the vaccine. She got out of the hospital on Saturday. She is still on prednisone and antibiotics and now on oxygen all the time. She is getting mixed messages from her doctors on whether or not to get her second vaccine tomorrow. Some say yes, others no. She has not felt well for the last 5 weeks. The patient underwent lab tests and procedures which included body temperature: high fever on an unspecified date. The outcome of the events was unknown.; Sender's Comments: Based on the information available the reported events are considered not related to suspect drug.

COVID19 VACCINE	PFIZER\BIONTECH	1106323-1	Unknown	Unknown	Sepsis; double pneumonia; This is a spontaneous report from a contactable consumer (patient's daughter). A 78-year-old female patient received her first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 30Jan2021 (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunization. Medical history included COPD from an unknown date. The patient's concomitant medications were not reported. Patient on tuesday (assessed as 2021) was hospitalized with double pneumonia and sepsis then was in the hospital until Saturday(assessed as 2021), when she was released. Patient is still on a breathing machine, which is not normal for her, and reporter is not sure if she should get the second dose of the vaccine which is scheduled for tomorrow since patient is still on antibiotics and Prednisone (assessed as treatment for sepsis and pneumonia). The outcome of the events was unknown. Information about lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1108886-1	65+ years	31-60 days	PFIZER-BIONTECH COVID-19 VACCINE EUA. PATIENT SENT TO HOSPITAL FROM NURSING HOME ON 3/15/21 WITH DIARRHEA, VOMITING AND AMS. ADMITTED AND REMAINS HOSPITALIZED ON 3/17. PATIENT TESTED POSITIVE FOR COVID-19 ON 3/15 AND HAS RECEIVED BOTH DOSES OF VACCINE MORE THAN 2 WEEKS AGO. HOSPITALIZATION REPORTED TO BE RELATED TO PATIENT SEPTIC WITH GI INFECTION. POSITIVE COVID INFECTION IS INCIDENTAL. PATIENT ON ROOM AIR. NO FINDINGS ON CHEST X-RAY.
COVID19 VACCINE	PFIZER\BIONTECH	1109696-1	60-64 years	4 days	Pt presented to the ER on 1/4 2021 with worsening sob, found to have acute ST elevation MI and new rapid atrial fib with RVR. He tested positive for covid 19 requiring new oxygen and received his first pfizer vaccine on 12/31. He was acutely transferred to rochester general hospital. He progressed to multiorgan failure, sepsis, mrsa bacteremia and died on 1/14/2021
COVID19 VACCINE	PFIZER\BIONTECH	1112425-1	65+ years	15-30 days	Progressive Left arm pain/shoulder soreness that began 5 days prior to hospital presentation. Seen in ambulatory clinic 7 days prior to presentation, given ibuprofen and percocet without relief. New swelling and erythema brought pt to hospital. Around time of vaccination, the pt was using triamcinolone for left forearm rash (described as small, more-spotty and resolved quickly). MRI revealed an abscess (10 x 6.8 x 1 cm) deep to the deltoid muscle and along the lateral aspect of the left proximal humerus. He also has another abscess within the posterior deltoid muscle (3.1 x 2.1 x 2.8 cm). There is surrounding myositis, fasciitis and cellulitis.
COVID19 VACCINE	PFIZER\BIONTECH	1113955-1	Unknown	Unknown	got hospitalized due to sepsis after the first dose.; This is a spontaneous report from a Pfizer-sponsored program, patient's daughter. A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration on 10Feb2021 as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The reporter asked to make a schedule change since her mother got hospitalized due to sepsis after the first dose. The first dose was on 10Feb2021, next dose is on 04Mar2021. The outcome of the event was unknown. Information about lot/batch number has been requested.
COVID19 VACCINE	PFIZER\BIONTECH	1114752-1	65+ years	15-30 days	12/31/2020: vaccine given 1/17/2021: symptom onset and subsequent hospital course: dyspnea, hypoxic, tachypnea, afib w/RVR, septic, NSTEMI
COVID19 VACCINE	PFIZER\BIONTECH	1116661-1	60-64 years	1 day	Patient was found in house by EMS with agonal respirations. Patient was intubated on scene and brought to ER. At ER, patient presented with a HR of 55, BP of 80/43, O2 of 99%, and a rectal temperature of 107.3F. Further work-up revealed thrombocytopenia with a platelet count of 63, WBC of 13.7, and an elevated lactate of 2.2. Imaging shows a kidney stone obstruction of the right ureter. Diagnosis of sepsis was made with patient admitted to the hospital. Repeat rectal temp after acetaminophen suppository and external cooling continues to be 107. Care is ongoing at time of this report.
COVID19 VACCINE	PFIZER\BIONTECH	1124124-1	18-29 years	2 days	29 y/o female presented to hospital with complaints of SOB, skin flares secondary to history of discoid lupus, protracted vomiting, and joint pain. Side effects began 2 days after her 2nd COVID vaccine. Pt was transferred to hospital from another institution due to O2 sat in the 60s (room air), leukocytosis, and AKI. Patient was treated empirically for sepsis/pneumonia as well as lupus flare. She was also initiated on high dose steroids. Possible reaction to vaccine. Chest CT showed diffuse ground-glass opacities and no signs of pulmonary embolism. Pt was transferred from hospital to another facility given progressive organ failure, most specifically liver failure.

