National Vaccine Information Center
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Search the U.S. Government's VAERS Data

Welcome to the VAERS *Wayback Machine*

Each month (or lately, each week), the U.S. Government publishes a new release of its VAERS database. Most of the differences between releases consist of new VAERS cases that were introduced since the previous release. But the government never closes a VAERS case, and may make changes to any case at any time. Sometimes cases are even deleted.

The VAERS *Wayback Machine* has a collection of old releases of the VAERS database, starting in 2003. It allows you to examine the government data more carefully and observe how the data changes over time. Here are some of the things that you can do with the VAERS Wayback Machine:

Search an Older Release of the VAERS Database

Do a search of an older VAERS release.

Release: 11/4/2022 Search

Search Results

From the 11/4/2022 release of VAERS data

Found 34 cases where Vaccine targets COVID-19 (COVID19 or COVID19-2) and Lot Number contains 'EM0477' and Patient Died and CDC Split Type contains 'NLPFIZER'

Vaccine/Manufacturer/Lot with Vaccination Date	Count	Percent
COVID19 / PFIZER/BIONTECH / EM0477 [Given: 2021-01-25 - 2021-12-02]	34	100%

Case Details (Sorted by Appearance Date)

Case Details

VAERS ID: 1023334 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-01-27
Onset: 2021-01-29
Days after vaccination: 2
Submitted: 0000-00-00
Entered: 2021-02-11

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Death
SMQs:
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-01-29
Days after onset: 0
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: VITAMINE B COMPLEX; METFORMIN; PARACETAMOL; LEVODOPA/CARBIDOPA; LACTULOSE; VALERIAN ROOT EXTRACT; VIDISIC CARBOGEL; ZOPICLON; OXAZEPAM; SINEMET
Current Illness: Parkinson"s disease; Type 2 diabetes mellitus
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC2021126257

Write-up: Death; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority-WEB. This is a report received from the Regulatory Authority. LAREB. Regulatory authority report number was NL-LRB-00437379. An 85-year-old female patient received BNT162B2 (COMIRNATY; Lot Number: EM0477), via an unspecified route of administration on 27Jan2021 as a single dose for COVID-19 immunisation. Ongoing medical history included type 2 diabetes mellitus and Parkinson''s disease. Concomitant medications included vitamin b complex (MANUFACTURER UNKNOWN), metformin (MANUFACTURER UNKNOWN), paracetamol (MANUFACTURER UNKNOWN), carbidopa/levodopa (MANUFACTURER UNKNOWN), lactulose (MANUFACTURER UNKNOWN), valeriana officinalis root/valeriana officinalis root extract (VALERIAN ROOT EXTRACT), carbomer (VIDISIC CARBOGEL), zopiclone (MANUFACTURER UNKNOWN), oxazepam (MANUFACTURER UNKNOWN), and carbidopa/levodopa (SINEMET); all taken for unknown indications from unknown dates and unknown if ongoing. On 29Jan2021, the patient died. The clinical course was as follows: The patient had no complaints on the day of vaccination and the day after vaccination. The day after vaccination, the patient even practiced with the physiotherapist on the theravital (exercise bicycle). The morning of the 2nd day after the vaccination, the patient was found dead in bed due to care. It was not reported if an autopsy was performed. The cause of death was unknown. No follow-up attempts possible. No further information expected.; Reported Cause(s) of Death: unknown cause of death

Case Details

VAERS ID: 1025960 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-01-28
Onset: 2021-01-29
Days after vaccination: 1
Submitted: 0000-00-00
Entered: 2021-02-12

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Cardiac failure, Dyspnoea, Oxygen saturation, Oxygen saturation decreased, Pyrexia
SMQs:, Cardiac failure (narrow), Anaphylactic reaction (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Cardiomyopathy (broad), Respiratory failure (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Infective pneumonia (broad), Noninfectious myocarditis/pericarditis (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-01-29
Days after onset: 0
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: LIXIANA; MACROGOL; LEVOTHYROXINE SODIUM; AMIODARONE; FUROSEMIDE

Current Illness: Atrial fibrillation; Cardiac failure; Renal impairment
Preexisting Conditions:
Allergies:
Diagnostic Lab Data: Test Date: 20210129; Test Name: Oxygen saturation; Result Unstructured Data: Test Result:<80 %; Test Date: 20210129; Test Name: pyrexia; Result Unstructured Data: Test Result:38 to 40.5 Centigrade
CDC Split Type: NLPFIZER INC2021126259
Write-up: Dyspnea with decrease in saturation <80% and cardiac decompensation, passed away shortly afterwards; Dyspnea with decrease in saturation <80% and cardiac decompensation, passed away shortly afterwards; Dyspnea with decrease in saturation <80% and cardiac decompensation, passed away shortly afterwards; Fever: 38 to 40.5 degrees Celsius; This is a spontaneous report from a contactable physician downloaded from the Agency Regulatory Authority-WEB, regulatory authority number NL-LRB-00437398. A 90-year-old male patient received a dose of BNT162B2 (COMIRNATY) from lot#EM0477 at 0,3ml single dose for COVID-19 immunization on 28Jan2021. Concomitant medication included edoxaban tosilate (LIXIANA) tablet 30mg, macrogol powder via oral solution 1g, levothyroxine sodium tablet 62ug, amiodarone tablet 200mg, furosemide tablet 20mg. Medical history included cardiac failure, atrial fibrillation and renal impairment, all ongoing. On 29Jan2021 the patient experienced Dyspnea with decrease in saturation <80%, cardiac decompensation and fever: 38 to 40.5 degrees Celsius. The patient passed away shortly afterwards. It was unknown if an authopsy was performed. The patient was treated for the events with paracetamol and oxygen administration. Reporter''s comments: Pfizer vaccine (Comirnaty). Past drug therapy Pfizer vaccine (Comirnaty): no. dyspnoea. Additional information ADR: started with fever T$g 39 degrees, a few hours later severe dyspnoea with saturation drop <80% and cardiac decompensation, died soon after. confounding factors: familiar with decompensation cardiac, atrial fibrillation and renal dysfunction. COVID19: Previous COVID-19 infection: No. Date and time of start of drug and date and time of last administration: asked but unknown for edoxaban, macrogol, levothyroxine, amiodaron, furosemide.Time Interval between Beginning of Drug Administration and Start of Reaction / Event: 30 h for pyrexia. No follow-up attempts are possible. No further information is expected.; Reporter''s comments: Pfizer vaccine (Comirnaty). Past drug therapy Pfizer vaccine (Comirnaty): no. dyspnoea. Additional information ADR: started with fever T$g 39 degrees, a few hours later severe dyspnoea with saturation drop <80% and cardiac decompensation, died soon after. confounding factors: familiar with decompensation cardiac, atrial fibrillation and renal dysfunction. COVID19: Previous COVID-19 infection: No. Date and time of start of drug and date and time of last administration: asked but unknown for edoxaban, macrogol, levothyroxine, amiodaron, furosemide.Time Interval between Beginning of Drug Administration and Start of Reaction / Event: 30 h for pyrexia.; Reported Cause(s) of Death: cardiac failure; oxygen saturation decreased; dyspnoea; pyrexia

Case Details

VAERS ID: 1029979 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-01-29
Onset: 2021-01-30
Days after vaccination: 1
Submitted: 0000-00-00
Entered: 2021-02-15

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Body temperature, Cardiac failure acute, Chills, Fatigue, Malaise, Pyrexia
SMQs:, Cardiac failure (narrow), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Cardiomyopathy (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Noninfectious myocarditis/pericarditis (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-01-31
Days after onset: 1
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: TEMAZEPAM; PREGABALINE; MACROGOL 400; BUMETANIDE; FUROSEMIDE; ASCAL CARDIO; BISACODYL; OXYCODON; OMEPRAZOL
Current Illness: Angina pectoris; Atrial fibrillation; Axonal neuropathy; Cauda equina

syndrome; Coronary artery disease; Heart failure; Hypertension; Mitral stenosis; Spinal cord injury; Vascular parkinsonism
Preexisting Conditions: Medical History/Concurrent Conditions: Spondylodiscitis
Allergies:
Diagnostic Lab Data: Test Date: 20210130; Test Name: body temperature; Result Unstructured Data: Test Result:Fever: 37.5 to 38 degrees Celsius Centigrade
CDC Split Type: NLPFIZER INC2021126265
Write-up: Fatigue; Not feeling well; Fever: 37.5 to 38 degrees Celsius; Chills; acute decompensatie; This is a spontaneous report from a contactable physician downloaded from the Medicines Agency (MA) Regulatory Authority-WEB and received via Regulatory Authority NL-LRB-00436526 .Safety Report Unique Identifier NL-LRB-00437560. A 96-year-old male patient received bnt162b2 (COMIRNATY, Lot#: EM0477), via Intramuscular on 29Jan2021 at single dose for covid-19 immunization. Medical history included heart failure, spinal cord injury, cauda equina syndrome, vascular parkinsonism, mitral stenosis, atrial fibrillation, hypertension, coronary artery disease, axonal neuropathy, spondylodiscitis, angina pectoris. Concomitant medications included omeprazol tablet msr 20mg bisacodyl tablet msr 5mg macrogol 400 carbasalaatcalcium poeder 100mg furosemide injectievlst 10mg/ml bumetanide tablet 5mg pregabaline temazepam oxycodon tablet 10mg. The patient with chills (death), malaise (death), fatigue (death), body temperature increased (death) following administration of covid-19 vaccin pfizer injvlst for covid 19 immunisation. The patient was known with heart failure which was increasing during the weeks before vaccination. According to the reporter, increased body temperature might have contributed to the heart failure what might have resulted in decompensation cordis. The patient was not hospitalized and deceased 1,5 day after vaccination. The outcome of body temperature increased is fatal, the outcome of chills is fatal, the outcome of fatigue is fatal and the outcome of malaise is fatal. Drugs and latency: 1. covid-19 vaccin pfizer injvlstchills: 1 days after start, malaise: 1 days after start, fatigue: 1 days after start, body temperature increased: 1 days after start. No autopsy was done. Case Summary and Reporter''s Comments Text: Pfizer vaccin (Comirnaty). Past drug therapy Pfizer vaccin (Comirnaty): no. Confounding factors: severe heart failure. Previous COVID-19 infection: No. Other diagnostic procedures: pt was familiar with heart failure, complaints have been increasing in recent weeks. I have not opted for a hospitalization because of mr and family. Furthermore, pt is very old. Follow-up 03Feb2021 Follow-up received: 1.pt died 31Jan in the night, so 1, 5th day after vaccination 2. Medical history Transverse lesion sensory right L2, left L1, motor right L2, left L21994 fibroslcerosis bladder neck wv bladder neck incision1987 TURP related to BPH2006 cauda equina syndrome2006 canal stenosis2006 lower body parkinson based on vascular white matter abnormalities2013 Heart failure with mitral stenosis and AF2013 Vascular stenosis and AF2013 Vascular stenosis with AF2013 2006 Chron, idiopathic axonal polyneuropathy 2016 Spondylodisciitis: antibiotics i.v.Atrial fibrillation Neurogenic bladder after partial spinal cord injury Angina pectoris 3. medication: omeprazole 20mg bisacodyl 5mg macrogolascalfurosemide 40mg im + bumetanide 8mg oral pregabaline temazepamoxycodone zn for breathlessness 4. No autopsy was done. No follow-up attempts possible. No further information expected.; Reporter''s Comments: Pfizer vaccin (Comirnaty). Past drug therapy Pfizer vaccin

(Comirnaty): no. Confounding factors: severe heart failure. Previous COVID-19 infection: No. Other diagnostic procedures: pt was familiar with heart failure, complaints have been increasing in recent weeks. I have not opted for a hospitalization because of mr and family. Furthermore, pt is very old.; Reported Cause(s) of Death: acute decompensatie; Fatigue; Not feeling well; Fever: 37.5 to 38 degrees Celsius; Chills

Case Details

VAERS ID: 1029981 (history)
Form: Version 2.0
Age: 91.0
Sex: Female
Location: Foreign

Vaccinated: 2021-01-27
Onset: 2021-01-31
Days after vaccination: 4
Submitted: 0000-00-00
Entered: 2021-02-15

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Cerebrovascular accident
SMQs:, Ischaemic central nervous system vascular conditions (narrow), Haemorrhagic central nervous system vascular conditions (narrow), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-01
Days after onset: 1
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness: Dementia
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC2021126266

