Search Results

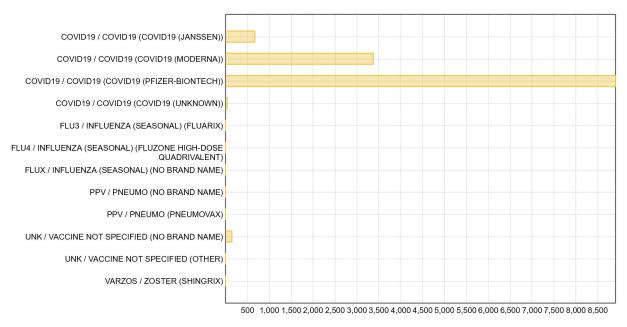
### From the 7/30/2021 release of VAERS data:

# Found 12,366 cases where Vaccine is COVID19 and Patient Died

### Graph

### **Count by Vaccine Names**

#### **Vaccine Names**



#### Count

| Chart type: Bar   □ Swap Axes □ Show Percent □ Stack Bars |  |
|---|--|
| Width (pixels): 1400 Height (pixels): 630 Resize          |  |

## Table

| <b>↓</b>                             |          | ↑ ↓       |  |
|--------------------------------------|----------|-----------|--|
| Vaccine/Manufacturer                 | Count    | Percent   |  |
| COVID19 / JANSSEN                    | 669      | 5.41%     |  |
| COVID19 / MODERNA                    | 3,375    | 27.29%    |  |
| COVID19 / PFIZER/BIONTECH            | 8,904    | 72%       |  |
| COVID19 / UNKNOWN MANUFACTURER       | 38       | 0.31%     |  |
| FLU3 / GLAXOSMITHKLINE BIOLOGICALS   | 1        | 0.01%     |  |
| FLU4 / SANOFI PASTEUR                | 1        | 0.01%     |  |
| FLUX / UNKNOWN MANUFACTURER          | 2        | 0.02%     |  |
| PPV / MERCK & CO. INC.               | 1        | 0.01%     |  |
| PPV / UNKNOWN MANUFACTURER           | 1        | 0.01%     |  |
| UNK / UNKNOWN MANUFACTURER           | 147      | 1.19%     |  |
| VARZOS / GLAXOSMITHKLINE BIOLOGICALS | 2        | 0.02%     |  |
| TOTAL                                | † 13,141 | † 106.27% |  |

<sup>†</sup> Because some cases have multiple vaccinations and symptoms, a single case can account for multiple entries in this table. This is the reason why the Total Count is greater than 12366 (the number of cases found), and the Total Percentage is greater than 100.

Case Details (Sorted by Age)

### This is page 1 out of 25

Result pages: 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 next

 VAERS ID: 930431 (history)
 Vaccinated:
 2021-01-06

 Form:
 Version 2.0
 Onset:
 2021-01-08

Age: Days after 2
Sex: Female vaccination:

 Location:
 Connecticut
 Submitted:
 0000-00-00

 Entered:
 2021-01-08

Administered by: Senior Living Purchased by: ?

Symptoms: Cardiac disorder, Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-08
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: Enteric Coded Aspirin, Atenolol, Centrum Silver, Citrical, Levothyroxin, Lisinipril, Phillips Colon Health Caps, Vitamin D

Current Illness: none

Preexisting Conditions: Aortic Stenosis, Status post Tavr procedure, Hypothyroidism, Hypertension, Thoracogenic Scoliosis, Polymyalgia Rheumatica, Heart Valve

Replacement, Hyperparathyroidism

Allergies: None

Diagnostic Lab Data: Unknown

CDC Split Type:

Write-up: Cardiac event, 2 days after vaccination, patient expired.

 VAERS ID: 934966 (history)
 Vaccinated:
 2021-01-02

 Form:
 Version 2.0
 Onset:
 2021-01-04

 Age:
 Days after
 2

Sex: Female vaccination:

Location: California Submitted: 0000-00-00 Entered: 2021-01-11

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

Administered by: Unknown Purchased by: ?