COVID19 VACCINE	PFIZER\BIONTECH	1124281-1	65+ years	10-14 days	79 yo with HFpEF, CKD, neurogenic bladder with chronic indwelling Foley admitted to Facility 01/21/21-01/28/21 with recurrent c. difficile/sepsis. Received COVID vaccine on 2/3/21 as outpatietn. Readmitted to Facility on 02/16/21 with sepsis with E. coli BSI from GU source, recurrent/persistent c. difficile colitis. Worsening sepsis. Family transitioned goals from full code to DNR/DNI and then to CMO. Patient expired 02/18/2021.
COVID19 VACCINE	PFIZER\BIONTECH	1125607-1	65+ years	15-30 days	Shortness of breath sepsis AKI (acute kidney injury) (CMS/HCC) Atrial fibrillation with rapid ventricular response (CMS/HCC) Acute respiratory failure with hypoxia (CMS/HCC) Pneumonia of both lower lobes due to infectious organism
COVID19 VACCINE	PFIZER\BIONTECH	1125655-1	65+ years	15-30 days	CHEST PAIN SHORTNESS OF BREATH Shortness of breath Pneumonia Elevated troponin Elevated CK Acute chest pain Elevated lactic acid level Pneumonia of both lungs due to infectious organism, unspecified part of lung Ground glass opacity present on imaging of lung Leukocytosis, unspecified type Hematuria, unspecified type Sepsis
COVID19 VACCINE	PFIZER\BIONTECH	1127472-1	65+ years	0 days	Fever, low oxygen saturation, severe encephalopathy, kidney failure, bilateral pulmonary infiltrates, sepsis, tachycardic, acidotic, intubated on ventilator since admission, paralyzed/sedated, ABG results showed high CO2 and O2 retention, edema, electrolyte imbalance, ARDS, low hemoglobin and hematocrit levels, blood transfusion needed
COVID19 VACCINE	PFIZER\BIONTECH	1130351-1	65+ years	1 day	Patient is a 74 year old y.o. female with history of atrial fibrillation, hypothyroidism who presents with acute onset early this a.m. nausea vomiting and change in mental status. History was obtained from the husband as patient is minimally responsive to verbal stimuli at this time. He states she was in her usual state of health until when she awoke this morning. Yesterday in usual state of health that she did have her 2nd COVID vaccine with the Pfizer variant. He states that day she was in her usual state of health with some mild arm pain on the left where she received the vaccine. This morning she awoke with a headache, fever, chills however was ambulating and conversing appropriately. She had no appreciable focal deficits at that time per the husband. She ate breakfast however she subsequently began vomiting. She progressed to a change in mental status with minimal responsiveness. She would say 1 or 2 words and that was it. They then presented emergency department. Diagnosed with severe sepsis, acute encephalopathy, acute meningitis, liver shock, autoimmune hepatitis, ascending cholangitis, acute pancreatitis.
COVID19 VACCINE	PFIZER\BIONTECH	1130394-1	65+ years	3 days	The patient initially presented (3/3/21) with headache, fevers, nausea, vomiting, diarrhea, myalgias, malaise. Patient related she was in her normal state of health and only started to feel poorly after she received her second COVID-19 vaccination three days earlier. She interestingly related that after her first Pfizer COVID-19 vaccination she had significant burning in her stomach that she noted but no other major symptoms and notably did not experience this severe burning in her stomach after the second dose. She denied any chest pain, current dyspnea, productive cough, sore throat, urinary symptoms, sick contacts. She has no history of C. difficile, no recent antibiotics, no recent spoiled foods, no recent travel, no history of radiation. She does have a history of GERD and has had gastritis with mild gastrointestinal bleeding in the past and undergone EGD negative for H. pylori infection. She also has undergone colonoscopies with polyps that have been removed and reported as tubular adenomas. As her hospitalization progressed, she was diagnosed with Severe Sepsis due to E. Coli bacteremia in setting of liver abscess, Cholelithiasis without acute cholecystitis, Atrial Fibrillation with rapid ventricular response, Transaminitis (which resolved). Patient was appropriately treated for these conditions. Also, her known uncontrolled diabetes was treated. Per an Infection Disease note on 3/9/21: The patient has had hx of biliary colic (self diagnosis) now with discovery of non-obstructive cholelithiasis on RUQ US it is plausible that the abscess originated from self limiting cholecystitis/cholangitis which would be consistent with recent abdominal pain exacerbated with oral intake. Difficult to state definitively any relation to COVID-19 vaccination, though may have resulted from associated dehydration. Additional COVID vaccine info (both Pfizer): first dose: 2/7/21 lot# EN 5318 second dose: 2/28/21 lot# EN6202
COVID19 VACCINE	PFIZER\BIONTECH	1131598-1	65+ years	15-30 days	shortness of breath AKI (acute kidney injury) (CMS/HCC) Atrial fibrillation with rapid ventricular response (CMS/HCC) Acute respiratory failure with hypoxia (CMS/HCC) Pneumonia of both lower lobes due to infectious organism sepsis death