Write-up: 27 Jan vaccination. 31 Jan CVA. 01Feb Death; This is a spontaneous report from a contactable physician. This is a report received from the Medicines Agency (MA) Regulatory Authority-WEB. Regulatory authority or other manufacturer number NL-LRB-00437578. A 91 years old female patient received BNT162B2 (Comirnaty, Batch/Lot number: EM0477) at single dose for COVID-19 immunisation on 27Jan2021. Relevant history included the patient had dementia at an advanced stage and ongoing. The patient was not sent to the hospital but was treated with comfort policy. The patient was not known with allergies. Relevant concomitant drugs were unknown. 4 days after vaccination (on 31Jan2021), the patient experienced a cerebro vascular accident (CVA) and one day later (On 01Feb2021), the patient deceased. The patient did not experience adverse reactions during the vacciantion. The outcome of cerebrovascular accident was fatal. It was unknown if autopsy was performed or not. Case Summary and Reporter"s Comments Text: Pfizer vaccine (Comirnaty); Past drug therapy Pfizer vaccine (Comirnaty): no; 27Jan vaccination. 31Jan CVA. 01Feb Death; Additional information ADR: 3-4 days after vaccination stroke; in view of extensive VG with advanced dementia in connection with family not submitted. Quickly deployed on comfort policy. No side effects during or after administration. No known allergy. Unknown connection; but for completeness mention. COVID19; Previous COVID-19 infection: No; Other diagnostic procedures: due to death I cannot view medication data for now; if desired, this can be requested later at the pharmacy. No follow-up attempts possible. No further information expected.; Reported Cause(s) of Death: CVA

Case Details

VAERS ID: 1035424 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-01-27
Onset: 2021-01-27
Days after vaccination: 0
Submitted: 0000-00-00
Entered: 2021-02-17

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Body temperature, Dyspnoea, Nausea, Oxygen saturation, Pyrexia, SARS-CoV-2 test
SMQs:, Anaphylactic reaction (broad), Acute pancreatitis (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Cardiomyopathy (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), COVID-19 (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-01-29
Days after onset: 2
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness: Elderly; Heart failure; Oedema

Preexisting Conditions:
Allergies:
Diagnostic Lab Data: Test Date: 20210124; Test Name: PCR test; Test Result: Negative ; Test Date: 20210129; Test Name: PCR test; Test Result: Negative ; Test Date: 20210128; Test Name: body temperature; Result Unstructured Data: Test Result:38 to 40.5 Centigrade; Test Date: 20210128; Test Name: saturation; Test Result: 80 %
CDC Split Type: NLPFIZER INC2021135245
Write-up: Fever 38 to 40.5 Centigrade; Dyspnoea; Nausea; This is a spontaneous report from a contactable consumer downloaded from the Regulatory Agency (NL-LRB-00437238. A 92-year-old female patient received bnt162b2 (COMIRNATY, lot number EM0477), via an unspecified route of administration on 27Jan2021 at single dose for covid-19 immunisation. Medical history included ongoing elderly, ongoing Heart failure, ongoing oedema. The patient''s concomitant medications were not reported. The patient experienced fever 38 to 40.5 centigrade on 28Jan2021, nausea on 27Jan2021, dyspnoea on 28Jan2021. The events were serious as fatal. The patient underwent lab tests and procedures which included PCR test: negative on 24Jan2021 and 29Jan2021. According to the physician, the cause of death was a cardiac arrest due to heart failure. Pyrexia was treated with paracetamol and dyspnoe with oxygen therapy (saturation 80%). The patient died on 29Jan2021. It was not reported if an autopsy was performed.; Reported Cause(s) of Death: Fever 38 to 40.5 Centigrade; Nausea; Dyspnoea; cardiac arrest due to heart failure; cardiac arrest due to heart failure

Case Details

VAERS ID: 1035425 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-01-30
Onset: 2021-01-31
Days after vaccination: 1
Submitted: 0000-00-00
Entered: 2021-02-17

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Body temperature, Body temperature increased, Cardiac disorder, Condition aggravated, Decreased appetite, Fatigue, Malaise, Nausea
SMQs:, Acute pancreatitis (broad), Neuroleptic malignant syndrome (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-02
Days after onset: 2
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: DIGOXINE; ACENOCOUMAROL; XALACOM; COLECALCIFEROL; SPIRONOLACTON; OMEPRAZOL; DUTASTERIDE; FUROSEMIDE
Current Illness: Cardiovascular disease, unspecified
Preexisting Conditions:

Allergies:
Diagnostic Lab Data: Test Date: 20210131; Test Name: body temperature; Result Unstructured Data: Test Result:37.5 to 38 Centigrade
CDC Split Type: NLPFIZER INC2021135242
Write-up: Decreased appetite; death, probably death as a result of acute heart death/ cardiac cause; death, probably death as a result of acute heart death/ cardiac cause; Nausea; malaise/ did not feel well. general malaise; Fatigue; Fever, 37.5 to 38 Centigrade; This is a spontaneous report from a contactable physician downloaded from the regulatory authority-WEB NL-LRB-00437276. A 90 years old male patient received the first dose of bnt162b2 (COMIRNATY) on 30Jan2021 at single dose (Lot EM0477) for covid-19 immunisation. Medical history included ongoing cardiovascular disease, unspecified. No Previous COVID-19 infection. No diagnostic procedures. Concomitant medication included digoxine (0.0625mg tablet) at 0.06 mg, acenocoumarol (1mg tablet) at 1mg, latanoprost, timolol maleate (XALACOM), colecalciferol (5600 iU Capsule) at 5600 iU/kg, spironolacton (25mg tablet) at 25mg, omeprazol (40mg Gastro-resistant capsule) at 40 mg, dutasteride (0.5mg capsule) at 0.5mg, and furosemide (40mg tablet) at 40mg. The patient experienced death, probably death as a result of acute heart death/ cardiac cause, 3 days after start (02Feb2021); nausea, 2 days after start (01Feb2021); malaise/ did not feel well. general malaise: 1 days after start (31Jan2021); fatigue: 1 days after start (31Jan2021); body temperature increased, Fever, 37.5 to 38 Centigrade: 1 days after start (31Jan2021); decreased appetite: latency unknown. Unexpectedly, the patient deceased 3 days after vaccination on 02Feb2021 in his sleep with no apparent cause. The cause of death is unclear, but a cardiac cause was suspected considering the cardiovascular disease in his medical history. Unclear if there is a causal relation between the vaccination and the death. Iom forensic doctor issued as natural death. Presumed death due to acute cardiac death because of history of cardiovascular disease. Confounding factors: History of cardiovascular disease. Death probably due to cardiac cause. It is unknown if autopsy done. Outcome of the event death, probably death as a result of acute heart death/ cardiac cause was fatal. Outcome of other events was unknown.; Reported Cause(s) of Death: death, probably death as a result of acute heart death/ cardiac cause; death, probably death as a result of acute heart death/ cardiac cause

Case Details

VAERS ID: 1035426 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-01-25
Onset: 2021-02-02
Days after vaccination: 8
Submitted: 0000-00-00
Entered: 2021-02-17

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Body temperature, Death, Heart rate, Oxygen saturation, Physical examination
SMQs:
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-02
Days after onset: 0
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness: Aspiration pneumonia; Ileus
Preexisting Conditions:
Allergies:
Diagnostic Lab Data: Test Date: 20210124; Test Name: temperature; Result Unstructured Data: Test Result:38.7 Centigrade; Test Date: 20210124; Test Name: Heart rate; Result Unstructured Data: Test Result:115x/min; Test Date: 20210124;

Test Name: oxygen saturation; Test Result: 90 %; Test Date: 20210124; Test Name: physical examination; Result Unstructured Data: Test Result:pulmonary crepitations (both sides), swollen abdom; Comments: pulmonary crepitations (both sides), swollen abdomen
CDC Split Type: NLPFIZER INC2021135251
Write-up: This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority number: NL-LRB-00437294. A 90-year-old female patient received first dose of bnt162b2 (COMIRNATY, lot# EM0477), via an unspecified route of administration on 27Jan2021 at single dose for COVID-19 vaccination, midazolam (injection fluid 5 mg/ml), via an unspecified route of administration from 27Jan2021 at 10 mg, cyclic (Freq: 4 h; 6x daily 10mg) for Discomfort and anxiety during death phase, morphine (injection fluid 10 mg/ml), via an unspecified route of administration from 25Jan2021 to an unspecified date at 1 DF (Injection liquid, 10 mg / ml (milligrams per milliliter)) for Pain due to ileus and pneumonia with dyspnoea, paracetamol (1000 mg suppository), via an unspecified route of administration from 25Jan2021 at 1000 mg, cyclic (Freq: 6 h; 1000mg 4x daily) for Abdominal pain with ileus. The patient''s concomitant medications were not reported. Three days before vaccination, the patient had pyrexia (38.7 degrees Celsius), a decreased oxygen saturation (90%), tachycardia (115/min), swollen abdomen and pulmonary crepitation (both sides). An ileus was suspected with possible aspiration pneumonia. Pain medication was started, morphine and paracetamol, two days before vaccination and a palliative setting was initiated. Since the patient was recovering on 27Jan2021, she was vaccinated with a covid-19 vaccine (Pfizer/BioNTech). But that same day, the patient health deteriorated again. A palliative setting was initiated again and midazolam was started. The patient deceased on 02Feb2021, 6 days after vaccination. According to the reporter, the cause of death was dedicated to the pre-existing disease, which already existed before vaccination. The patient underwent lab tests and procedures which included temperature: 38.7 centigrade on 24Jan2021, heart rate: 115x/min on 24Jan2021, oxygen saturation: 90 % on 24Jan2021, physical examination: pulmonary crepitations (both sides), swollen abdomen on 24Jan2021. The action taken in response to the event for midazolam and paracetamol was Not Applicable, for morphine was dose increased. The patient died on 02Feb2021. It was not reported if an autopsy was performed. Case summary and reporter''s comments: Pfizer vaccine (Comirnaty). Past drug therapy Pfizer vaccine (Comirnaty): no. Patient died on 02Feb2021. Additional information ADR: Patient presented on 24Jan2021 with fever T 38.7C, O2 sat 90% and tachycardia 115x / min, with vomiting and noticeable bulging and painful stomach. Pulmonary crepitus on both sides. Thought of ileus with possible aspiration pneumonia, diaphragm stimulation. On 25Jan dying path route was used aimed at comfort. Patient barely ate and drank. Because patient 27Jan2021 suddenly recovered, started eating and drinking again, recovery was considered. Given recovery, it was not possible to determine a death prognosis of less than 3 months. It was decided to vaccinate with the Pfizer Comirnaty round of vaccination on 27Jan. However, the same evening of 27Jan still deteriorated and dying path route was restarted with midazolam added due to unrest. The patient died on 02Feb2021. Consultation took place with forensic doctor who issued a natural death in view of pre-existing suffering before vaccination. The vaccination contribution to the death is

considered none. confounding factors: ileus. Previous COVID-19 infection: No. Other diagnostic procedures: No. No follow-up attempts possible. No further information expected.; Sender"s Comments: The 90-year-old patient had pre-existing ileus and pneumonia, and already accepted palliative setting prior to vaccination. The cause of death was reported as underlying ileus and pneumonia, and unrelated to the first dose of bnt162b2 (COMIRNATY).; Reported Cause(s) of Death: possibly aspiration pneumonia; ileus

Case Details

VAERS ID: 1035429 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-01-27
Onset: 2021-01-31
Days after vaccination: 4
Submitted: 0000-00-00
Entered: 2021-02-17

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Asthma, Cardiac asthma, Electrocardiogram
SMQs:, Cardiac failure (narrow), Anaphylactic reaction (broad), Asthma/bronchospasm (narrow), Eosinophilic pneumonia (broad), Hypersensitivity (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 0000-00-00
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: METFORMIN; FLIXOTIDE; MELATONIN; SIMVASTATIN
Current Illness: Asthma; COPD; Intellectual disability
Preexisting Conditions: Medical History/Concurrent Conditions: Exposure to COVID-19
Allergies:
Diagnostic Lab Data: Test Date: 20210131; Test Name: ECG; Result Unstructured Data: Test Result:ST-elevations within normal range; Comments: Acute Myocardial