Symptoms: COVID-19, Death, Pneumonia, Pyrexia, Respiratory failure, SARS-CoV-2 test positive

SMQs:, Anaphylactic reaction (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), 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), Acute central respiratory depression (narrow), Guillain-Barre syndrome (broad), Eosinophilic pneumonia (broad), Hypersensitivity (broad), Respiratory failure (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Infective pneumonia (narrow), Hypokalaemia (broad), Opportunistic infections (broad), COVID-19 (narrow)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-01-04 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:

Preexisting Conditions: Medical History/Concurrent Conditions: Alzheimer"s disease

Allergies:

Diagnostic Lab Data: Test Date: 20201225; Test Name: COVID-19; Test Result: Negative; Test Date: 20210104; Test Name: COVID-19; Test Result: Positive CDC Split Type: USPFIZER INC2021011125

Write-up: COVID-19; COVID-19; Pneumonia; respiratory failure; This is a spontaneous report from a contactable consumer. An 80-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 02Jan2021 for COVID-19 immunization. Medical history included Alzheimer"s and others. No known allergies. Concomitant medications included unspecified medications. The reporter"s mother in law was tested for COVID-19 at a nursing facility on 25Dec2020 and she was negative. On 02Jan2021, she received the first dose of Pfizer vaccine. On 04Jan2020, she developed a high fever, needed oxygen and was positive for COVID-19. Date of death was 04Jan2021. The cause of her death was listed as pneumonia, respiratory failure and COVID-19. No autopsy performed. No treatment received. No one knew if the vaccination contributed to her death. It was hard to know if her death was due to the administration of the vaccine or it exacerbated the COVID19 symptoms which led to her death. Since this was unknown, it could have been a possibility. The reporter wanted to give us this information because we might want to consider having high risk population, patients with underlying conditions, older population tested for COVID-19 prior to the vaccination, as this is not currently a recommendation or a requirement. All is very new and they are all learning so the reporter wanted to share this information with us. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. There are medications the patient received within 2 weeks of vaccination. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has been tested for COVID-19. The

outcome of the events was fatal. Information about Lot/Batch has been requested.; Sender"s Comments: The association between the fatal event lack of effect (pneumonia, respiratory failure and COVID-19) with BNT162b2 can not be fully excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19; Pneumonia, respiratory failure and COVID-19

**VAERS ID:** <u>938097</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Unknown Entered: 2021-01-12 Sex:

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: 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:

CDC Split Type: USPFIZER INC2021017780

Write-up: died; This is a spontaneous report from a non-contactable consumer via a Pfizer-sponsored program. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. It was reported the patient was a doctor, died after the vaccine with no apparent disease. It was not reported if an autopsy was performed. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>950935</u> (<u>history</u>) 2021-01-12 Vaccinated: Form: Version 2.0 Onset: 2021-01-15

Age: Days after 3 vaccination: Sex: Female

Submitted: 0000-00-00 Location: California Entered: 2021-01-17

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EL8982 / 1 | LA / IM      |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-01-15 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:** 

**Preexisting Conditions:** Allergies: Diagnostic Lab Data: CDC Split Type:

Write-up: Resident expired

VAERS ID: 955879 (history) Vaccinated: 2020-12-22 Form: Version 2.0 0000-00-00 Onset: Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-01-19

Location: Ohio

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021034599

Write-up: expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar death events for 8 patients. This report is for 5th of 8 patients. A patient of unspecified age and gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Sender"s Comments: The limited information provided in this report does not allow a full assessment of the case. The event death with unknown cause is assessed as related to the suspect drug per company guidance. This case will be reassessed when additional information, particularly the clinical course before death, complete medical history and concomitant medication and autopsy report, becomes available.,Linked Report(s): US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: expired before receiving the second dose

 VAERS ID: 955880 (history)
 Vaccinated: 2020-12-22

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-01-19

Location: Ohio

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

Administered by: Other Purchased by: ?

Symptoms: Death SMQs: Life Threatening?

Life Threatening? No Birth Defect? No Died? Yes

Date died: 0000-00-00
Permanent Disability? No
Recovered? 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:

CDC Split Type: USPFIZER INC2021034603

Write-up: passed unexpectedly; This is a spontaneous report from a contactable nurse communicated to a Pfizer colleague. This nurse reported similar death events for 8 patients. This report is for 8th of 8 patients. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 22Dec2020 at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient passed unexpectedly on an unspecified date. The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The limited information provided in this report does not allow a full assessment of the case. The event death with unknown cause is assessed as related to the suspect drug per company guidance. This case will be reassessed when additional information, particularly the clinical course before death, complete medical history and concomitant medication and autopsy report, becomes available. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s): US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: passed unexpectedly

 VAERS ID: 960426 (history)
 Vaccinated: 2020-12-22

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-01-21

Location: Ohio

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH
 -/1
 -/

Administered by: Unknown Purchased by: ?