COVID19 VACCINE	PFIZER\BIONTECH	1132146-1	65+ years	31-60 days	Patient tested COVID+ 2/1, admitted 2/21 (20 days prior to admission). Vaccine 12/26, 1/20. Primary dx at DC Ecoli Sepsis from UTI. Treated PNA w/antibiotics. DCd
COVID19 VACCINE	PFIZER\BIONTECH	1136470-1	65+ years	10-14 days	SYNCOPE, fall, head contusion FATIGUE DIARRHEA Pneumonia due to SARS-associated coronavirus Diverticulitis Hyponatremia Hypoxia Sepsis, due to unspecified organism, unspecified whether acute organ dysfunction present (CMS/HCC)
COVID19 VACCINE	PFIZER\BIONTECH	1143222-1	65+ years	15-30 days	CHEST PAIN WEAKNESS - GENERALIZED Hyperkalemia Lactic acidosis Hyponatremia SEPSIS EKG abnormalities Acute kidney injury (CMS/HCC) Neutropenia (CMS/HCC) DEATH
COVID19 VACCINE	PFIZER\BIONTECH	1145472-1	65+ years	10-14 days	Acute respiratory failure due to COVID-19 (CMS/HCC) Sepsis
COVID19 VACCINE	PFIZER\BIONTECH	1146436-1	65+ years	4 days	Covid-19 weakness diarrhea pneumonia hypoxia Acute Kidney Injury Sepsis
COVID19 VACCINE	PFIZER\BIONTECH	1150959-1	65+ years	8 days	sepsis; gallbladder attack; passed out from the gallbladder attack; Gets dizzy; Weakness; she was trying to gain her strength from being sick; her head hurt from the fall; her head hurt from the fall; she had to walk slower because she got dizzy; This is a spontaneous report from Pfizer. A 68-year-old female contactable consumer reporting for herself received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot EN6200, expiry date Jun2021) on 16Feb2021 at 14:45, in left arm, for COVID-19 immunisation. The patient received the COVID-19 vaccine for age and several comorbidities. No other vaccines were administered within 4 weeks. Medical history included ongoing high blood pressure diagnosed 25 years ago, ongoing hypothyroidism diagnosed 25 years ago, liver resection in 2007 for a benign tumor (she had not been sick and it was found accidentally), liver bile duct stopped up from 2017 and ongoing (due to scar tissue from the liver resection surgery; she had an emergency stent placed in her bile duct), chronic Crohn's disease, ongoing thyroid disorder. The patient previously received flu vaccines on unspecified dates for immunization experiencing unspecified side effects some years ago, but this past year she didn't have a reaction. The patient previously received pneumonia shots on unspecified dates since few years. Family history included gallbladder problems in her sisters and mother. Concomitant medications included oral amlodipine (manufacturer: Lupin, expiry date: 23Feb2022) from an unspecified date (a few years ago) and ongoing, 5 mg at night, for blood pressure, oral telmisartan (MICARDIS; manufacturer: Alembic, expiry date: 02Mar2022) from an unspecified date (few years ago) and ongoing, 80 mg at night, for blood pressure, oral metoprolol (manufacturer: Mylan, expiry date: 09Feb2022), from an unspecified date (few years ago) and ongoing, 25 mg twice daily, morning and night, for blood pressure, oral levothyroxine sodium (SYNTHROID) from an unspecified date (20 years ago or more), 75 ug daily in morning, with water, hour before any eating or other medications, for thyroid disorder. The patient experienced sepsis on 25Feb2021 with outcome of recovered on 03Mar2021, gallbladder attack on 24Feb2021 with outcome of recovering, passed out from the gallbladder attack on an unspecified date in 2021 with outcome of unknown, got dizzy on an unspecified date in 2021 with outcome of not recovered, weakness from being hospitalized on an unspecified date in 2021 with outcome of not recovered, she was trying to gain her strength from being sick on an unspecified date in 2021 with outcome of unknown, her head hurt from the fall on an unspecified date with outcome of unknown. The patient was hospitalized for sepsis due to a gallbladder attack from 25Feb2021 to 03Mar2021. The events gallbladder attack and sepsis required also an ER visit. They did not require a physician office visit. Additional clinical course of the events included the following details. Gallbladder attack turned into infection/sepsis quickly. She previously had an emergency stent placed in her bile duct and now there was a stone in the bile duct and she was unsure if it was related; they will either remove her gallbladder or place a permanent stent. They removed stones and ""goop"" and placed a stent. Her gallbladder still needed to be operated on, but she was not sick with sepsis anymore. Regarding gallbladder attack the patient reported that it was controlled until further tests and surgery were performed. They couldn't do the surgery due to the infection which had cleared up but she did not want the surgery right now. A stent was placed in the duct until something was done and the stone will

