COVID Vaccine VAERS Reports for Sepsis - April 2, 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	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	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	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	0974040-1	65+ years	0 days	high fever, severe pain, dizziness, vomitting, internal bleeding, stroke, sepsis

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	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	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	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	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	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	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	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	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	KNOWN MANUFACTUI	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.
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	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	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	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	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	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	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	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	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	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	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	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	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	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	1024451-1	65+ years	1 day	CHF, Resp failure, intubated, on Levophed, suspected septic and cardiogenic shock.
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	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	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
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	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	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	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	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
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	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	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	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	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	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	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	MODERNA	1058594-1	65+ years	4 days	Total Kidney failure, 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	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	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	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	MODERNA	0937774-1	30-39 years	5 days	Fever/Cough/Body Aches. Covid +, Pneumonia and Sepsis
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	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	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	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	MODERNA	1046641-1	65+ years	6 days	Patient hospitalized for sepsis due to UTI. Patient was treated with antibiotics and discharged
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	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	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	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	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	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	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	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	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	MODERNA	0918839-1	30-39 years	8 days	Gallbladder removed, septic, 11mm axillary lymph node.
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	1017937-1	65+ years	8 days	Fever, confusion, sepsis, hospitalized
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	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
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	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
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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	1054592-1	65+ years	31-60 days	Resident expired on 2/24/21, under hospice care.
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	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	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	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	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	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	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	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	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	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	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.

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: Apr 14, 2021 2:46:29 PM

Suggested Citation: Accessed at http://wonder.cdc.gov/vaers.html on Apr 14, 2021 2:46:29 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 110 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 4/2/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information: 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/