Symptoms: Death
SMQs:
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:

CDC Split Type: USPFIZER INC2021034595

Write-up: expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar death events for 8 patients. This report is for 1st of 8 patient. A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history was and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate evaluation, including the review and alraysis of aggregate data for adverse events. Any safety concern including the review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate action in response, will be promptly notified to Regulatory Authorities and Investigators, as appropriate action in response, and Investigators, and Inves INC-2021034601 same drug, reporter and event but different patient, US-PFIZER INC-2021034603 same drug, reporter and event but different patient, US-PFIZER INC-2021034596 same drug, reporter and event but different patient.; Reported Cause(s) of Death: expired before receiving the second dose

VAERS ID: <u>960427 (history)</u> Vaccinated: 2020-12-22 Version 2.0 Onset: 0000-00-00 Form: Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-01-21

Location: Ohio

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021034596

Write-up: expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 2nd of 8 patients. A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: expired before receiving the second dose

VAERS ID: <u>960428</u> (history) Vaccinated: 2020-12-22 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: 2021-01-21 Sex: Unknown Entered:

Location: Ohio

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

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021034597

Write-up: expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 3rd of 8 patients. A patient of unspecified age and gender received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender"s Comments: Based on the reasonable temporal association, the Company cannot completely exclude the possible causality between the reported death and the administration of COVID 19 vaccine, bnt162b2. However, more information on the patient's underlying medical condition, concomitant medications, patient"s age group, clinical course and relevant lab tests would be helpful for the Company to make a more meaningful causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RA, IEC, as appropriate.; Reported Cause(s) of Death: expired before receiving the second dose

VAERS ID: 960429 (history) Vaccinated: 2020-12-22 Version 2.0 Form: Onset: 0000-00-00 Age: Submitted: 0000-00-00 Sex: Unknown Entered: 2021-01-21

Location: Ohio

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

Purchased by: ?

Administered by: Other Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021034598

Write-up: expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 4th of 8 patient. A patient of unspecified age and gender received the first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunization. The patient"s medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number has been requested.; Sender"s Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s): US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: expired before receiving the second dose

VAERS ID: <u>960430</u> (history) Vaccinated: 0000-00-00 Version 2.0 0000-00-00 Form: Onset: Submitted: 0000-00-00 Age: Unknown 2021-01-21 Sex: Entered:

Purchased by: ?

Location: Ohio

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

Administered by: Other Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021034600

Write-up: 7 residents expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 8 patients. This report is for 6th of 8 patients. A patient of unspecified age and gender received first dose bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at SINGLE DOSE for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The event death is assessed as related to BNT162b2 vaccine and documented as such in the global safety database until sufficient information is available to allow an unrelated causality assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s): US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: 7 residents expired before receiving the second dose

 VAERS ID: 960431 (history)
 Vaccinated: 2020-12-22

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-01-21

Location: Ohio

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

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 0000-00-00 Permanent Disability? No Recovered? 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:

CDC Split Type: USPFIZER INC2021034601

Write-up: expired before receiving the second dose; This is a spontaneous report from a contactable nurse. This nurse reported similar death events for 8 patients. This report is for 7th of 8 patient. A patient of unspecified age and gender received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 22Dec2020 at single dose for covid-19 immunisation. The patient medical history was and concomitant medications were not reported. The patient expired before receiving the second dose on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/Batch number is requested.; Sender's Comments: Current information is very limited for full assessment. The patient died following the vaccine use; further information such as patient demographics, complete medical history, concomitant medications, concurrent illness and event term details especially death cause and autopsy results are needed for meaningful evaluation. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s): US-PFIZER INC-2021034595 same drug, reporter and event but different patient; Reported Cause(s) of Death: expired before receiving the second dose

 VAERS ID: 962308 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-01-21

Location: Utah

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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: Dementia; Hospice care (on hospice, frail, but in good condition)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021045659

Write-up: died; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported that an 83-year-old female patient (reporter mother) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection), via an unspecified route of administration on an unspecified date at single dose

for covid-19 immunization. Medical history included hospice care and dementia. The patient"s concomitant medications were not reported. The patient died one day after getting vaccine. She was reportedly in good health the day before receiving vaccine. She was on hospice, frail, but in good condition and checked by a hospice nurse the day before which she reported her in good health considering. She was with dementia but stable in her health. The reporter read investigating 23 deaths of people receiving vaccine in similar conditions. The patient died on an unspecified date. It was not reported if an autopsy was performed.; Reported Cause(s) of Death:

VAERS ID: 963902 (history) Vaccinated: 2020-12-28 Form: Version 2.0 Onset: 2020-12-30

Age: Days after vaccination: Sex: Male Submitted: 0000-00-00 Location: Unknown Entered: 2021-01-22

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

Purchased by: ?