COVID19 VACCINE	PFIZER\BIONTECH	1154141-1	65+ years	15-30 days	loss of appetite, abdominal pain, weight loss, death Narrative: 02/12/21: GI VISIT-ASSESSMENT: 1-R/O Gastric or Cecal Cancer with Peritoneal Carcinomatosis is most the cause of his weight loss and early satiety. Liver and Pancreas on CT Scan unremarkable. 2- Weight loss and early satiety may be due to Gastric Mass with metastasis or Colon Mass. 02/17/21: ED VISIT AND ADMISSION w/ CC 4 weeks of poor appetite and 2 weeks of inability to hold down food and abdominal pain, decreased BM and decreased urination Assessment on admission: acute kidney insufficiency, Possible partial Gastric outlet obstruction 2/2 malignancy, GI malignancy with peritoneal carcinomatosis as per CT scan 2/11, asymptomatic bacteruria hyperkalemia and AKI during admission 02/21/21: pt signed out of hospital AMA due to 'personal problems' 02/22/21: pt returned to hospital for continuation of care and was readmitted with same c/o 02/24/21: pt tachycardic and hypotensive w/ altered mental status; rapid response team called, transferred to icu; impression: acute severe sepsis with uremia; during procedure to place nephrostomy tubes, pt goes into wide complex vtach then vfib and ACLS done w/ compressions, ROSC @ 2255 w/ BP 70-41, Norepi started; pt intubated 02/25/21: pt extubated 02/25/21@2106: pt with inferior lateral stemi 03/01/21: pt w/ sudden deterioration with decreased LOC and increased WOB., intubated, found to be profoundly hypoxemic, developed severe metabolic acidosis and hyperkalemia, severe refractory hypotension 03/02/21: pt unresponsive without pulse or respirations, NOK declined autopsy no prior covid infection noted, no immediate reaction after covid vaccine, pt was hospitalized leading up to death with unrelenting abdominal pain, AKI, metabolic abnormalities. It is unlikely that vaccine led to patient's death.
COVID19 VACCINE	PFIZER\BIONTECH	1160210-1	65+ years	7 days	Patient was a 79 yo F who presented to hospital on 1/29/2021. On admission patient was severely hypoxic with symptoms of SOB, cough, and severe dyspnea . The patient was COVID-19 positive on admission with symptoms starting 4 days prior to admission. Patient's labs on admission showed elevated ferritin, CRP, and d-dimer. Patient was diagnosed with COVID-19 infection with sepsis and respiratory failure with hypoxia. On arrival to hospital patient's O2 sats were in 60's and improved to upper 80s after nebulizer treatment. Patient was started on azithromycin 500mg once daily for 3 days, ceftriaxone 2g once daily for 2 days, dexamethasone 6mg once daily for 3 days, zinc 220 mg once daily for one dose, and duo-neb 3ml q4h for 3 days. Patient's respiratory status declined and was placed on BiPAP and comfort measures. The patient continued to decline until her passing on 2/3/2021.
COVID19 VACCINE	PFIZER\BIONTECH	1168255-1	18-29 years	2 days	Hospitalization with pneumonia and E coli sepsis on 4/2/2021 Symptoms started with sore arm on 3/30/2021. Patient called healthcare provider on 3/31/2021 because patient developed headache, myalgias, fatigue, fever to 100. On 4/2/2021, patient presented to ER and admitted to hospital with fever, chills, shortness of breath, productive cough, labored breathing. CXR showed left upper lobe pneumonia and small pleural effusion. Blood culture subsequently grew E. coli. Work up for source of E. coli is ongoing including CT scan due to patient's history of rectal inflammation and presacral abscess several months back.
COVID19 VACCINE	PFIZER\BIONTECH	1191410-1	65+ years	2 days	3 days after the covid-19 vaccine, she had a seizure and was taken to the hospital. She was diagnosed with sepsis and died 02/22/2021.
COVID19 VACCINE	PFIZER\BIONTECH	1192142-1	60-64 years	10-14 days	61 yo male w/ history of DM, HTN, CKD IV and sleep apnea presents on 4/9/2021 with dsypnea that started while sleeping last night around 10PM. Also c/o cough , fatigue, diffuse wheezing. Had temp 99.9, chills. Does not use home oxygen and never smoked. Does not use a CPAP machine for his sleep apnea. He denies any recent ill contacts or new illness. diagnosed with sepsis and severe b/l pneumonia and significant hypoxia and admitted to the hospital on ivf, abx, oxygen. Currently follows with wound care for a right foot ulcer and is taking ciprofloxacin. For his diabetes he requires U-500 insulin. Today in ED he is on 5L oxy mask due to hypoxia. Noted to have leukocytosis. Normal lactate. CXR suggestive of pneumonia with bilateral diffuse consolidations.
COVID19 VACCINE	PFIZER\BIONTECH	1200619-1	65+ years	4 days	Death Sepsis abdominal pain
COVID19 VACCINE	PFIZER\BIONTECH	1200851-1	65+ years	31-60 days	Acute hypoxemic respiratory failure (CMS/HCC) Chest pain sepsis Death
COVID19 VACCINE	PFIZER\BIONTECH	1202742-1	65+ years	15-30 days	Vaccine 2/4, 2/25. Admit 3/25. Covid PNA and sepsis. Treated w/abx, steroid, and zinc. DCd to home.
COVID19 VACCINE	PFIZER\BIONTECH	1205690-1	60-64 years	31-60 days	Patient hospitalized for urosepsis, unlikely related to prior vavvine.
COVID19 VACCINE	PFIZER\BIONTECH	1207033-1	60-64 years	10-14 days	Pt received his 2nd covid 19 vaccination on 3/27/21. he was hospitalized on 4/10/2021 with severe bilateral pneumonia with hypoxia, respiratory failure and sepsis. He was treated with antbiotics, steroids, oxygen, nebulizers and discharged on 4/13/21