Infarction cannot be realiable determined.
CDC Split Type: NLPFIZER INC2021135261
Write-up: exacerbation of asthma; Cardiac asthma; This is a spontaneous report from a contactable physician downloaded from the Regulatory Agency[NL-LRB-00437887], received via Regulatory Authority. A 70-years-old male patient received bnt162b2 (COMIRNATY, Strength 0.3 ml, LOT# EM0477), via an unspecified route of administration on 27Jan2021 at single dose for covid-19 immunisation. Medical history included ongoing chronic obstructive pulmonary disease, ongoing intellectual disability, ongoing asthma, contact with someone who tested positive for SARS-CoV-2 virus. Concomitant medication included metformin, fluticasone propionate (FLIXOTIDE), melatonin, simvastatin. On 31Jan2021, the patient experienced asthma aggravated (exacerbation), cardiac asthma. Seriousness criteria for both events was fatal. Event description: Four days after vaccination, the patient became dyspnoeic, restless, had a low oxygen saturation, low blood pressure and tachycardia. An ECG was performed on 31Jan2021 which showed ST-elevations within a normal range. An acute myocardial infarction could not be reliable determined. The patient was treated with prednisone, salbutamol/ipratropium, amoxicillin/clavulanic acid and oxygen. Unfortunately, the patient deceased due to the asthma exacerbation/cardiac asthma, between 4-7 days after vaccination. The reporter described that the day before vaccination, the patient had contact with someone who tested positive for SARS-CoV-2 virus. An attempt to test the patient for a COVID-19 infection failed, due to a moderate intellectual disability. The patient died on an unspecified date. It was not reported if an autopsy was performed. Case Summary and Reporter"s Comments: Pfizer vaccine (Comirnaty). Past drug therapy Pfizer vaccine (Comirnaty): no. Exacerbation of asthma / cardiac asthma (cause of death reported by the attending GP). Additional information ADR: 4th day after vaccination sudden breathlessness, agitation, low saturation, low blood pressure, fast pulse, ECG: seen tachycardia and fluctuating baseline: AMI cannot be reliably determined, ST elev within the norms. The day before vaccination I was in contact with a companion who tested positive for corona. Corona test tried, but not successful (with moderate intellectual disability). confounding factors; confounding factors: asthma / COPD, possible corona infection? COVID19: Previous COVID-19 infection: No. Other diagnostic procedures: ECG: seen tachycardia and variable baseline: AMI cannot be reliably determined, ST-elev within the norms.; Reporter"s Comments: Pfizer vaccine (Comirnaty). Past drug therapy Pfizer vaccine (Comirnaty): no. Exacerbation of asthma / cardiac asthma (cause of death reported by the attending GP). Additional information ADR: 4th day after vaccination sudden breathlessness, agitation, low saturation, low blood pressure, fast pulse, ECG: seen tachycardia and fluctuating baseline: AMI cannot be reliably determined, ST elev within the norms. The day before vaccination I was in contact with a companion who tested positive for corona. Corona test tried, but not successful (with moderate intellectual disability). confounding factors; confounding factors: asthma / COPD, possible corona infection? COVID19: Previous COVID-19 infection: No. Other diagnostic procedures: ECG: seen tachycardia and variable baseline: AMI cannot be reliably determined, ST-elev within the norms.; Reported Cause(s) of Death: Cardiac asthma; exacerbation of asthma

Case Details

VAERS ID: 1035431 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-01-29
Onset: 2021-02-01
Days after vaccination: 3
Submitted: 0000-00-00
Entered: 2021-02-17

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Body temperature increased, Choking, Fatigue, Malaise, SARS-CoV-2 test negative
SMQs:, Anaphylactic reaction (broad), Angioedema (broad), Neuroleptic malignant syndrome (broad), Hypersensitivity (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), COVID-19 (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-04
Days after onset: 3
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: PARACETAMOL; OMEPRAZOLE; LACTULOSESTROOP; OXYCODONE; CITALOPRAM
Current Illness: Demented
Preexisting Conditions: Medical History/Concurrent Conditions: Infection NOS (frequent infections)

Allergies:
Diagnostic Lab Data: Test Date: 20210203; Test Name: body temperature increased; Result Unstructured Data: Test Result:37.5 to 38 Centigrade; Test Date: 20200201; Test Name: COVID-19 test; Test Result: Negative
CDC Split Type: NLPFIZER INC2021141429
Write-up: This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority NL-LRB-00438556 and safety report unique identifier [NL-LRB-00439092]. A 94-year-old female patient received bnt162b2 (COMIRNATY, Lot # EM0477) at single dose on 29Jan2021 for covid-19 immunisation. Medical history included ongoing demented with declining life expectancy, frequent infections. No previous COVID-19 infection. Concomitant medication included paracetamol (PARACETAMOL, tablet 500mg) at 500mg unknown, omeprazole (OMEPRAZOLE, capsule msr 40mg) at 40mg unknown, lactulose (LACTULOSE STROOP) at 670mg/ml (500mg/g), oxycodone (OXYCODONE, tablet 5mg) at 5mg unknown, citalopram (CITALOPRAM, coated tablet) at 10mg unknown. The patient experienced fatigue and not feeling well on 01Feb2021, fever/body temperature increased: 37.5 to 38 degrees celsius on 03Feb2021, choking due to malaise in Feb2021. The patient underwent lab tests and procedures which included body temperature increased: 37.5 to 38 centigrade on 03Feb2021, Sars-cov-2 test: negative on 01Feb2020. The patient died 6 days after vaccination on 04Feb2021. The outcome of all events was fatal. It was not reported if an autopsy was performed. The primary cause of death of the patient was respiratory tract infection in advanced dementia with descending lifeline The reporter mentioned that the adverse events following immunisation (choking due to malaise and fatigue) may have accelerated death, could have contributed to the patient''s death. The reporter suspected fatigue / drowsiness, causing choking as influencing specific side effect. The patient''s health status before and at the time of vaccination very vulnerable and fragile for years. Estimated life expectancy was more than 4 weeks.; Reporter''s comments:BioNTech / Pfizer vaccine (Comirnaty) Past drug therapy BioNTech / Pfizer vaccine (Comirnaty): no confounding factors confounding factors: dementia with declining lifeline and frequent infections COVID19 Previous COVID-19 infection: No 05Feb2021 Follow up received by email; changes in the notification: Summary, Patient death date, cause of death1a. What was the primary cause of death of the patient? 1b. On what date did your patient die? 2. What is your estimate of the contribution that the side effects of the vaccine may have made to the death? - none / - very unlikely / side effects from the vaccine may have accelerated death / - side effects from the vaccine have very likely accelerated death / - it is extremely unlikely that this patient would be without these side effects in the short term deceased 3. If you suspect an influence of the side effects, what specific side effect do you suspect? 4. What was the patient''s health status before and at the time of vaccination? Was there an infection? 5. Around the time of the vaccination, did your patient have another corona test or was there a suspicion of corona? 1a respiratory tract infection in advanced dementia with descending lifeline1b 04Feb20211a2 side effects of the vaccine may have accelerated death3 fatigue / drowsiness, causing choking4 . very vulnerable, but life expectancy still longer than 4 weeks, but vulnerable for years. 5. yes, this one was negative. 01Feb2020; Reported Cause(s) of Death: respiratory infection

Case Details

VAERS ID: 1035432 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-01-27
Onset: 2021-01-31
Days after vaccination: 4
Submitted: 0000-00-00
Entered: 2021-02-17

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / 2	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Body temperature, Cough, Pyrexia, SARS-CoV-2 test
SMQs:, Anaphylactic reaction (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), COVID-19 (broad)
Life Threatening? Yes
Birth Defect? No
Died? Yes
Date died: 0000-00-00
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: CINNARIZINE; PRAVASTATIN; KETOCONAZOL; OXYCODON; PARACETAMOL; VITAMINE B COMPLEX; CALCIUM CARBONATE; CLOPIDOGREL; UREA
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data: Test Date: 20210201; Test Name: Body temperature; Result

Unstructured Data: Test Result:Fever rose to 40 Centigrade; Test Date: 2021; Test Name: Body temperature; Result Unstructured Data: Test Result:38 to 40.5 Centigrade; Test Date: 2021; Test Name: COVID 19 rapid test; Result Unstructured Data: Test Result:Negative; Test Date: 2021; Test Name: COVID-19 PCR test; Result Unstructured Data: Test Result:Negative
CDC Split Type: NLPFIZER INC2021142718
Write-up: Cough; Fever 38 to 40.5 degrees Celsius; This is a spontaneous report downloaded from the Regulatory Authority-WEB, NL-LRB-00438893, safety report unique identifier NL-LRB-00439102. A contactable physician reported that an 81 years old female patient (weight 93.7 kgs) received the second dose of BNT162B2 (COMIRNATY, Lot. EM0477) at 0.3 mL, single dose, on 27Jan2021, for COVID-19 immunisation. Relevant medical history was unknown. Concomitant medications included oral cinnarizine, tablet 25 mg, from an unspecified date, for an unknown indication; oral pravastatin tablet 20 mg, from an unspecified date, for an unknown indication; ketoconazol shampoo 20 mg/g, from an unspecified date, for an unknown indication; oral oxycodone hydrochloride capsule 5 mg, from an unspecified date, for an unknown indication; oral paracetamol tablet, 1000 mg, from an unspecified date, for an unknown indication; oral vitamine B complex, tablet, from an unspecified date, for an unknown indication; oral calcium carbonate chewable tablet, 1.25 g, from an unspecified date, for an unknown indication; oral clopidogrel, tablet 75 mg, from an unspecified date, for an unknown indication and urea cream 100 mg/g, from an unspecified date, for an unknown indication. On 31Jan2021, the patient experienced cough and pyrexia (38 to 40.5 degrees Celsius). The adverse events were assessed as serious: cough (death, life threatening) and pyrexia (death). It was unknown if autopsy was done. Reporter''s comments: BioNTech / Pfizer vaccine (COMIRNATY). Past drug therapy BioNTech / Pfizer vaccine (COMIRNATY): no cough and fever. On 31Jan2021 patient developed fever and cough, PCR COVID 19 negative. At 01Feb2021 the fever rose to 40.0 Centigrade. Previous COVID-19 infection: No. Other diagnostic procedures: COVID 19 PCR negative; COVID 19 rapid test negative.; Reporter''s Comments: BioNTech / Pfizer vaccine (COMIRNATY). Past drug therapy BioNTech / Pfizer vaccine (COMIRNATY): no cough and fever. On 31Jan2021 patient developed fever and cough, PCR COVID 19 negative. At 01Feb2021 the fever rose to 40.0 Centigrade. Previous COVID-19 infection: No. Other diagnostic procedures: COVID 19 PCR negative; COVID 19 rapid test negative.; Reported Cause(s) of Death: Cough; Pyrexia

Case Details

VAERS ID: 1045454 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-02-02
Onset: 2021-02-03
Days after vaccination: 1
Submitted: 0000-00-00
Entered: 2021-02-22

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Body temperature, Body temperature increased, Cardiac arrest, Malaise, Myalgia
SMQs:, Torsade de pointes/QT prolongation (broad), Rhabdomyolysis/myopathy (broad), Anaphylactic reaction (broad), Neuroleptic malignant syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Acute central respiratory depression (broad), Cardiomyopathy (broad), Eosinophilic pneumonia (broad), Respiratory failure (broad), Tendinopathies and ligament disorders (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Noninfectious myocarditis/pericarditis (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-05
Days after onset: 2
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:

Other Medications: MACROGOL; ENALAPRIL; ELIQUIS; CRANBERRY
Current Illness: Hospitalization
Preexisting Conditions:
Allergies:
Diagnostic Lab Data: Test Name: Body temperature; Result Unstructured Data: Test Result:unknown results; Test Date: 20210203; Test Name: Body temperature; Result Unstructured Data: Test Result:increased
CDC Split Type: NLPFIZER INC2021158432
Write-up: dead on 05Feb2021, Acute cardiac arrest was considered the cause of death; Did not feel fit/malaise; Muscle pain/Myalgia; Subfebrile complaints/body temperature increased; This is a spontaneous report from a contactable physician downloaded from the Medicines Agency (MA) Regulatory Authority-WEB regulatory authority number NL-LRB-00439119. An 88-year-old female patient received bnt162b2 (COMIRNATY, batch/lot: EM0477), via an unspecified route of administration on 02Feb2021 at single dose for covid-19 vaccination. Medical history included ongoing staying at a psychogeriatric ward. Concomitant medication included macrogol, enalapril tablet 10mg, apixaban (ELIQUIS) Film-coated tablet 5 mg, cranberry. The patient was staying at a psychogeriatric ward and experienced myalgia, body temperature increased and malaise on 03Feb2021, which had recovered the following day. Event details: The patient had subfebrile complaints the day after vaccination (03Feb2021) and did not feel fit; also had some muscle pain. The day after (04Feb2021), there was no fever and she was not sick. She was found dead in bed in the morning on 05Feb2021. Acute cardiac arrest was considered the cause of death for external examination. The patient underwent lab test included body temperature on an unspecified date with unknown results. The patient recovered from body temperature increased, malaise, and myalgia on 04Feb2021, and the outcome of cardiac arrest was fatal. The patient died on 05Feb2021. It was not reported if an autopsy was performed.; Reported Cause(s) of Death: Acute cardiac arrest