Administered by: Unknown

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2020-12-30 Days after onset: 0 Permanent Disability? No Recovered? No

Office Visit? No ER Visit? No

ER or Doctor Visit? No Hospitalized? No

Other Medications: ACETAMINOPHEN;;;; HYDROCODONE/ACETAMINOPHEN;;; SENNA PLUS [SENNA ALEXANDRINA]; VITAMIN D3

Current Illness: Acute kidney failure; Alzheimer"s disease; Encephalopathy; Hypertension; Urinary retention; UTI

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDČ Split Type: USPFIZER INC2021019154

Write-up: Death; This is a spontaneous report from four non-contactable consumers via a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. A 78year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on 28Dec2020 at a single dose for COVID-19 immunization. Ongoing medical history included Alzheimer"s Disease, encephalopathy, hypertension, acute kidney failure, urinary retention and recent urinary tract infection (UTI), all from an unspecified date. Concomitant medication included acetaminophen (MANUFACTURER UNKNOWN), bisacodyl (MANUFACTURER UNKNOWN), bupropion (MANUFACTURER UNKNOWN), escitalopram (MANUFACTURER UNKNOWN), hydrocodone bitartrate, paracetamol (HYDROCODONE/ACETAMINOPHEN), loperamide (MANUFACTURER UNKNOWN), ondansetron (MANUFACTURER UNKNOWN), senna alexandrina (SENNA PLUS), vitamin d3 (MANUFACTURER ÜNKNOWN). The patient had no known drug allergies. The patient experienced death on 30Dec2020. The vaccine was given on 28Dec2020 with no adverse events and no issues on 29Dec2020. The patient died on 30Dec2020, at approximately 2:00 AM. It was unknown if an autopsy was performed. It was unknown if the event was related to the suspect drug, the administrator marked as natural causes. No follow-up attempts are possible; information about batch/lot number cannot be obtained.; Reported Cause(s) of Death: Death

**VAERS ID:** <u>965547 (history)</u> Vaccinated: 2020-12-28 Onset: Form: Version 2.0 2020-12-29

Days after Age: vaccination: Sex: Male

Submitted: 0000-00-00 Location: Unknown Entered: 2021-01-22

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EH9899 / 1 LA / OT

Administered by: Unknown Purchased by: ? Symptoms: Cardio-respiratory arrest. Death

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (broad), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Acute central respiratory depression (broad), Respiratory failure (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-29 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: ASA; ; ; ZYPREXA; FLOMAX [MORNIFLUMATE]; ; VIT C; ; DEPAKOTE; ; ; ALBUTEROL [SALBUTAMOL]; BUSPAR; FIBERCON

Preexisting Conditions: Medical History/Concurrent Conditions: Aspiration; Bipolar disorder; Depressive disorder; Dysphagia; GERD; Hyperlipidemia; Hypertension; Rectal bleeding; Schizophrenia; Violent behavior

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021019107

Write-up: resident coded and expired; This is a spontaneous report from a non-contactable consumer via Pfizer Sponsored Program. A 63-year-old male patient received the 1st dose of bnt162b2 (BNT162B2, Lot # EH9899) intramuscular at single dose at left arm on 28Dec2020 for Covid-19 immunisation. Medical history included no current Illness, no known allergies, but preexisting conditions: dysphagia, violent behaviors, depressive disorder, schizophrenia, aspiration, gastrooesophageal reflux disease (GERD), hyperlipidaemia, bipolar disorder, rectal bleeding, hypertension. The patient had no birth defect. Concomitant medication included asa (ASA) at 81mg, lisinopril (LISINOPRIL) at 10mg daily, ferrous sulfate (FERROUS SULFATE) at 325 (unit unknown), olanzapine (ZYPREXA) at 20mg,

morniflumate (FLOMAX [MORNIFLUMATE]) at 0.4 (unit unknown), famotidine (FAMOTIDINE) at 20mg, ascorbic acid (VIT C), carbamazepine (CARBAMAZEPINE) at 250mg bid, valproate semisodium (DEPAKOTE) at 750mg bid, metformin (METFORMIN) at 1000 (unit unknown) bid, sertraline (SERTRALINE) at 100 (unit unknown) bid, albuterol [salbutamol] (ALBUTEROL [SALBUTAMOL]), buspirone hydrochloride (BUSPAR) at 10mg tid, polycarbophil calcium (FIBERCON). The patient died on 29Dec2020. The patient had no ER or Doctor visit and was not hospitalized. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: resident coded and expired