COVID19 VACCINE	PFIZER\BIONTECH	1207237-1	65+ years	10-14 days	Death Hypokalemia LBBB (left bundle branch block) Pneumonia Anemia Hypoxia Fever Multifocal pneumonia Pneumonia due to COVID-19 virus2.82 Sepsis
COVID19 VACCINE	PFIZER\BIONTECH	1209081-1	65+ years	9 days	Cardiac Arrest Death Sepsis due to methicillin susceptible Staphylococcus aureus
COVID19 VACCINE	PFIZER\BIONTECH	1209121-1	50-59 years	0 days	3/29/2021 Pfizer COVID vaccine #1. Reports feeling poorly since that day. 4/3/2021 ED visit for complaint of SOB, fever, body aches. Admitted for sepsis. 4/4 intubated. 4/12 extubated. 4/14 remains hospitalized. Workup negative for infectious cause. Oncologist consulted, does not appear cancer related. MD suspects reaction to vaccine.
COVID19 VACCINE	PFIZER\BIONTECH	1209158-1	65+ years	61-120 days	Death Sepis Acute Kidney injury
COVID19 VACCINE	PFIZER\BIONTECH	1212233-1	65+ years	4 days	death Weakness Fever Sepsis
COVID19 VACCINE	PFIZER\BIONTECH	1212771-1	65+ years	0 days	an 87 year old male with ESRD on PD, pAfib, CAD, HTN, HLD, hypothyroidism, who was brought in after a witness cardiac arrest. Patient apparently received the first dose of the Covid vaccine (pfizer) at around 11 am. He was doing fine the rest of the day until later in the evening when he had shortness of breath without chest pain, abdominal pain, nausea, vomiting. Upon EMS arrival, the patient appeared to have some agonal breathing and then went down, was in PEA arrest, received CPR with 1 dose of calcium, 1 dose of bicarbonate, and 3 doses of epinephrine with return of spontaneous circulation. Upon arrival in the ED, patient had an intraosseous line, on dopamine for soft blood pressure. Patient has been successfully intubated.
COVID19 VACCINE	PFIZER\BIONTECH	1213302-1	65+ years	15-30 days	He received his first COVID19 shot (Pfizer) reportedly on 3/2/21, then began a new chemotherapy regimen on 3/10/21. On 3/18, he fell to the floor and could not get up. He was admitted to the hospital for sepsis, pneumonia, and chemotherapy-induced neutropenia, treated on IV antibiotics and discharged on PO antibiotics. His home insulin was also decreased but continued to have hypoglycemic to hyperglycemic events. Insulin was decreased in clinic afterward and was compliant on antibiotics. Returned to hospital again a few days later for sepsis and pneumonia/effusion. He later went to a nursing facility / on hospice. He ultimately required supplemental oxygen and breathing increasingly became labored. Patient ultimately died on 4/9/21.
COVID19 VACCINE	PFIZER\BIONTECH	1214100-1	60-64 years	10-14 days	Thrombocytopenia AKI (acute kidney injury) Neutropenic fever C. difficile colitis Hypotension, unspecified hypotension type Sepsis
COVID19 VACCINE	PFIZER\BIONTECH	1214870-1	50-59 years	15-30 days	R06.03 - Respiratory distress J18.9 - Multifocal pneumonia K72.90 - Liver failure without hepatic coma, unspecified chronicity (CMS/HCC) U07.1 - COVID-19 A41.9 - Sepsis, unspecified organism
COVID19 VACCINE	PFIZER\BIONTECH	1215826-1	65+ years	15-30 days	I26.99 - Pulmonary emboli (CMS/HCC) J18.9 - Atypical pneumonia N17.9 - Acute kidney injury (CMS/HCC) R73.9 - Hyperglycemia A41.9 - Sepsis (CMS/HCC)
COVID19 VACCINE	PFIZER\BIONTECH	1218410-1	65+ years	7 days	Patient presented after falling on February 5 with injury to her scalp. She apparently also fell on 2/4/21. Family was uncertain as to whether patient loss consciousness. According to family, patient has been weak over the last day or 2 with no other complaints aside from some diarrhea. EMS was notified PM Feb 5, and the patient was found to have atrial fibrillation with elevated heart rate to the 160s and hypoxic to the low 80% range on room air. She had a low-grade temperature and elevated respiratory rate according to EMS. Evaluation in the ED demonstrated bilateral chest infiltrates on chest x-ray (right greater than left), elevated heart rate with atrial fibrillation, and back pain. Imaging demonstrated a T11 compression fracture (possibly new), elevated pro-calcitonin (2.80 ng/mL) and elevated troponin (1.45 ng/mL). Her venous blood gas showed mild hypoxemia (7.39/25/41/33/57), and head CT did not show acute changes and her cervical CT was negative for fracture. Pelvic x-ray did not show fracture. She was covid positive. Admitted for acute hypoxemic respiratory failure and severe sepsis secondary to COVID-19 pneumonia and acute metabolic encephalopathy. Received 3 days of remdesivir and 4 days of IV dexamethasone. Also ceftriaxone was given 4 days for possible UTI. Goal of care switched to inpatient hospice on 2/8/21.