Case Details

VAERS ID: 1045457 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-01-30
Onset: 2021-02-02
Days after vaccination: 3
Submitted: 0000-00-00
Entered: 2021-02-22

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Glomerular filtration rate, Sudden death
SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad), Noninfectious myocarditis/pericarditis (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-02
Days after onset: 0
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: FERROFUMARAAT; FOLIUMZUUR; LORAZEPAM; CLOPIDOGREL
Current Illness: Estimated glomerular filtration rate decreased (33 ml/min)
Preexisting Conditions:
Allergies:
Diagnostic Lab Data: Test Name: Estimated glomerular filtration rate; Result

Unstructured Data: Test Result:33 ml/min; Comments: decreased
CDC Split Type: NLPFIZER INC2021158437
Write-up: Sudden death; This is a spontaneous report received from a contactable Physician, downloaded from the Regulatory Authority NL-LRB-00441525. A male aged 91 years received BNT162B2 (COMIRNATY, Lot number EM0477) on 30Jan2021 at single dose for COVID-19 immunisation. Medical history included ongoing estimated glomerular filtration rate decreased (33 ml/min). Concomitant medications included ferrofumaraat, clopidogrel, folic acid (FOLIUMZUUR), lorazepam. Physician reported that patient suffered from constipation, but was treated and recovered (as reported). Patient died after that. The patient suddenly passed away on 02Feb2021. The cause of death was suddenly passed away. It was unknown whether autopsy was done. No follow-up attempts are possible. No further information is expected. ; Reported Cause(s) of Death: Suddenly passed away

Case Details

VAERS ID: 1045458 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-01-28
Onset: 2021-01-29
Days after vaccination: 1
Submitted: 0000-00-00
Entered: 2021-02-22

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Glomerular filtration rate, Sudden death
SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad), Noninfectious myocarditis/pericarditis (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-01-29
Days after onset: 0
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: OMEPRAZOL; ZOLPIDEM; LOPERAMIDE; FOLIUMZUUR; SOTALOL; CITALOPRAM; FUROSEMIDE
Current Illness: Cardiac disorder; Vascular dementia
Preexisting Conditions: Medical History/Concurrent Conditions: Tuberculosis
Allergies:

Diagnostic Lab Data: Test Name: lab; Result Unstructured Data: Test Result:55
CDC Split Type: NLPFIZER INC2021158439
Write-up: Sudden death; This is a spontaneous report received from a contactable Physician, downloaded from the regulatory authority NL-LRB-00441531. An 82-year-old female patient received bnt162b2 (COMIRNATY, lot number EM0477), via an unspecified route of administration on 28Jan2021 at single dose for covid-19 immunisation. Medical history included tuberculosis, ongoing cardiac disorder, ongoing vascular dementia. Concomitant medication included omeprazole (OMEPRAZOL), zolpidem, loperamide, folic acid (FOLIUMZUUR), sotalol, citalopram and furosemide. The patient experienced sudden death on 29Jan2021. The patient underwent lab tests and procedures which included eGFR (glomerular filtration rate): 55 on unknown date. The patient was found deceased on the toilet the day after vaccination. Reported other possible cause was suspicion of colon malignity. The patient died on 29Jan2021. It was not reported if an autopsy was performed. No follow-up attempts possible. No further information expected.; Reported Cause(s) of Death: Sudden death; suspicion of colon malignity

Case Details

VAERS ID: 1048591 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-02-02
Onset: 2021-02-03
Days after vaccination: 1
Submitted: 0000-00-00
Entered: 2021-02-23

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Headache, Nausea, Pyrexia, SARS-CoV-2 test positive
SMQs:, Acute pancreatitis (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (narrow)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-03
Days after onset: 0
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: PARACETAMOL; AMLODIPINE; ACENOCOUMAROL; HYDROCHLOORTHIAZIDE
Current Illness: Heart failure
Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19 (little

disease symptoms)
Allergies:
Diagnostic Lab Data: Test Date: 20210203; Test Name: pyrexia; Result Unstructured Data: Test Result:38 to 40.5 Centigrade; Test Date: 20200909; Test Name: corona test; Test Result: Positive
CDC Split Type: NLPFIZER INC2021158428
Write-up: Nausea; Fever: 38 to 40.5 degrees Celsius/pyrexia; Headache; This is a spontaneous report from a contactable other healthcare professional downloaded from the Medicines Agency (MA) Regulatory Authority-WEB NL-LRB-00439085. An 85 years old female patient received BNT162B2 (COMIRNATY, PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot number: EM0477, Solution for injection) via an unspecified route of administration on 02Feb2021 at single dose for covid-19 immunisation. Medical history included ongoing heart failure, COVID-19 on 09Sep2020. Previous COVID-19 infection was included little disease symptoms. Concomitant medication included paracetamol tablet 500mg, hydrochloorthiazide tablet 12,5mg, acenocoumarol tablet 1mg, amlodipine tablet 5mg. There was no past drug therapy reported. It was reported patient experienced nausea (death), fever: 38 to 40.5 degrees Celsius/pyrexia (death), headache, all events occurred on 03Feb2021 (1 days after start). The drugs and latency were 1 day. It was not sure if death was due to vaccine. There was fever in elderly client with heart complaints. There was confounding factors: heart failure. The patient underwent lab tests and procedures which included corona test on 09Sep2020: positive. There were no other diagnostic procedures. The patient recovered from headache on 03Feb2021, the outcome of nausea and fever: 38 to 40.5 degrees Celsius/pyrexia were fatal. No follow-up attempts are possible. No further information expected.; Reported Cause(s) of Death: Fever: 38 to 40.5 degrees Celsius/pyrexia; Nausea

Case Details

VAERS ID: 1048592 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-02-03
Onset: 2021-02-05
Days after vaccination: 2
Submitted: 0000-00-00
Entered: 2021-02-23

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Dyspnoea, Pallor, SARS-CoV-2 test, Sudden cardiac death
SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (broad), Arrhythmia related investigations, signs and symptoms (narrow), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Cardiomyopathy (broad), Hypotonic-hyporesponsive episode (broad), COVID-19 (broad), Noninfectious myocarditis/pericarditis (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-05
Days after onset: 0
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: CLOPIDOGREL; PARACETAMOL; MOVICOLON; CALCI CHEW D3
Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Humerus fracture (Admitted to a nursing home for temporary admission due to this fracture); Transient ischemic attack (clopidogrel therapy had been initiated)
Allergies:
Diagnostic Lab Data: Test Date: 20210128; Test Name: COVID-19 test; Test Result: Negative
CDC Split Type: NLPFIZER INC2021158430
Write-up: sudden cardiac death (death); Patient got dyspneic in the morning; Suddenly looked pale; This is a spontaneous report from a contactable physician downloaded from the Agency Regulatory-WEB with Regulatory authority report number [NL-LRB-00439117]. A 91-year-old female patient received bnt162b2 (COMIRNATY, Solution for injection, Batch/lot number: EM0477), via an unspecified route of administration on 03Feb2021 at single dose for covid-19 immunisation. Medical history included humerus fracture from Jan2021 to an unknown date, the patient was admitted to a nursing home for temporary admission due to this fracture, transient ischaemic attack from an unknown date, for which clopidogrel therapy had been initiated. Concomitant medication included clopidogrel (tablet), paracetamol (tablet), macrogol, potassium chloride, sodium bicarbonate, sodium chloride (MOVICOLON), calcium carbonate, colecalciferol (CALCI CHEW D3). Routine COVID-19 test at day of admission, 6 days prior to vaccination on 28Jan2021 was negative. The patient experienced sudden cardiac death (death) on 05Feb2021, reported as serious with serious criteria death, patient got dyspneic in the morning and suddenly looked pale on 05Feb2021, reported as non-serious. It was also reported that the patient did not experience any side effects from vaccination. Whilst sitting in a chair patient became suddenly dyspnoeic and pale, collapsed and died within 10-15 minutes. The patient underwent lab test which included COVID-19 test: negative on 28Jan2021. The patient died on 05Feb2021. It was not reported if an autopsy was performed. The outcome of events dyspnoea and pallor facial was unknown and the outcome of sudden cardiac death was fatal. Nursing home physician rated relationship with vaccination as unlikely ("probably sheer coincidence") and named "sudden cardiac death" as most probably cause of death.; Reported Cause(s) of Death: sudden cardiac death

Case Details

VAERS ID: 1048594 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-01-28
Onset: 2021-01-29
Days after vaccination: 1
Submitted: 0000-00-00
Entered: 2021-02-23

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Oxygen saturation, Oxygen saturation decreased, Respiratory rate
SMQs:, Acute central respiratory depression (broad), Respiratory failure (broad), Infective pneumonia (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-01-30
Days after onset: 1
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: ESOMEPRAZOLE
Current Illness: Aspiration pneumonia; Axonal neuropathy; Malnutrition; Mixed dementia (end stage); Venous insufficiency
Preexisting Conditions: Medical History/Concurrent Conditions: Anemia (probably myelodysplastic syndrome); Gastric haemorrhage; Reflux oesophagitis
Allergies:
Diagnostic Lab Data: Test Date: 20210129; Test Name: saturation; Test Result: 72

%; Test Date: 20210129; Test Name: respiratory rate; Result Unstructured Data: Test Result:95 breaths per minute
CDC Split Type: NLPFIZER INC2021158441
Write-up: decreased oxygen saturation; This is a spontaneous report from a contactable physician downloaded from the Agency Regulatory Authority-WEB. This is a report received from the Regulatory Authority. Regulatory authority report numbers were NL-LRB-00441201 and NL-LRB-00441824. A 68-year-old male patient received BNT162B2 (COMIRNATY; Lot Number: EM0477), via an unspecified route of administration on 28Jan2021 as a single dose for COVID-19 immunisation. Ongoing medical history included venous insufficiency from Jun2020, end stage mixed dementia from Aug2017, pneumonia aspiration from Jan2021, mild sensorimotor axonal polyneuropathy from 2012, and poor nutritional status from an unknown date. Other relevant medical history included gastric haemorrhage from Dec2020 to an unknown date, reflux oesophagitis from an unknown date and unknown if ongoing, and anaemia (probably myelodysplastic syndrome) from 2019 to an unknown date. Prior to the vaccination, the patient was not diagnosed with COVID-19. Concomitant medications included esomeprazole (MANUFACTURER UNKNOWN) taken for an unknown indication from an unknown date and unknown if ongoing. On 29Jan2021, the patient experienced decreased oxygen saturation; which was fatal. The clinical course was as follows: Shortly before the vaccination, the patient experienced an aspiration pneumonia. One day after vaccination, the patient experienced decreased oxygen saturation at 72% and high breathing frequency of 95 breaths per minute. A Corona test was not performed. Two days after vaccination, the patient was deceased. The clinical outcome of oxygen saturation decreased was reported as fatal. The patient died on 30Jan2021. An autopsy was not performed. According to the reporting physician, the patient''s death was caused by the aspiration pneumonia which occurred just before the vaccination. The patient''s nutritional status was bad and the patient had an advanced stage of dementia. The representative of the patient suspected the COVID-19 vaccine. No follow-up attempts possible. No further information expected.; Reported Cause(s) of Death: decreased oxygen saturation; Aspiration pneumonia

Case Details

VAERS ID: 1048596 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-02-02
Onset: 2021-02-04
Days after vaccination: 2
Submitted: 0000-00-00
Entered: 2021-02-23

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / 1	- / -
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	UNKNOWN / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Body temperature, Nausea, Oxygen saturation decreased, Pneumonia aspiration, Pyrexia, SARS-CoV-2 test positive, Vomiting
SMQs:, Acute pancreatitis (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Acute central respiratory depression (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Respiratory failure (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (narrow)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-06
Days after onset: 2
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No

ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: PARACETAMOL; COLECALCIFEROL; OMEPRAZOL; MACROGOL
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19; Intellectual disability
Allergies:
Diagnostic Lab Data: Test Date: 20210204; Test Name: Body temperature; Result Unstructured Data: Test Result:38.5 Centigrade; Test Date: 20210110; Test Name: corona, confirmed by test; Test Result: Positive
CDC Split Type: NLPFIZER INC2021163812
Write-up: low saturation; then fever, temperature 38.5 centigrade; Vomiting; Nausea; suspected aspiration pneumonia; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority-WEB NL-LRB-00441933, received from Regulatory Authority. A 94-year-old female patient received 1st dose of bnt162b2 (COMIRNATY, strength: 0.3 ml, lot number: EM0477), via an unspecified route of administration on 03Feb2021 at single dose for covid-19 immunisation, oxycodone hydrochloride (OXYCODON, strength: 5 mg), via an unspecified route of administration from 02Feb2021 to 05Feb2021 at Freq:8 h;3d5mg for pain with fracture humerus. Medical history included COVID-19 from 10Jan2021, intellectual disability. Concomitant medication included paracetamol (strength: 500 mg), colecalciferol, omeprazole (strength: 40 mg), macrogol. The patient experienced low saturation, then fever, temperature 38.5 centigrade, vomiting, nausea on 04Feb2021. Later on the day after vaccination (04Feb2021), abnormalities were seen in the lungs. Suspicion of reported: aspiration pneumonia. Treatment: Nausea was treated with metoclopramide zetpil 10mg 3 times a day 1. Drugs and latency: 1. covid-19 vaccine pfizer Injectable solution for events: 1 day after start; 2. oxycodon capsule 5mg for events: 2 days after start. The patient underwent lab tests and procedures which included body temperature: 38.5 centigrade on 04Feb2021, corona confirmed by test: positive on 10Jan2021. The action taken in response to the events for oxycodone hydrochloride was permanently withdrawn on 05Feb2021. The outcome of events was fatal. The patient died on 06Feb2021. It was not reported if an autopsy was performed. Case Summary and Reporter''s Comments Text: BioNTech/Pfizer vaccine (Comirnaty) ----------Past drug therapy BioNTech/Pfizer vaccine (Comirnaty): no ---------- vomiting, then fever and low saturation ---------- Additional information ADR: Patient with intellectual disability, living in institution. Patient had a positive COVID test on 10Jan2021, but has not been very ill. Therefore consciously opted for vaccination. Day after vaccination vomiting and possible pain from humerus fracture, also temperature 38.5 centigrade. Later in the day also some abnormalities of the lungs. Suspicion aspiration pneumonia. She passed away on 06Feb2021. ---------- COVID19 ----------Previous COVID-19 infection: disease symptoms: none ---------- Other ----------diagnostic procedures: no No follow-up attempts possible. No further information expected.;

Reporter"s Comments: Summary of Reporter Comment: Patient with intellectual disability, living in institution. Positive COVID test on 10Jan2021, but has not been very ill. Therefore consciously opted for vaccination. Day after vaccination vomiting and possible pain from humerus fracture, also temperature 38.5 C. Later in the day also some abnormalities of the lungs. Suspicion aspiration pneumonia. She passed away on 06Feb2021. Previous COVID-19 infection: disease symptoms: none, Other diagnostic procedures: no; Reported Cause(s) of Death: low saturation; then fever, temperature 38.5 centigrade; Vomiting; Nausea; suspected aspiration pneumonia

Case Details

VAERS ID: 1056349 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-01-28
Onset: 2021-01-30
Days after vaccination: 2
Submitted: 0000-00-00
Entered: 2021-02-26

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Death
SMQs:
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-01-30
Days after onset: 0
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: MACROGOL; PARACETAMOL; CYANOCOBALAMINE; CALCIUMCARBONAAT; BUMETANIDE; CLOPIDOGREL; COLECALCIFEROL; LOSARTAN; PANTOPRAZOLE
Current Illness: Heart failure
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC2021191256
Write-up: Death; This is a spontaneous report received from a contactable other health professional downloaded from the Regulatory Agency NL-LRB-00444824. A 93-

year-old male patient received BNT162B2 (COMIRNATY, lot number: EM0477), via an unspecified route of administration on 28Jan2021 at single dose for COVID-19 immunization. Medical history included ongoing severe heart failure. Concomitant medication included macrogol at one dose form, paracetamol (formulation: tablet, strength: 1000 mg) at 1000 mg, cyanocobalamine (formulation: tablet) at 1000 ug, calciumcarbonaat (formulation: chewable tablet) at one dose form (680/80 mg), bumetanide (formulation: tablet) at 0.5 mg , clopidogrel (formulation: tablet) at 75 mg, colecalciferol (formulation: capsule) at 5600 iU, losartan (formulation: film-coated tablet) at 25 mg and pantoprazole (formulation: gastro-resistant tablet) at 40 mg. The patient death occurred on 30Jan2021, unknown cause of death. It was not reported if an autopsy was performed. No follow-up attempts possible. No further information expected.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: 1056350 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-02-04
Onset: 2021-02-04
Days after vaccination: 0
Submitted: 0000-00-00
Entered: 2021-02-26

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Blood test, Chills, Cystitis, Fatigue, Hepatic failure, Malaise, Urine analysis
SMQs:, Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 0000-00-00
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data: Test Name: blood test; Result Unstructured Data: Test Result:unknown; Test Name: urine test; Result Unstructured Data: Test Result:unknown
CDC Split Type: NLPFIZER INC2021191261

Write-up: liver failure leading to death; Cystitis; occur general malaise; Fatigue; Cold shivers; This is a spontaneous report from a contactable consumer downloaded from the Regulatory Agency NL-LRB-00444927. A 95-year-old female patient received first dose of BNT162B2 (COMIRNATY, lot number: EM0477), via an unspecified route of administration on 04Feb2021 at single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced fatigue and cold shivers on 04Feb2021; liver failure leading to death, cystitis and general malaise, all on 07Feb2021. The patient underwent lab tests and procedures which included blood test and urine analysis: both results were unknown on an unspecified date. The patient died on an unspecified date, unknown cause of death. It was not reported if an autopsy was performed. No follow-up attempts possible. No further information expected. ; Reported Cause(s) of Death: unknown cause of death

VAERS ID: 1061850 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-02-04
Onset: 2021-02-04
Days after vaccination: 0
Submitted: 0000-00-00
Entered: 2021-03-01

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Malaise, Nausea, SARS-CoV-2 test positive
SMQs:, Acute pancreatitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (narrow)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-01
Days after onset: 3
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: CITALOPRAM
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19; Seizure; Vascular dementia
Allergies:
Diagnostic Lab Data: Test Date: 20201021; Test Name: COVID-19 virus test; Test

Result: Positive
CDC Split Type: NLPFIZER INC2021191182
Write-up: Nausea; Malaise; This is a spontaneous report downloaded from the Medicines Agency regulatory authority-WEB [Lareb (LRB) number NL-LRB-00443788] from a contactable physician. An 84-year-old male patient received bnt162b2 (COMIRNATY) (lot# EM0477), via an unspecified route of administration, on 04Feb2021, at single dose, for COVID-19 immunisation. Medical history included vascular dementia from Sep2019, seizure from 12Jan2021, COVID-19 from 21Oct2020. Concomitant medication included citalopram (unknown manufacturer). The patient experienced nausea and malaise both on 04Feb2021 with fatal outcome in Feb2021 (within 8 days after vaccination). The patient underwent lab tests and procedures which included COVID-19 virus test: positive on 21Oct2020. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Malaise; nausea

Case Details

VAERS ID: 1061853 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-02-04
Onset: 2021-02-07
Days after vaccination: 3
Submitted: 0000-00-00
Entered: 2021-03-01

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Computerised tomogram, Ischaemic cerebral infarction, SARS-CoV-2 test
SMQs:, Ischaemic central nervous system vascular conditions (narrow), Embolic and thrombotic events, arterial (narrow), COVID-19 (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-08
Days after onset: 1
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? Yes, ? days

Extended hospital stay? No
Previous Vaccinations:
Other Medications: IMODIUM; IPRAMOL; ITRACONAZOL
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: Autism; Mental disability
Allergies:
Diagnostic Lab Data: Test Name: CT-scan; Result Unstructured Data: Test Result:showed a major ischemic stroke; Test Date: 20210201; Test Name: COVID-19 test; Test Result: Negative
CDC Split Type: NLPFIZER INC2021191170
Write-up: Received 1st vaccination on 04Feb. Found on 07Feb morning with ischemic cardiovascular accidennt, died of it; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority-WEB [NL-LRB-00445065]. A 65-years-old male patient received the first dose of bnt162b2 (COMIRNATY; Lot # EM0477) vaccine , via an unspecified route of administration on 04Feb2021 at single dose for covid-19 immunisation . Medical history included autism spectrum disorder, mental disability. Concomitant medication included loperamide hydrochloride (IMODIUM), ipratropium bromide, salbutamol sulfate (IPRAMOL), itraconazol (ITRACONAZOL). The patient received 1st vaccination on 04Feb2020. found on 07Feb2020 morning with ischemic cardiovascular accidennt, on 07Feb2021. The patient underwent lab tests and procedures which included computerised tomogram: showed a major ischemic stroke, sars-cov-2 test: negative on 01Feb2021. The patient died on 08Feb2021 because of the event. It was not reported if an autopsy was performed. Course of the event Hemiparesis on the left with among other things compulsive head. Large ischemic CVA on CT on the right. Unable to eat and died in hospital on 08Feb2021. Patient was severely mentally disabled with autism. One month before, Covid had prevailed in his group home, the patient himself was not infected. He had a fever on the evening of 01Feb2021, was then tested for Covid, was negative. No follow-up attempts possible. No further information expected.; Reported Cause(s) of Death: large ischemic stroke

Case Details

VAERS ID: 1065048 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-01-29
Onset: 2021-01-31
Days after vaccination: 2
Submitted: 0000-00-00
Entered: 2021-03-02

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Cachexia, Depressed level of consciousness, Fatigue, Malaise
SMQs:, Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Hypotonic-hyporesponsive episode (broad), Generalised convulsive seizures following immunisation (broad), Hypoglycaemia (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-13
Days after onset: 13
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: PARACETAMOL; ESOMEPRAZOLE; FENTANYL
Current Illness: Reduced general condition (before vaccination)
Preexisting Conditions: Medical History/Concurrent Conditions: Alzheimer"s disease; Cognitive disorder; Diabetes mellitus; Fractured sacrum; Gonarthrosis;

Hypertension; Incontinence of urine (due to cognitive problem); Infection (antibiotic); Osteoporosis; Phacoemulsification (OD2007); Pneumonia; Prosthesis fracture (Status after left neck prosthesis due to fracture); Scabies; Type 2 diabetes mellitus
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC2021199233
Write-up: cachexia; partly conscious; Not feeling well; Fatigue; This is a spontaneous report from a contactable physician downloaded from the Medicines Agency (MA) regulatory authority-WEB NL-LRB-00444118, Safety Report Unique Identifier NL-LRB-00445742. An 89 years old female patient received the first dose of bnt162b2 (COMIRNATY, Solution for injection, lot number: EM0477), via an unspecified route of administration on 29Jan2021 at single dose (1 dose form) for COVID-19 immunisation. Medical history included Hypertension, Osteoporosis, Diabetes mellitus from 2015, Gonarthrosis from 2012, Alzheimer''s disease, Pneumonia from 2014, Infection toe wv antibiotic from 2011, Scabies from 2010, phacoemulsification from 2007 (reported as "OD2007"), sacrum fracture in osteoprorosis from 2003, Status after left neck prosthesis due to fracture from 1992, Type 2 diabetes mellitus (DM2) from 1990, Incontinence of urine due to cognitive problem, health was already declining before vaccination and ongoing. Concomitant medications included paracetamol, esomeprazole, fentanyl patch. On 31Jan2021, the patient experienced not feeling well (death), fatigue (death) following administration bnt162b2 for covid 19 immunisation. Physician described that the patient''s health was already declining before vaccination and that there was doubt if the patient should be vaccinated. Her health declining was predominantly caused by her stopping to eat and drink. Drugs and latency for bnt162b2 and malaise/ fatigue was 2 days after start. It was reported that follow-up on 16Feb2021, the patient died on 13Feb2021 due to cachexia when stopping drinking, partly conscious. The patient was already vulnerable, admitted to a nursing institution for psychogeriatric patients, there were still doubted as to whether she should be vaccinated, eventually she died after consultation. The decline was mainly indicated in the context of the decline in stopping eating and drinking. Events not feeling well, fatigue and cachexia Resulted in death. No corona test was taken. No autopsy was performed. The outcome of the event partly conscious was unknown, of the events was fatal. Case Summary and Reporter''s Comments: BioNTech / Pfizer vaccine (Comirnaty) Past drug therapy BioNTech / Pfizer vaccine (Comirnaty): no confounding factors confounding factors: Alzheimer''s dementia COVID19 Previous COVID-19 infection: No; Other diagnostic procedures: no comments to report form: Already worsening with doubts about whether she should be vaccinated. Would say she died in deterioration with the corona vaccination rather than that she died as a result of the vaccination. No follow-up attempts are possible. No further information is expected.; Reporter''s Comments: BioNTech / Pfizer vaccine (Comirnaty) Past drug therapy BioNTech / Pfizer vaccine (Comirnaty): no confounding factors confounding factors: Alzheimer''s dementia COVID19 Previous COVID-19 infection: No; Other diagnostic procedures: no comments to report form: Already worsening with doubts about whether she should be vaccinated. Would say she died in deterioration with the corona vaccination rather

than that she died as a result of the vaccination. ; Reported Cause(s) of Death: cachexia; malaise; fatigue