 VAERS ID: 969648 (history)
 Vaccinated:
 2020-12-29

 Form:
 Version 2.0
 Onset:
 2020-12-30

Age: Days after Sex: Female vaccination:

 Location:
 Unknown
 Submitted:
 0000-00-00

 Entered:
 2021-01-25

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death, Erythema, Skin warm, Swelling

**SMQs:**, Anaphylactic reaction (broad), Angioedema (broad), Haemodynamic oedema, effusions and fluid overload (narrow), Hypersensitivity (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-01 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: Alzheimer"s disease; COPD

Preexisting Conditions: Allergies: Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: death of unknown cause; Swelling on Right side of the neck and under chin; Warmth on right side of neck and under chin; Redness on right side of neck and under chin; A spontaneous report was received from a healthcare professional concerning an 89-year-old, female patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and experienced events of redness, warmth and swelling on right side of neck and under chin, and death of unknown cause. The patient"s medical history included Alzheimer"s and chronic obstructive pulmonary disease (COPD). No concomitant medications were reported. On 29 Dec 2020, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: Unknown) intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient experienced the events of redness, warmth and swelling on right side of neck and under chin. There was no indication that the patient was transferred out to hospital, which was unlikely because she was under hospice care. On 01 Jan 2021, the patient died due to an unknown cause of death. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 01 Jan 2020. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter"s Comments: This case concerns a 89-year-old, female subject with a medical history of Alzheimer"s and chronic obstructive pulmonary disease (COPD) who experienced redness, warmth and swelling on R side of neck and under chin occurred 2 days after administration of the first and only dose of the mRNA-1273 vaccine and patient expired 4 days after mRNA-1273 vaccine administration. Lot # of the vaccine was not provided. De-challenge and re-challenge are not applicable. The events of redness, warmth and swelling on R side of neck and under chin are temporarily associated with the administration pending additional information. Fatal outcome was considered unrelated to mRNA-1273 administration pending additional information. Fatal outcome

 VAERS ID: 970042 (history)
 Vaccinated:
 2020-12-30

 Form:
 Version 2.0
 Onset:
 2020-12-30

 Age:
 Days after

 Sex:
 Female
 vaccination:
 0

Location: Unknown Submitted: 0000-00-00
Entered: 2021-01-25

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PEIZER-BIONTECH)) / PEIZER/BIONTECH | EL0142 / 1 | RA / -       |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-30 Days after onset: 0 Permanent Disability? No

Permanent Disability? N 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:

CDC Split Type: USPFIZER INC2021019156

Write-up: patient passed away with in 90 minutes of getting vaccine; This is a spontaneous report from three non-contactable consumer reporting on behalf of the

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patient via a Pfizer sponsored program, Corporate (Pfizer) Social Media Platforms. A 90 (unspecified unit) old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection, lot number: EL0142, unknown expiration), via an unspecified route of administration in right arm (reported as AR) on 30Dec2020 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. It was reported that the patient was a nursing home patient and received the first dose of COVID vaccine on 30Dec2020. The patient was monitored for 15 minutes after getting shot. Staff reported that the patient was 15 days post COVID. The patient passed away with in 90 minutes of getting vaccine on 30Dec2020. The patient did not require office/ ER visit. An autopsy was not performed. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Patient passed away with in 90 minutes of getting vaccine

VAERS ID: <u>970043</u> (history) Vaccinated: 2020-12-10 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-01-25

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death, Diarrhoea

SMQs:, Pseudomembranous colitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Noninfectious diarrhoea (narrow)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2020-12-10 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: Diarrhoea; Gastrointestinal disorder; Pseudomembranous colitis

Allergies:

Diagnostic Lab Data:

CDČ Split Type: USPFIZER INC2021019157

Write-up: Reported causes of death: Diarrhoea; This is a spontaneous report from a contactable healthcare professional via agency and a non-contactable consumer via a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. An elderly patient of an unspecified age (also reported as were in their early to mid-60"s) and gender received BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine), via an unspecified route of administration on 10Dec2020 at a single dose for COVID-19 immunisation. Medical history included pseudomembranous colitis (broad), gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), and noninfectious diarrhoea (narrow). The patient"s concomitant medications were not reported. The patient experienced diarrhoea on an unspecified date in 2020. It was reported that most of the deaths after the COVID-19 vaccine occurred within 24-48 hours after the shot. The write-ups that accompanied the reports furnished details about these sad fatalities, including the astonishing fact that some of the decreased had actually experienced and recovered from COVID-19 (raising questions about why they were vaccinated). It was also reported that the event was not life-threatening, did not result to a birth defect or permanent disability, did not require any office/ER/doctor visit, and did not require any hospitalization. The patient died on 10Dec2020. It was not reported if an autopsy was performed. The reported cause of death: diarrhoea. No follow up attempts are possible, information about the lot/batch number cannot be obtained.; Sender's Comments: Based on the available information the event diarrhea resulting in death is attributed to patients preexisting medical conditions including pseudomembranous colitis, gastrointestinal nonspecific symptoms and therapeutic procedures, and noninfectious diarrhea. However, based on a close chronological association (same day) contributory role of BNT162B2 (Pfizer-BIONTECH Covid-19 Vaccine) to event exacerbation cannot be completely excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Reported causes of death: Diarrhoea

VAERS ID: <u>970162</u> (history) Vaccinated: 0000-00-00 Version 2.0 Onset: 0000-00-00 Form: Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-01-25

Location: Maryland

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021046017

Write-up: received the vaccine on Tuesday and was found dead at his kitchen table Wednesday afternoon; This is a spontaneous report from a contactable consumer. An 89 years old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unknown date, at single dose, for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient received the vaccine on Tuesday (unspecified date) and was found dead at his kitchen

table on Wednesday afternoon (unspecified date). Cause of death was unknown. It was unknown if an autopsy was performed. Information about batch/lot number has been requested.; Reported Cause(s) of Death: received the vaccine on Tuesday and was found dead at his kitchen table Wednesday afternoon

VAERS ID: 971559 (history) Vaccinated: 2021-01-01 Form: Version 2.0 Onset: 2021-01-19

Days after Age: 18 vaccination: Sex: Female

Submitted: 0000-00-00 Location: Texas Entered: 2021-01-25

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No

Died? Yes Date died: 2021-01-19 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: Preexisting Conditions:** 

Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021053200

Write-up: her mother passed away 7-8 days after receiving the vaccine; This is a spontaneous report from a contactable consumer, the daughter of the patient. A female patient of an unspecified age received the first dose of COVID-19 mRNA VACCINE (MANUFACTURER UNKNOWN), via an unspecified route of administration in Jan2021 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 19Jan2021 about 7-8 days after receiving the vaccine, the patient passed away. The patient was fine before she received the vaccine and then passed away 7-8 days later. The cause of death was not reported. It was not reported if an autopsy was performed. The reporter thought her mother"s death had everything to do with the COVID-19 vaccine. The lot number for the vaccine was not provided and will be requested during follow up.; Reported Cause(s) of Death: Death

VAERS ID: <u>971562</u> (history) Vaccinated: 0000-00-00 Version 2.0 Form: Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-01-25

Location: New York

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

Administered by: Unknown Purchased by: ? Symptoms: Death, Immune thrombocytopenia

SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Systemic lupus erythematosus (broad), Hypersensitivity (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Immune-mediated/autoimmune disorders (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:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021058222

Write-up: died; acute immune thrombocytopenia; This is a spontaneous report from two contactable consumers. A patient of unspecified age and gender received BNT162B2(lot number and expiration date not provided) via an unspecified route of administration on unspecified date at single dose for COVID-19 immunization. The patient"s medical history and concomitant medications were not reported. The patient died after receiving the covid vaccine on an unknown date. The patient developed acute immune thrombocytopenia on an unknown date. It was unknown if autopsy was performed. The cause of death was unknown. The outcome of the event "died" was fatal and of the event " acute immune thrombocytopenia" was unknown. The reporter wondered if a platelets blood problem may lead to death and if who have a blood platelets condition like essential thrombocytosis should not risk taking the vaccine. Information on the lot/batch number has been requested. Reported Cause(s) of Death: Died

VAERS ID: 978873 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-01-27

Location: California

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

Administered by: Unknown Purchased by: ? Symptoms: Death, SARS-CoV-2 test positive

SMQs:, Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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:** 

Allergies:

Diagnostic Lab Data: Test Date: 202012; Test Name: Covid-19; Test Result: Positive

CDC Split Type: USPFIZER INC2021068689

Write-up: died several hours after receiving a Covid-19 vaccine; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient's medical history and concomitant medications were not reported. The patient died several hours after receiving a Covid-19 vaccine on an unspecified date. The patient died on an unspecified date. It was not reported if an autopsy was performed. The person had tested positive for the virus (Covid-19) in late Dec2020. Information on the batch/lot number has been requested.; Reported Cause(s) of Death: died several hours after receiving a Covid-19 vaccine