COVID19 VACCINE	PFIZER\BIONTECH	1224697-1	Unknown	Unknown	He was septic; This is a spontaneous report from a contactable consumer. An 83-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number and expiration date unspecified), via an unspecified route of administration on 28Jan2021 as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient was septic. It was reported that his other vaccination was closely 21 days after that's okay, so they took him to primary care physician. He will be perused in rehab and they were supposed to do on 04Mar2021. They were asking if his second shot is going to be good. His primary care said it to Johnson and Johnson, but it was not supposed to mix them. Outcome of event was unknown. Follow-up attempts are completed. No further information is expected.
COVID19 VACCINE	PFIZER\BIONTECH	1229396-1	65+ years	3 days	Death R41.82 - Altered mental status N39.0 - Urinary tract infection N17.9 - Acute kidney injury (CMS/HCC) A41.9 - Sepsis (CMS/HCC)
COVID19 VACCINE	PFIZER\BIONTECH	1233385-1	65+ years	15-30 days	Pt presented with abd pain, dark stool, altered mental status, febrile, hypotensive, septic, cardiogenic shock, progressed to multi organ dysfunction.
COVID19 VACCINE	PFIZER\BIONTECH	1235811-1	50-59 years	15-30 days	COVID pneumonia; Hematological; bleeding; having hemoxysis; slight troponin increase; GI bleed; headaches; COVID-19 test was positive; COVID-19 test was positive; nauseous; abdominal discomfort; body aches; This is a spontaneous report from a contactable physician. A 52-year-old female patient received her first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration at the age 52-year-old on 12Mar2021 at single dose for COVID-19 immunisation. Medical history included hemodialysis for many years, adherent to medical care, multiple DVTs and Pes (On anticoagulants), morbid obesity, Patient was on dialysis for renal failure and had lupus anticoagulant (positive), Afib, allergic to shellfish. Family history included renal failure and had lupus anticoagulant. Concomitant medications included warfarin sodium (COUMADIN); metoprolol; amitriptyline; calcitriol; ergocalciferol (VIT D); calcium; calcium acetate (PHOSLO); amiodarone; albuterol. The patient previously allergic to Cipro, clindamycin, doxycyclin, Lyrica, tetracycline. The patient previously was non-responder to hepatitis B vaccine. The patient previously received first dose of BNT162B2(PFIZER-BIONTECH COVID-19 VACCINE) on 17Feb2021 for COVID-19 immunisation. The patient hasn't been treated with immunomodulating or immunosuppressing medications or received any other vaccines around the time of COVID-19 vaccination. The patient wasn't smoker/ former smoker. There was no any other vaccinations within four weeks prior to the first administration date of the suspect vaccine. A nephrologist who reported patient in her hemodialysis unit who were vaccinated with BNT162b2 but were recently diagnosed with COVID-19. More detail is below on each patient. The patient COVID results were sent to the local health department for genetic sequencing (pending) and SARS titers were drawn (pending). Unfortunately, the HD unit does not have B/L information (although the B/L # was put on the patient's COVID vaccine cards, a record was not kept in the HD unit). Day she came in for dialysis she was already short of breath she said she'd had body aches for 5 days, got short of breath on 05Apr2021. The day before, started getting cough, nauseous, chills, abdominal discomfort on 04Apr2021. The patient was sent to the ER from dialysis and was admitted for SOB on 05Apr2021 and passed away on 09Apr2021 due to a GI bleed. Patient is over 500lbs so was unable to fit into hospital imaging equiment for CT scans or weight measurements. COVID-19 test was positive on 05Apr2021; the patient experienced COVID pneumonia on 05Apr2021. The patient admitted on 05Apr2021 to regular floor. The patient was moved to an Intensive Care Unit on 06Apr2021. The patient experienced short of breath on 05Apr2021 and required much more O2 than normal. Sometimes required BP support while on Dialysis and BP was 113/61 in ER. Pressure dropped to 100/70 and required mitrodrine after fluid was removed. The patient needed 4 liters supplemental O2 vs. only needing 2 liters at home. The patient experienced tachypnea and hypoxemia and no Respiratory failure. Respiration was 22. After 5 litres of O2 improved. Pulse 93 in ER. Cardiovascular: There was no heart failure, cardiogenic shock, Acute myocardial infarction, arrhythmia and myocarditis. The patient Had chest pain which resolved when O2 was administered. Gastrointestinal/Hepatic: There was no Vomiting, Diarrhea. The patient experienced nausea but no vomiting or diarrhea and complained of abdominal pain. There was no Jaundice and acute liver failure. Neurological: There was no