Case Details

VAERS ID: 1070417 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-01-28
Onset: 2021-02-08
Days after vaccination: 11
Submitted: 0000-00-00
Entered: 2021-03-03

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Cardiac failure, SARS-CoV-2 test
SMQs:, Cardiac failure (narrow), Cardiomyopathy (broad), COVID-19 (broad), Noninfectious myocarditis/pericarditis (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-12
Days after onset: 4
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness: Hospitalization; Rehabilitation therapy
Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19; Dementia; Femoral neck fracture; Hip prosthesis insertion
Allergies:
Diagnostic Lab Data: Test Date: 20201230; Test Name: SARS-CoV-2 test; Test Result: Positive ; Comments: CT value 25; Test Date: 20210111; Test Name:

SARS-CoV-2 test; Test Result: Positive ; Comments: CT value 35
CDC Split Type: NLPFIZER INC2021213098
Write-up: Heart failure; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority-WEB NL-LRB-00446835. A 77-years-old female patient received first dose of BNT162B2 (COMIRNATY, lot number: EM0477), via an unspecified route of administration on 28Jan2021 at single dose for COVID-19 immunisation. Medical history included COVID-19 from 30Dec2020, mild dementia, femoral neck fracture, hip prosthesis insertion. Patient was admitted for rehabilitation on 03Dec2020 after a femoral neck fracture and hip replacement; was discharged home on 28Jan2021 (the day of vaccination). Due to the pandemic, SARS-CoV-2 test was taken which turned out to be positive (CT value 25) on 30Dec2020. She had been nursed in isolation until 11Jan2021. She had not had any corona related complaints at all. On 11Jan2021, the SARS-CoV-2 test was still positive (CT value 35), on the basis of the new FMS guideline, she had been declared non-infectious and the isolation had been lifted. The patient did not have any COVID-19 related symptoms during her stay. The patient had no cardiac history. Concomitant medications were not reported. On 08Feb2021, the general practitioner visited her because of symptoms of heart failure, which was treated with furosemide. On 12Feb2021, she was found lifeless by her husband; CPR was performed without successful. The patient died due to heart failure on 12Feb2021. It was unknown if an autopsy was done or not. Reporter''s Comments: Past drug therapy BioNTech/Pfizer vaccine (Comirnaty): no; heart failure and death. Additional information ADR: Patient was admitted for rehabilitation after a neck fracture and hip replacement; was discharged home on 28Jan2021 (the day of vaccination). On 08Feb2021 the GP visited her because of signs of heart failure, on 12Feb2021 she was found lifeless by her husband; resuscitation was unsuccessful. Important info: she was admitted to our rehabilitation center on 03Dec2020. Due to the pandemic, a corona PCR test was taken which turned out to be positive CT value 25. She has been nursed in isolation until 11Jan2021. She has not had any corona related complaints at all. On 11Jan2021 the PCR was still positive (CT value 35). On the basis of the new FMS guideline, she has been declared non-infectious and the isolation has been lifted. The remaining stay in the rehabilitation center also had no complaints. Secondary diagnosis: her mild dementia was not familiar with cardiac problems, so the development of heart failure is striking. Vaccinated 4 weeks apart from pos PCR on the basis of National Institute for Public Health and the Environment guideline. COVID19: Previous COVID-19 infection: disease symptoms: none Other diagnostic procedures: no No follow-up attempts possible. No further information expected.; Reporter''s Comments: Past therapy (Comirnaty): no; heart failure and death. On 08Feb2021 the GP visited her due to heart failure, on 12Feb2021 she was found lifeless; resuscitation was unsuccessful. Important info: on 30Dec2020, PCR test positive. On 11Jan2021 PCR still positive. Secondary diagnosis: her mild dementia was not familiar with cardiac problems, so the development of heart failure is striking. Vaccinated 4 weeks apart from pos PCR. Previous COVID19: no disease symptoms; no other diagnostic procedures.; Reported Cause(s) of Death: Heart failure

Case Details

VAERS ID: 1070419 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-02-04
Onset: 2021-02-06
Days after vaccination: 2
Submitted: 0000-00-00
Entered: 2021-03-03

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	UNKNOWN / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Pneumonia aspiration, Somnolence, Vomiting
SMQs:, Acute pancreatitis (broad), Anticholinergic syndrome (broad), Dementia (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Hypoglycaemia (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-10
Days after onset: 4
Permanent Disability? No
Recovered? No
Office Visit? Yes
ER Visit? No
ER or Doctor Visit? No
Hospitalized? Yes, ? days
Extended hospital stay? No
Previous Vaccinations:

Other Medications: PARACETAMOL
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19 (disease symptoms: quite); Parkinson''s disease aggravated; Parkinsonism
Allergies:
Diagnostic Lab Data: Test Name: CT brain; Result Unstructured Data: Test Result:showed no abnormalities; Test Date: 20200328; Test Name: corona, bevestigd met test; Test Result: Positive
CDC Split Type: NLPFIZER INC2021212821
Write-up: Aspiration pneumonia; Vomiting; Somnolence; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority-WEB NL-LRB-00448059. An 85-year-old male patient received BNT162B2 (COMIRNATY, Batch/lot number: EM0477), via an unspecified route of administration on 04Feb2021 at 0.3 mL, single for covid-19 immunisation, clozapine (strength: 6.25mg tablet) via an unspecified route of administration from 2020 at 12.5 mg once daily for severe hallucinations in advanced Parkinson''s. Medical history included parkinsonism, advanced Parkinson''s, previous COVID-19 infection on 28Mar2020 (disease symptoms: quite). Concomitant medication included paracetamol (strength: 500mg). It was reported that patient experienced somnolence/no drowsiness on 06Feb2021 (2 days after use of covid-19 vaccine) and requiring treating with a short-term hospitalization and visiting a neurologist. The patient developed aspiration pneumonia on 10Feb2021 (6 days after use of covid-19 vaccine) due to vomiting on 07Feb2021 (3 days after use of covid-19 vaccine) leading to aspiration and required hospitalization. The patient with advanced Parkinson''s eventually died on 10Feb2021. Clozapine tablet was also considered suspect. The patient underwent lab test which included ''corona, bevestigd met test'': positive on 28Mar2020 and diagnostic procedure CT brain by neurologist which showed no abnormalities (undated). The action taken in response to the events for clozapine was dose reduced. The patient died on 10Feb2021. The reported cause of death was vomiting and aspiration pneumonia. It was not reported if an autopsy was performed. The outcome of vomiting and aspiration pneumonia is fatal, the outcome of somnolence is unknown. Reporter''s Comments: Hospitalization information: re-submitted due to vomiting where aspiration also occurred, eventually died on 10Feb2021, so 6 days after vaccination the patient with advanced Parkinson''s died due to aspiration pneumonia. Additional information ADR: reduced approachable vomiting. Hospitalization information: resent due to vomiting where aspiration also occurred, eventually died on 10Feb2021, so 6 days after vaccination the patient with advanced Parkinson''s died as a result of aspiration pneumonia. Confounding factors: advanced Parkinson''s. No follow-up attempts are possible. No further information expected.; Reported Cause(s) of Death: aspiratiepneumonie bij vergevorderde m Parkinson; vomiting

Case Details

VAERS ID: 1076577 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-02-05
Onset: 2021-02-06
Days after vaccination: 1
Submitted: 0000-00-00
Entered: 2021-03-05

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Body temperature, Chills, Dyspnoea, Hypotension, Myalgia, Pyrexia
SMQs:, Rhabdomyolysis/myopathy (broad), Anaphylactic reaction (narrow), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Cardiomyopathy (broad), Eosinophilic pneumonia (broad), Tendinopathies and ligament disorders (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Dehydration (broad), Hypokalaemia (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 0000-00-00
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: Cervical vertebral

fracture (neck fracture for which surgery and then delirium.); Delirium; Femur fracture
Allergies:
Diagnostic Lab Data: Test Date: 20210210; Test Name: pyrexia; Result Unstructured Data: Test Result:38 to 40.5 Centigrade; Comments: fever: 38 to 40.5 celsius degrees
CDC Split Type: NLPFIZER INC2021221946
Write-up: dyspnoea: severity increased progressively; hypotension: severity increased at a progressive rate; Fever: 38 to 40.5 Celsius degrees; Cold shivers; Myalgia; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority-WEB and received via Regulatory Authority NL-LRB-00445703. An elderly male patient (also reported as "a male aged 90 years") received BNT162B2 (COMIRNATY, lot number: EM0477), via an unspecified route of administration on 05Feb2021 at single dose (reported as "1 DF") for covid-19 immunisation. Medical history included femur fracture, delirium, neck fracture for which surgery and then delirium. No previous COVID-19 infection. No past drug therapy BioNTech/Pfizer vaccine. The patient''s concomitant medications were not reported. The patient experienced fever: 38 to 40.5 celsius degrees on 10Feb2021, myalgia on 06Feb2021, cold shivers on 10Feb2021, dyspnoea: severity increased progressively on 11Feb2021, hypotension: severity increased at a progressive rate on 10Feb2021. The case was reported as serious due to death outcome of all reported events. It was reported that the patient with dyspnoea (death), chills (death), myalgia (death), pyrexia (death), hypotension (death) following administration of covid-19 Pfizer vaccine. Chills was treated with paracetamol, dyspnoea is treated with oxygen and palliative care, hypotension is treated with oxygen and palliative care and pyrexia is treated with paracetamol. The outcome of chills is fatal, the outcome of dyspnoea is fatal, the outcome of hypotension is fatal, the outcome of myalgia is fatal and the outcome of pyrexia is fatal. The severity of dyspnoea and hypotension increased at a progressive rate. Drugs and latency: dyspnoea: 6 days after start, chills: 5 days after start, myalgia: 1 days after start, pyrexia: 5 days after start, hypotension: 6 days after start. Treatment received for all reported events. The patient died on an unspecified date in 2021. It was unknown if an autopsy was performed. No follow-up attempts are possible. No further information is expected. ; Reported Cause(s) of Death: fever: 38 to 40.5 celsius degrees; myalgia; cold shivers; dyspnoea: severity increased progressively; hypotension: severity increased at a progressive rate

VAERS ID: 1076581 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-02-04
Onset: 2021-02-05
Days after vaccination: 1
Submitted: 0000-00-00
Entered: 2021-03-05

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Cerebrovascular accident, Confusional state, Depressed level of consciousness, Epilepsy, Pyrexia, SARS-CoV-2 test, Vomiting
SMQs:, Acute pancreatitis (broad), Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Systemic lupus erythematosus (broad), Anticholinergic syndrome (narrow), Ischaemic central nervous system vascular conditions (narrow), Haemorrhagic central nervous system vascular conditions (narrow), Dementia (broad), Convulsions (narrow), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Hypotonic-hyporesponsive episode (broad), Generalised convulsive seizures following immunisation (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Hypoglycaemia (broad), COVID-19 (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-07
Days after onset: 2
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:

Other Medications: PARACETAMOL; PASSIFLORA ALATA EXTRACT; OMEPRAZOL; EUTHYROX; MACROGOL
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19 (with no symptoms)
Allergies:
Diagnostic Lab Data: Test Date: 20201216; Test Name: corona, bevestigd met test; Test Result: Positive
CDC Split Type: NLPFIZER INC2021221962
Write-up: CVA; sudden confusion / gibberish; Consciousness decreased; Fever; with vomiting; epileptic seizure; This is a spontaneous report from a contactable other healthcare professional downloaded from the Regulatory Authority-WEB manufacturer report number NL-LRB-00452103. A 95-years-old male patient received bnt162b2 (COMIRNATY, lot# EM0477), via an unspecified route of administration on 04Feb2021 at single dose for COVID-19 immunisation. Medical history included COVID-19 with no symptoms from 16Dec2020. Concomitant medications included paracetamol, passiflora alata extract, omeprazole (OMEPRAZOL), levothyroxine sodium (EUTHYROX), macrogol. No past drug therapy. The patient was died 3 days after vaccination due to sudden confusion / gibberish, consciousness decreased, fever, with vomiting, epileptic seizure, the events onset date was on 05Feb2021. It started with a confusional state and fever, followed by a decreased level of consciousness and seizure with vomiting. After this the patient did not regain consciousness again. Confounding factors: CVA (cerebrovascular accident) / epileptic seizure. No diagnostic procedures. The patient underwent lab tests and procedures which included corona confirmed by test: positive on 16Dec2020. The patient died on 07Feb2021. It was not reported if an autopsy was performed. No follow-up attempts possible. No further information expected.; Reported Cause(s) of Death: CVA; sudden confusion / gibberish; Consciousness decreased; Fever; with vomiting; epileptic seizure

VAERS ID: 1076585 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-02-02
Onset: 2021-02-01
Submitted: 0000-00-00
Entered: 2021-03-05

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Blood test, Death, Urinary tract infection
SMQs:
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-10
Days after onset: 9
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: MORFINE; MIDAZOLAM
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data: Test Date: 202102; Test Name: blood tests; Result Unstructured Data: Test Result:increased infection parameters
CDC Split Type: NLPFIZER INC2021226280
Write-up: Death; infection (probably a complicated urinary tract infection) / increased infection parameters; This is a spontaneous report from contactable physician downloaded from the Medicines Agency (MA) WEB NL-LRB-00453421. A 91-year-old female patient received the first dose of bnt162b2 (COMIRNATY, Solution for

injection, lot number: EM0477), via an unspecified route of administration on 02Feb2021 at single dose for COVID-19 immunisation. The patient''s medical history was not reported. Concomitant medications included morfine, midazolam. Following the first administration of bnt162b2, 8 days after, the patient experienced death on 10Feb2021. It was unknown if an autopsy was performed. According to the reporter, the patient deceased due to an infection (probably a complicated urinary tract infection) (Feb2021). Blood test showed increased infection parameters (Feb2021). In the reporter''s opinion, death as a result of infection, but report due to not long after COVID vaccination. Confounding factors: infection (probably complicated urinary tract infection). The patient didn''t have previous COVID-19 infection. The outcome of the events was fatal. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: death; infection (probably a complicated urinary tract infection) / increased infection parameters

VAERS ID: 1084920 (history)
Form: Version 2.0
Age: 88.0
Sex: Female
Location: Foreign

Vaccinated: 2021-01-27
Onset: 2021-01-27
Days after vaccination: 0
Submitted: 0000-00-00
Entered: 2021-03-09

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Loss of consciousness, Nausea, Vomiting
SMQs:, Torsade de pointes/QT prolongation (broad), Acute pancreatitis (broad), Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Hypotonic-hyporesponsive episode (broad), Generalised convulsive seizures following immunisation (broad), Hypoglycaemia (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 0000-00-00
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: COLECALCIFEROL; VASELINE CETOMACROGOL CREAM; MOVICOLON
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: Dementia vascular;

TIA
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC2021221943
Write-up: vomiting, a few minutes after administration; Loss of consciousness; Nausea; This is a spontaneous report a contactable physician downloaded from the Regulatory Authority [regulatory authority NL-LRB-00449312]. A 88-years-old female patient received BNT162B2 (COMIRNATY, lot number:EM0477) , via an unspecified route of administration on 27Jan2021 at single dose for covid-19 immunisation. Medical history included dementia vascular, transient ischaemic attack. Concomitant medication included colecalciferol, cetomacrogol, paraffin, liquid, propylene glycol, white soft paraffin (VASELINE CETOMACROGOL CREAM), macrogol, potassium chloride, sodium bicarbonate, sodium chloride (MOVICOLON). Ten minutes following the vaccination, the patient became nauseous, had to vomit and became unconscious. The patient was treated with adrenaline which was not effective. The patient deceased after an unknown period.The patient died on an unspecified date. It was not reported if an autopsy was performed. All events were fatal. Case Summary and Reporter''s Comments Text : BioNTech / Pfizer vaccine (Comirnaty) -Past drug therapy BioNTech / Pfizer vaccine (Comirnaty): no -vomiting, few minutes after administration- Additional information ADR: then loss of consciousness -confounding factors-confounding factors: dementia Not Otherwise Specified (mixed, vascular component with TIA)-COVID19-Previous COVID-19 infection: No-Other- diagnostic procedures: no No follow-up attempts are possible. No further information is expected.; Reporter''s Comments: BioNTech / Pfizer vaccine (Comirnaty) -Past drug therapy BioNTech / Pfizer vaccine (Comirnaty): no -vomiting, few minutes after administration- Additional information ADR: then loss of consciousness -confounding factors-confounding factors: dementia Not Otherwise Specified (mixed, vascular component with TIA)-COVID19-Previous COVID-19 infection: No-Other- diagnostic procedures: no; Reported Cause(s) of Death: nausea; loss of consciousness; vomit

VAERS ID: 1106068 (history)
Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-01-26
Onset: 2021-02-04
Days after vaccination: 9
Submitted: 0000-00-00
Entered: 2021-03-16

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Acute coronary syndrome, Circulatory collapse, Heart rate increased, Hypotension, Shock
SMQs:, Anaphylactic reaction (narrow), Neuroleptic malignant syndrome (broad), Myocardial infarction (narrow), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Torsade de pointes, shock-associated conditions (narrow), Hypovolaemic shock conditions (narrow), Toxic-septic shock conditions (narrow), Anaphylactic/anaphylactoid shock conditions (narrow), Hypoglycaemic and neurogenic shock conditions (narrow), Embolic and thrombotic events, arterial (narrow), Hypotonic-hyporesponsive episode (broad), Hypersensitivity (narrow), Dehydration (broad), Hypokalaemia (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-05
Days after onset: 1
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: D-CURA; BISACODYL; CALCI CHEW; ACETYLCYSTEINE; AZITROMYCINE; FOSTER [BECLOMETASONE DIPROPIONATE;FORMOTEROL

FUMARATE]; VENTOLINE [SALBUTAMOL]; ATROVENT
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: COPD
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC2021256604
Write-up: Hypotension; Collapse vascular, the first days after corona vaccination nothing unusual, collapse after day 9; Heart rate increased; hypotensive shock after an acute coronary syndrome; hypotensive shock after an acute coronary syndrome; This is a spontaneous report downloaded from the regulatory authority-WEB NL-LRB-00455939. The report was received from a contactable Physician via the Netherlands regulatory authority. A 78-year-old female patient received BNT162b2 (COMIRNATY, Solution for injection, Lot number EM0477), via an unspecified route of administration on 26Jan2021 at single dose for covid-19 immunisation. Medical history included chronic obstructive pulmonary disease. Concomitant medication included colecalciferol (D-CURA) 25.000ie capsule, bisacodyl tablet gastro-resistant 5mg, calcium carbonate (CALCI CHEW) 500 mg , acetylcysteine 600mg, azithromycin tablet 250mg, beclometasone dipropionate/ formoterol fumarate (FOSTER) aerosol 100/6ug/dosis, salbutamol (VENTOLINE) aerosol 100ug/dosis, ipratropium bromide (ATROVENT) aerosol 20ug/dosis. First days after vaccination nothing unusual. On 04Feb2021, nine days after vaccination patient had a collapse vascular, most suitable for a hypotensive shock after an acute coronary syndrome. Patient died a day later on 05Feb2021. The reported fatal events were collapse vascular, hypotension and heart rate increased. Patient had no medical history of cardiac risk factors although COPD was 2-3 years old. It is questionable whether it is related to the corona vaccination, but given the seriousness and the fact that this was so unexpected, a report was made. Confounding factors: Advanced COPD which also increases cardiovascular risk. No follow-up attempts are needed. No further information is expected.; Reported Cause(s) of Death: hypotensive shock matching with acute coronary syndrome

VAERS ID: 1109864 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-02-04
Onset: 2021-02-06
Days after vaccination: 2
Submitted: 0000-00-00
Entered: 2021-03-18

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Arrhythmia
SMQs:, Cardiomyopathy (broad), Cardiac arrhythmia terms, nonspecific (narrow)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 0000-00-00
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? Yes, ? days
Extended hospital stay? No
Previous Vaccinations:
Other Medications: FUROSEMIDE; METOPROLOL; NEULEPTIL [PERICIAZINE]; PERINDOPRIL ERBUMINE; AMIODARON [AMIODARONE]; ACENOCOUMAROL; ROSUVASTATINE [ROSUVASTATIN]; GLUCIENT SR
Current Illness: Arrhythmia; Implantable cardioverter defibrillator insertion
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC2021256558
Write-up: Arrhythmia; This is a spontaneous report from a contactable physician via the Agency (LRB), downloaded from the Agency Regulatory Agency-WEB (NL-LRB-00454760). A 70-year-old male patient received the first dose of BNT162B2

(COMIRNATY; Lot number EM0477) via an unspecified route of administration on 04Feb2021 at single dose for COVID-19 immunisation. Relevant medical history included ongoing implantable defibrillator insertion and ongoing arrhythmia. Concomitant medications included furosemide 40 mg, metoprolol 100 mg, periciazine (NEULEPTIL) 5 mg, perindopril erbumine 2 mg, amiodarone (AMIODARON) 200 mg, acenocoumarol 1 mg, rosuvastatin [ROSUVASTATINE] 10 mg and metformin hydrochloride (GLUCIENT SR) 500 mg. On 06Feb2021, the patient experienced arrhythmia for which he was hospitalized on the same day. The reporter specified that the patient had previous hospitalization''s due to this arrhythmia. After a hospitalization of 2 weeks, the patient deceased on an unspecified date in 2021. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Based on his known heart rhythm problem

VAERS ID: 1132976 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-02-04
Onset: 2021-02-05
Days after vaccination: 1
Submitted: 0000-00-00
Entered: 2021-03-25

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / UNK	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Fatigue, Malaise, Small intestinal obstruction
SMQs:, Gastrointestinal obstruction (narrow)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 0000-00-00
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: MADOPAR
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: Parkinsonism
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC2021297567
Write-up: Ileal obstruction; Not feeling well; Fatigue; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority-WEB. Regulatory Authority Number is NL-LRB-00473781. An 85-year-old male patient received BNT162B2 (COMIRNATY, lot number EM0477) at single dose on 04Feb2021 via an unknown route for COVID-19 vaccination. Medical history included parkinsonism. No Previous COVID-19 infection. Concomitant drug included

benserazide hydrochloride, levodopa (MADOPAR tablet 100/25mg). No past drug therapy with COMIRNATY. The patient experienced fatigue on 05Feb2021, not feeling well on 06Feb2021, and Ileal obstruction on 11Feb2021. The events were serious with seriousness criteria of death. Ileal obstruction was treated with enema, and malaise was treated with enema. Drugs and latency for the events was: ileal obstruction: 7 days after covid-19 vaccine; fatigue: 1 days after covid-19 vaccine; malaise: 2 days after covid-19 vaccine. Patient died on an unknown date. It was unknown if autopsy was done. Outcome of the events was fatal. Additional information: 7 days after vaccination, the patient was assessed and an obstructive ileus discovered. No follow-up attempts are possible, information on batch numbers cannot be obtained.; Reported Cause(s) of Death: not feeling well; fatigue; Ileal obstruction

VAERS ID: 1165547 (history)
Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-01-28
Onset: 2021-01-30
Days after vaccination: 2
Submitted: 0000-00-00
Entered: 2021-04-04

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Cerebrovascular accident, Transient ischaemic attack
SMQs:, Ischaemic central nervous system vascular conditions (narrow), Haemorrhagic central nervous system vascular conditions (narrow), Embolic and thrombotic events, arterial (narrow), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 0000-00-00
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions: Medical History/Concurrent Conditions: Brain damage; Cerebrovascular accident; Dementia; Elderly
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC2021342696
Write-up: Transient ischemic attack/ neurological deterioration after TIA; Cerebrovascular accident with disarthria, loss of strength and loss of consciousness;