VAERS ID: <u>978876 (history)</u> Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Entered: 2021-01-27 Sex: Male

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Autoimmune disorder, Death

SMQs:, Immune-mediated/autoimmune disorders (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:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021070550

Write-up: Autoimmune disease; This is a spontaneous report from a Pfizer-sponsored program from a contactable nurse. A male patient of an unspecified age received bnt162b2 (BNT162b2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on an unspecified date, at single dose, for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced autoimmune disease on an unspecified date. The patient died on an unspecified date due to autoimmune disease. It was unknown if an autopsy was performed. The information on the lot/batch number has been requested.; Sender's Comments: The information available in this report is limited and does not allow a medically meaningful assessment of the case. The company cannot completely exclude a causal relationship between the fatal autoimmune disease and suspect vaccine BNT162B2. Additional information regarding therapy duration, relevant medical history, underlying conditions, concomitant medications and detailed clinical course around the event onset will aid in comprehensive assessment of the case. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.; Reported Cause(s) of Death: Autoimmune disease

**VAERS ID:** <u>985933</u> (history) Vaccinated: 2020-12-29 Form: Version 2.0 2020-12-30 Onset: Days after Age: vaccination: Female Sex:

Submitted: 0000-00-00 Location: Unknown Entered: 2021-01-29

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Blood creatinine increased, Blood urea increased, Chest X-ray abnormal, Death, Dyspnoea, Erythema, Influenza virus test negative, Leukocytosis, Lung infiltration, Pulmonary congestion, Pyrexia, Respiratory rate increased, White blood cell count increased

SMQs:, Rhabdomyolysis/myopathy (broad), Acute renal failure (broad), Cardiac failure (broad), Anaphylactic reaction (narrow), Interstitial lung disease (narrow), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Retroperitoneal fibrosis (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Cardiomyopathy (broad), Eosinophilic pneumonia (broad), Chronic kidney disease (broad), Hypersensitivity (broad), Tumour lysis syndrome

(broad), Drug reaction with eosinophilia and systemic symptoms syndrome (narrow), Infective pneumonia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-01 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:

Preexisting Conditions: Medical History/Concurrent Conditions: Dementia; Walking disability

Diagnostic Lab Data: Test Date: 20201231; Test Name: creatinine; Test Result: Inconclusive; Test Date: 20201231; Test Name: BUN; Test Date: 20201231; Test Name: Result: Inconclusive; Result: Inconcl Room air; Test Date: 20201231; Test Name: WBC

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Died; Increased respirations (22 and labored at times); Pulse 105; 94% O2 on RA; Labored breathing at times; leukocytosis; elevated BUN; left lower lung congestion; elevated creatinine; Temperature of 102.0F; Redness on face; A spontaneous report was received from a nurse concerning a 92-year-old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced redness on face, increased respirations, labored breathing at times, temperature of 102F, pulse of 105, 94 percent O2, leukocytosis, elevated BUN, left lower lung congestion, elevated creatinine, and death. The patient"s medical history, as provided by the reporter, included dementia and reduced mobility. No relevant concomitant medications were reported. On 29 Dec 2020, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, the patient began to experience redness on her face, increased toses of intra-1273 intra-intra-1273 intra-intra-1273 intra-intra-1273 intra-intra-1273 intra-intra-1273 intra-intra-1273 intra-intra-1273 intra-intra-1273 intra-intra-1273 intra-1273 int applicable. The patient died on 01 Jan 2021, the cause of death was unknown.; Reporter's Comments: This case concerns a 92-year-old, female subject with medical history of dementia and reduced mobility, who experienced the serious unexpected events of death, respiratory rate increased, heart rate increased, oxygen saturation decreased, elevated BUN, elevated creatinine, left lung congestion and dyspnoea and the non-serious events of erythema and pyrexia. The events of respiratory rate increased, heart rate increased, oxygen saturation decreased, dyspnoea, erythema and pyrexia occurred 2 days after the first dose of the study medication administration, and the event of death occurred 4 days after the first dose of the study medication administration. Very limited information regarding the events is available at this time and no definite diagnosis or autopsy report have been provided. Additional information has been requested.; Reported Cause(s) of Death: Died

**VAERS ID:** <u>986123 (history)</u> 2021-01-19 Vaccinated: 2021-01-24 Version 2.0 Onset: Form:

Days after Age: 5 vaccination: Male

Sex: Submitted: 0000-00-00 Location: Arizona Entered: 2021-01-29

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

Administered by: Unknown Purchased by: ?