COVID19 VACCINE	PFIZER\BIONTECH	1235832-1	Unknown	Unknown	wound up in the ER with hypoxia and sepsis; wound up in the ER with hypoxia and sepsis; shortness of breath; increased confusion; This is a spontaneous report from a contactable Nurse. A female patient of an unspecified age received first dose of bnt162b2 (BNT162B2), via an unspecified route of administration on 26Mar2021 (Lot Number: EL9269; Expiration Date: 01May2021) as single dose for Covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. It was reported that the female patient who we sent out with shortness of breath and increased confusion, she wound up in the ER (emergency room) with hypoxia and sepsis and she passed away. The events were serious as hospitalization and death. The patient died on an unspecified date. It was not reported if an autopsy was performed.; Sender's Comments: Based on the limited available information, the Company considered there was not a reasonable possibility that the reported events were related to the suspect product BNT162B2 (COMIRNATY). 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: increased confusion; shortness of breath; wound up in the ER with hypoxia and sepsis; wound up in the ER with hypoxia and sepsis
COVID19 VACCINE	PFIZER\BIONTECH	1238286-1	65+ years	5 days	This 85 year old white male hospice patient received the Covid shot on 2/16/21 and went to the ED on 2/21/21 and was admitted on 2/22/21 with altered mental status, pneumonia, severe sepsis, bladder cancer, UTI, dementia and died on 4/19/21. Please refer to the other details submitted within this report and contact the person who submitted this report via email for additional follow up details and investigation.
COVID19 VACCINE	PFIZER\BIONTECH	1242582-1	60-64 years	0 days	Pfizer-BioNTech COVID-19 Vaccine EUA Pt presented to ED on 4/10/21 @0523 with c/o SOB, F/C and cough. Admitted to ICU with acute hypoxic respiratory failure on BiPAP, non-STEMI, acute decompensated heart failure, acute kidney injury and suspected severe sepsis. Reportedly received 2nd dose of COVID-19 vaccine 2 days prior. Shortly after admit, pt developed worsening respiratory status requiring intubation @1045. Pt with continued hypoxemia despite 100% FiO2 and PEEP of 15. Pt experienced cardiac arrest with PEA @1100 with return of spontaneous circulation. Repeat arrest with PEA@1135 with return of spontaneous circulation. Family decision to change code status to DNR CCA, repeat arrest- time of death 1203.
COVID19 VACCINE	PFIZER\BIONTECH	1243574-1	65+ years	31-60 days	Cause of death is believed to be a fatal arrhythmia resulting from advanced old age and aggravated by sepsis due to COVID-19 infection along with gastroenteritis. The death was natural and not unexpected. Tobacco is not believed to have contributed to t
COVID19 VACCINE	PFIZER\BIONTECH	1246256-1	65+ years	5 days	Hospice Care Sepsis associated hypotension Discharge Diagnoses: acute on chronic hypoxic/hypercapnic resp failure requiring intubation, acute on chronic CHF, severe COPD with likely exacerbation, possible CAP, likely medical non compliance
COVID19 VACCINE	PFIZER\BIONTECH	1255316-1	Unknown	Unknown	liver bleed; pneumonia; kidney failure; Sepsis; lungs filled up with fluid; heart issues; were told they would need to wait 90 days as they were to far out of the date range; were told they would need to wait 90 days as they were to far out of the date range; This is a spontaneous report from a Pfizer-sponsored program, COVAX US Support. A contactable consumer (patient's spouse) reported that a male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Jan2021 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient received the first dose on 29Jan2021 and could not receive the second vaccine due to being hospitalized on an unspecified date due to gall bladder removal, sepsis, kidney failure, heart issues, lungs filled up with fluid, pneumonia, and liver bleed. The patient went to the facility to receive second vaccine and were told they would need to wait 90 days as they were to far out of the date range and was refused. The doctor refuses to administer the vaccine (other company) as they have started with the Pfizer vaccine. The outcome of the events was unknown. Information about batch/lot number has been requested.

COVID19 VACCINE	PFIZER\BIONTECH	1255351-1	Unknown	Unknown	This is a spontaneous report from a contactable pharmacist. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number and expiration date not reported) via an unspecified route of administration in Jan2021 at a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient got their first shot in January and was then hospitalized with sepsis. Did not come out of the hospital for 35 days. Dates of hospitalization not specified. The patient also experienced arm hurt on an unspecified date. Outcome of the events was unknown. Information on the lot/batch number has been requested.; Sender's Comments: Based on currently known drug safety profile, the reported event sepsis more likely represented intercurrent illness, but not related to BNT162B2. 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 RAs, Ethics Committees, and investigators, as appropriate.
COVID19 VACCINE	PFIZER\BIONTECH	1255643-1	30-39 years	2 days	Looked like he was in sepsis; thrombus occluding his IMV protruding into part of the SMV; Thrombocytopenia; Bacteremia with E. Coli; Unable to tolerate diet; Abdominal pain; Nausea; Vomiting; Muscle aches; Chills; Fever; This is a spontaneous report from a contactable physician. A 36-year-old male patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration, on 06Apr2021 at 10:00, at the age of 36 years old, for COVID-19 immunization. The patient's medical history included diverticulitis ongoing since 05Nov2018. Concomitant drugs included escitalopram oxalate (LEXAPRO) ongoing since an unspecified date. There were no other vaccinations 4 weeks prior to receiving BNT162b2. Two days after vaccination, on 08Apr2021, the patient developed nausea, vomiting, muscle aches, chills, and fever. The patient continued to have these symptoms and then developed abdominal pain on 11Apr2021, so the patient went to ER. Nausea, vomiting, muscle aches, chills, fever, and abdominal pain were reported as medically significant events. A CT of the abdomen and pelvis was performed on 11Apr2021, which seemed at that time to reveal only uncomplicated diverticulitis. Therefore, the patient was sent home with oral antibiotics. Then, the patient presented back to ER on 14Apr2021: the patient couldn't tolerate his diet and was experiencing worsening of abdominal pain. Another CT of abdomen and pelvis was therefore done on 14Apr2021, which this time revealed a thrombus occluding his IMV protruding into part of the SMV and the portal vein. In light of this finding, on 14Apr2021 the medical staff retroactively looked at the patient's CT scan from 11Apr2021 and they found that the thrombus was already present but less evident than on 14Apr2021. The patient also looked like he was in sepsis, so the medical team was performing a full septic work-up and the patient was hospitalized on 14Apr2021. The patient was terrified, and the medical staff were ruling out acute mesenteric ischemia. On 14Apr2021, blood work showed thrombocytopenia, and a bacteria blood test showed bacteremia with E. Coli. The event thrombus was reported as serious since medically significant, life threatening, and requiring hospitalization. No information regarding seriousness was provided for thrombocytopenia and bacteremia. Treatment with heparin drip was started (ongoing at the time of the reporting) and the patient improved. However, the reporter stated that at the time of the last reporting, all of the patient's symptoms were ongoing, that all of the patient's symptoms had worsened. At the time of the last reporting the patient was in the ICU. The patient had not recovered from the all reported events. The reporter did not know if the reported events were related to BNT162b2, however she added that diverticulitis could also cause all the patient's side effects. Information on the lot/ batch number has been requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the thrombosis, sepsis and other reported events due to temporal relationship. However, the reported events 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 including MRI of abdomen and vascular angiogram, 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