This is a spontaneous report from a contactable physician downloaded from the Agency Regulatory Authority-WEB, regulatory authority number NL-LRB-00483125. A 82-years-old male patient received bnt162b2 (COMIRNATY), dose 1 via an unspecified route of administration on 28Jan2021 (Batch/Lot Number: EM0477) as single dose for covid-19 immunisation. Medical history included elderly, dementia, cerebrovascular accident, pre-existent brain damage. The patient''s concomitant medications were not reported. The patient experienced transient ischemic attack/ neurological deterioration after (death) on 30Jan2021, cerebrovascular accident with disarthria, loss of strength and loss of consciousness (death) on 30Jan2021. This serious spontaneous report from a physician concerns a male aged 82 years, with transient ischemic attack (death), cerebrovascular accident (death) following administration of covid-19 vaccin pfizer injectable solution (action taken: not applicable) for covid 19 immunisation. The outcome of cerebrovascular accident (CVA) is fatal and the outcome of transient ischemic attack (TIA) is fatal. No previous COVID-19 infection. The patient died on an unspecified date. It was not reported if an autopsy was performed. No follow-up attempts possible. No further information expected.; Reported Cause(s) of Death: CVA; tia

Case Details

VAERS ID: 1250700 (history)

Form: Version 2.0
Age:
Sex: Male
Location: Foreign

Vaccinated: 2021-01-28
Onset: 2021-02-09
Days after vaccination: 12
Submitted: 0000-00-00
Entered: 2021-04-24

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / 1	- / -

Administered by: Other **Purchased by:** ?
Symptoms: Acute cardiac event, Chronic obstructive pulmonary disease, Dyspnoea, Pulmonary embolism, Respiratory failure
SMQs:, Anaphylactic reaction (broad), Myocardial infarction (narrow), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (broad), Torsade de pointes, shock-associated conditions (broad), Hypovolaemic shock conditions (broad), Toxic-septic shock conditions (broad), Anaphylactic/anaphylactoid shock conditions (broad), Hypoglycaemic and neurogenic shock conditions (broad), Embolic and thrombotic events, venous (narrow), Acute central respiratory depression (narrow), Pulmonary hypertension (broad), Guillain-Barre syndrome (broad), Cardiomyopathy (broad), Other ischaemic heart disease (narrow), Hypersensitivity (broad), Respiratory failure (narrow), Hypokalaemia (broad), Noninfectious myocarditis/pericarditis (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-02-11
Days after onset: 2
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: RISPERIDONE; SEREVENT; MOVICOLON; SALBUTAMOL
Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: COPD
Allergies:
Diagnostic Lab Data:
CDC Split Type: NLPFIZER INC2021431099
Write-up: respiratory insufficiency; acute cardiac event; lung embolism; exacerbation of chronic obstructive pulmonary disease; acute dyspnoea; This is a spontaneous report from a contactable physician downloaded from the Agency Regulatory Authority-WEB, regulatory authority number NL-LRB-00508880. An 83-year-old male patient received the first dose of bnt162b2 (COMIRNATY, lot number: EM0477), via an unspecified route of administration on 28Jan2021 as SINGLE DOSE for COVID-19 immunisation. Medical history included chronic obstructive pulmonary disease (COPD). The patient had no previous COVID-19 infection. Concomitant medications included risperidone; salmeterol xinafoate (SEREVENT); macrogol, potassium chloride, sodium bicarbonate, sodium chloride (MOVICOLON); and salbutamol (SALBUTAMOL). On 09Feb2021, 12 days after start, the patient experienced acute dyspnoea. On an unspecified date, the patient experienced respiratory insufficiency, lung embolism, and acute cardiac event. The patient died on 11Feb2021. Patient had a symptomatic policy so no further investigations were done, which resulted in a difficulty to find out the cause of death. Cause of death according to reporter was respiratory insufficiency due to lung embolism or acute cardiac event or exacerbation of chronic obstructive pulmonary disease. It was not reported if an autopsy was performed. The events acute dyspnoea and respiratory insufficiency resulted to fatal outcome while outcome of lung embolism, acute cardiac event, and exacerbation of chronic obstructive pulmonary disease was unknown. Reporter''s Comments: BioNTech / Pfizer vaccine (Comirnaty): Past drug therapy BioNTech / Pfizer vaccine (Comirnaty): no Acute dyspnoea: Additional information adverse drug reaction: A few days after vaccination severe shortness of breath, but also Chronic obstructive pulmonary disease in history COVID-19: Previous COVID-19 infection: No. Other: diagnostic procedures: Due to symptomatic policy, no additional research was performed, so that the cause of death cannot be properly determined No follow-up attempts are possible. No further information is expected.; Reporter''s Comments: BioNTech / Pfizer vaccine (Comirnaty): Past drug therapy BioNTech / Pfizer vaccine (Comirnaty): no Acute dyspnoea: Additional information adverse drug reaction: A few days after vaccination severe shortness of breath, but also Chronic obstructive pulmonary disease in history COVID-19: Previous COVID-19 infection: No. Other: diagnostic procedures: Due to symptomatic policy, no additional research was performed, so that the cause of death cannot be properly determined; Reported Cause(s) of Death: respiratory insufficiency; acute dyspnoea

Case Details

VAERS ID: 1980445 (history)

Form: Version 2.0
Age:
Sex: Female
Location: Foreign

Vaccinated: 2021-12-02
Onset: 2016-01-01
Submitted: 0000-00-00
Entered: 2021-12-25

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EM0477 / 3	- / -
UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER	UNKNOWN / UNK	- / OT

Administered by: Other **Purchased by:** ?
Symptoms: Cardiac failure, Chronic obstructive pulmonary disease, Depression, EGFR status assay, Gastrointestinal haemorrhage, Hypovolaemic shock, Immunisation, Rectal haemorrhage, Renal failure
SMQs:, Rhabdomyolysis/myopathy (broad), Acute renal failure (narrow), Cardiac failure (narrow), Haemorrhage terms (excl laboratory terms) (narrow), Retroperitoneal fibrosis (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (broad), Torsade de pointes, shock-associated conditions (broad), Hypovolaemic shock conditions (narrow), Toxic-septic shock conditions (broad), Anaphylactic/anaphylactoid shock conditions (broad), Hypoglycaemic and neurogenic shock conditions (broad), Gastrointestinal haemorrhage (narrow), Ischaemic colitis (broad), Cardiomyopathy (broad), Depression (excl suicide and self injury) (narrow), Chronic kidney disease (narrow), Tumour lysis syndrome (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Dehydration (narrow), Noninfectious myocarditis/pericarditis (broad)
Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2021-12-08
Days after onset: 2168
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No

ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: BUMETANIDE; FLUOXETINE; VIDISIC CARBOGEL; PARACETAMOL; CALCIUM CARBONATE AND VITAMIN D3; VASELINE CETOMACROGOL CREAM; SPIRONOLACTON; DURATEARS [DEXTRAN 70;HYPROMELLOSE]; ATORVASTATINE [ATORVASTATIN]; MICROLAX [SODIUM CITRATE;SODIUM LAURYL S
Current Illness: COPD; Depression; Heart failure; Renal insufficiency (egfr 29); Type 2 diabetes mellitus
Preexisting Conditions: Medical History/Concurrent Conditions: Allergy multiple; Atrial fibrillation
Allergies:
Diagnostic Lab Data: Test Name: EGFR; Result Unstructured Data: Test Result:29
CDC Split Type: NLPFIZER INC202101785914
Write-up: Rectal blood loss; massive gastrointestinal blood loss and death on 08Dec2021; Hypovolemic shock; booster; Depression; Renal insufficiency; Heart failure; COPD; This is a spontaneous follow-up report received from a contactable physician from Regulatory Authority, via License Party (RA). Regulatory number: NL-LRB-00726502 (RA). Other Case identifier: NL-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-135662 (RA). This case was received via health authority (Reference number: NL-LRB-00726502) on 13-Dec-2021 and was forwarded to RA on 13-Dec-2021. This spontaneous case was reported by a physician and describes the occurrence of fatal GASTROINTESTINAL HAEMORRHAGE (Gastrointestinal bleeding), fatal RECTAL HAEMORRHAGE (Rectal blood loss), fatal HYPOVOLAEMIC SHOCK (Hypovolemic shock), CARDIAC FAILURE (Heart failure) and RENAL FAILURE (Renal insufficiency) in 91-year-old female patient who received apixaban (Eliquis) tablet for Cerebrovascular accident prophylaxis. The occurrence of additional non-serious events is detailed below CO-SUSPECT PRODUCTS included dose Covid-19 Vaccine on 03Dec2021,as dose 3 (booster), single for COVID-19 immunisation. Relevant medical history included: "Heart failure", start date: Jul2018 (ongoing); "Depression", start date: Nov2021 (ongoing); "Type 2 diabetes mellitus", start date: Jan2000 (ongoing); "COPD", start date: Jan2016 (ongoing); "Renal insufficiency", start date: Apr2019 (ongoing), notes: egfr 29; "Atrial fibrillation" (unspecified if ongoing); and Allergy multiple (oxycodon, opioiden, nitrofurantoine). In 2008, the patient started Eliquis (unknown route). On 29-Jan-2021, the patient started Covid-19 Vaccine (unknown route) first dose. On 26-Feb-2021, the dose was changed to second dose. On 02-Dec-2021, the dose was changed to third dose. In January 2016, the patient experienced CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD). In July 2018, the patient experienced CARDIAC FAILURE (seriousness criterion medically significant). In April 2019, the patient experienced RENAL FAILURE (seriousness criterion medically significant). In November 2021, the patient experienced DEPRESSION. On 08-Dec-2021, the patient experienced GASTROINTESTINAL HAEMORRHAGE (seriousness criteria death and medically significant). On an unknown date, the patient experienced RECTAL HAEMORRHAGE (seriousness criteria death and medically

significant) and on 08Dec2021, HYPOVOLAEMIC SHOCK (seriousness criteria death and medically significant). The action taken with Eliquis(Unknown) was unknown. The patient died on 08-Dec-2021. The reported cause of death was Rectal blood loss, Hypovolemic shock and Gastrointestinal bleeding. It is unknown if an autopsy was performed. At the time of death, CARDIAC FAILURE, RENAL FAILURE, DEPRESSION and CHRONIC OBSTRUCTIVE PULMONARY DISEASE did not resolve. The patient''s EGFR was 29. Patient received the co suspect drug covid-19 vaccin pfizer injvlst. Patient received the concomitant medications: BUMETANIDE, start date: 26Mar2021; FLUOXETINE, start date: 18Nov2020; VIDISIC CARBOGEL, start date: 18Jan2016; PARACETAMOL, start date: 30Jun2016; CALCIUM CARBONATE AND VITAMIN D3, start date: 04Jun2018; VASELINE CETOMACROGOL CREAM, start date: 22May2018; SPIRONOLACTON, start date: 20Aug2021; DURATEARS [DEXTRAN 70;HYPROMELLOSE], start date: 10May2016; ATORVASTATINE [ATORVASTATIN], start date: 04Jun2018; MICROLAX [SODIUM CITRATE;SODIUM LAURYL SULFOACETATE;SORBITOL], start date: 01Mar2018; BISOPROLOL, start date: 18Sep2019; PREGABALINE, start date: 29Apr2019; SALBUTAMOL, start date: 01Oct2019; VASELINE [PARAFFIN], start date: 29May2020; ACETYLCYSTEINE, start date: 26Sep2018; TRIMBOW, start date: 06Sep2019 as aerosol For Eliquis(Unknown), the reporter did not provide any causality assessments. Apixaban(ELIQUIS) is under agreement with company. No follow-up attempts are possible. No further information is expected.; Sender''s Comments: RA Comment: This patient died and had multiple events after receiving apixaban therapy. Based on the anticoagulant action of apixaban, its role in the reported bleeding events gastrointestinal hemorrhage, rectal hemorrhage which could have led to hypovolemic shock are considered as related to the suspect. Based on the etio-pathogenesis, cardiac failure and renal failure are considered as not related to the suspect. Pfizer comment:Based on the information available the reported events are considered not related to suspect drug.Underlying condition might be regarded as a conceivable explanation for the reported event ; Reported Cause(s) of Death: Rectal blood loss; Hypovolemic shock; massive gastrointestinal blood loss