COVID19 VACCINE	PFIZER\BIONTECH	1255708-1	50-59 years	2 days	SOB; Sepsis; aspiration pneumonia; This is a spontaneous report based on the information received by Pfizer. A contactable Other HCP reported that a 59-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), dose 1 via an unspecified route of administration at the age of 59-year-old on 31Mar2021 (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. Medical history included chronic UTI, and splenectomy for unknown reason, RMS (Rhabdomyosarcoma). Concomitant medication included ocrelizumab (OCREVUS). On 02Apr2021, it was reported that patient experienced: Went into hospital due to SOB (Shortness of breath) on 02Apr2021, died on 07Apr2021 related to aspiration pneumonia on an unspecified date. Patient developed Sepsis as well on an unspecified date. Patient became a DNR on 06Apr2021 then passed on 07Apr2021. The patient was hospitalized for SOB from 02Apr2021 to an unknown date. The patient died on 07Apr2021. It was not reported if an autopsy was performed. The outcome of event aspiration pneumonia was fatal. The outcome of events SOB and Sepsis was not recovered. Information on the lot/batch number has been requested.; Sender's Comments: Based on the information currently available and known drug safety profile, the reported events more likely represented intercurrent illnesses, but not related to Bnt162b2. 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 RAs, Ethics Committees, and investigators, as appropriate. ; Reported Cause(s) of Death: aspiration pneumonia
COVID19 VACCINE	PFIZER\BIONTECH	1267950-1	65+ years	10-14 days	This 97 year old female received the Covid shot on 2/06/21 and went to the ED and was admitted on 2/17/21 with AMS, UTI, Sepsis from e.coli, and subsequently on 3/10/21 and again on 3/24 and recevied the 2nd Covid shot on 4/9/21 and died on 4/19/21. Please refer to the other details submitted within this report and contact the person who submitted this report via email for additional follow up details and investigation.
COVID19 VACCINE	PFIZER\BIONTECH	1293211-1	65+ years	31-60 days	J18.9 - Pneumonia I95.9 - Hypotension R09.02 - Hypoxia I48.91 - Atrial fibrillation with rapid ventricular response (CMS/HCC) A41.9 - Sepsis, unspecified organism
COVID19 VACCINE	PFIZER\BIONTECH	1293257-1	65+ years	31-60 days	J96.01 - Acute respiratory failure with hypoxia (CMS/HCC) R57.9 - Shock (CMS/HCC) A41.9 - Sepsis, unspecified organism
COVID19 VACCINE	NKNOWN MANUFACTUR	1008644-1	65+ years	0 days	A few hours following the vaccine administration patient was found febrile and encephalopathic. She was admitted to the ICU with hypernatremia due to presumed dehydration and Sepsis due to UTI. Patient remains in the ICU today. Hypernatremia improving with IVFs. Receiving antibiotics for UTI.

Dataset: The Vaccine Adverse Event Reporting System (VAERS)
Query Parameters:
State / Territory: The United States/Territories/Unknown
Symptoms: BACTERIAL SEPSIS; BILIARY SEPSIS; CATHETER SEPSIS; CLOSTRIDIUM DIFFICILE SEPSIS; ENTEROBACTER SEPSIS; ENTEROCOCCAL SEPSIS; ESCHERICHIA SEPSIS; FUNGAL SEPSIS; GROUP B STREPTOCOCCUS NEONATAL SEPSIS; HAEMOPHILUS SEPSIS; HERPES SEPSIS; KLEBSIELLA SEPSIS; MENINGOCOCCAL SEPSIS; NEUTROPENIC SEPSIS; PNEUMOCOCCAL SEPSIS; POST PROCEDURAL SEPSIS; PSEUDOMONAL SEPSIS; PULMONARY SEPSIS; SALMONELLA SEPSIS; SEPSIS; SEPSIS NEONATAL; SEPSIS SYNDROME; STAPHYLOCOCCAL SEPSIS; STENOTROPHOMONAS SEPSIS; STREPTOCOCCAL SEPSIS; UROSEPSIS; VIRAL SEPSIS
Vaccine Products: COVID19 VACCINE (COVID19)
VAERS ID: All
Group By: Vaccine Type; Vaccine Manufacturer; VAERS ID; Age; Onset Interval
Show Totals: False
Show Zero Values: Disabled

Help: See http://wonder.cdc.gov/wonder/help/vaers.html for more information.

Query Date: May 17, 2021 7:37:10 PM

Suggested Citation: Accessed at http://wonder.cdc.gov/vaers.html on May 17, 2021 7:37:10 PM

Messages:

1. The full results are too long to be displayed, only non-zero rows are available.
2. VAERS data in CDC WONDER are updated every Friday. Hence, results for the same query can change from week to week.
3. These results are for 233 total events.
4. 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.
5. Click on a VAERS ID to see a report containing detailed information for the event.

Footnotes:
1. Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Caveats:
1. 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.   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.

3. 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: http://wonder.cdc.gov/wonder/help/vaers.html#Suppress.
4. Data contains VAERS reports processed as of 5/7/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information: http://wonder.cdc.gov/wonder/help/vaers.html#Reporting.
5. For more information on how many persons have been vaccinated in the US for COVID19 to date, see https://covid.cdc.gov/covid-data-tracker/#vaccinations/