Symptoms: Death, Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-24 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: Preexisting Conditions:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021072348

Write-up: passed away-heart attack; This is a spontaneous report from a contactable consumer, the daughter of the patient from a Pfizer Sponsored program Pfizer First Connect. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: UNKNOWN), via an unspecified route of administration on 19Jan2021 as a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 24Jan2021, the patient passed away due to a heart attack. It was not reported if an autopsy was performed. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Reported Cause(s) of Death: passed away-heart attack

VAERS ID: 991450 (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-01-30

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | - / UNK    | - / IM       |

Administered by: Unknown Purchased by: ? Symptoms: Muscle spasms, Muscle tightness, Myalgia, Neck pain

SMQs:, Rhabdomyolysis/myopathy (broad), Dystonia (broad), Eosinophilic pneumonia (broad), Arthritis (broad), Tendinopathies and ligament disorders (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: Lisinopril, furosemide, omeprazole, amlodipine, meclizine, loratadine

Preexisting Conditions: Coronary artery disease (CAD); Hypertension (HTN); Renal Disease (e.g. CKD, HD, ESRF)

Allergies:

Diagnostic Lab Data:

CDC Split Type:

Write-up: The patient developed left sided neck and trapezoid tightness and pain after receiving the moderna covid vaccine in her left shoulder. The injection site is non tender and does not show any erythema or tenderness. The tenderness is over the left trapezius and left lateral neck area. It also feel tight like a muscle spasm.

VAERS ID: 993822 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Entered: 2021-02-02 Sex: Male

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 0000-00-00 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No Hospitalized? No

ER or Doctor Visit? No **Previous Vaccinations:** Other Medications: **Current Illness: Preexisting Conditions:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021075824

Write-up: he got both doses then a few days later he died; This is a spontaneous report from a contactable consumer reporting for a friend"s father. A male patient of an unspecified age received the second dose of bnt162b2 (BNT162B2) vaccine, via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the first dose on an unknown date. The patient died few days after receiving the second dose of the vaccine on an unspecified date. It was not reported if an autopsy was performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: he got both doses then a few days later he died

VAERS ID: 993823 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Entered: 2021-02-02 Sex: Male

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death, Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (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:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021077709

Write-up: died due to heart attack; This is a spontaneous report from a contactable consumer (reporting for her son-in-law) from the Pfizer-sponsored program Pfizer First Connect. A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patients medical history and concomitant medications were not reported. The patient died due to heart attack on an unspecified date. The patient died on an unspecified date. It was unknown if an autopsy was performed. Follow-up (28Jan2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts completed. No further information is expected.; Reported Cause(s) of Death: died due to heart attack

Vaccinated: 0000-00-00 VAERS ID: 993832 (history) Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Unknown Entered: 2021-02-02 Sex:

Location: Maine

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs: 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:

CDC Split Type: USPFIZER INC2021081901

Write-up: At the end of the conversation, caller stated that recently saw in (place name) that someone passed away 3 hours after receiving the injection.; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on unspecified date at single dose for COVID-19 immunization. Medical history and concomitant medication were not reported. Caller, calling on behalf of her sister who has pseudocholinesterase imbalance, would like to know if the Covid vaccine has any contraindication or interaction with succinylcholine. Caller stated that her and her sister are scheduled to receive the first dose of the vaccine this weekend. Caller stated that her sister had a severe reaction to succinylcholine and did not wake up for four days. Caller stated that her sister has to wear a medical bracelet because of this condition. Caller reported that her sister"s son has the same severe reaction to succinylcholine. Caller also stated that when she was a director in the lab, she heard of a person passing away in the OR due to the same reaction with succinylcholine. At the end of the conversation, caller stated that recently saw in (state name) that someone passed away 3 hours after receiving the injection. It was unknow if autopsy was done. Information on the lot/Batch number has been requested.; Sender's Comments: The information currently available does not allow a medically meaningful assessment for the event "passed away" with unknown cause of death. The case will be reassessed should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.; Reported Cause(s) of Death: At the end of the conversation, caller stated that recently saw in (place name) that someone passed away 3 hours after receiving the injection.

VAERS ID: <u>1000233</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Entered: 2021-02-04 Sex: Male

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: 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:

CDC Split Type: USPFIZER INC2021098743

Write-up: just died; This is a Spontaneous report from a Pfizer Sponsored Program from a contactable consumer. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient just died on an unspecified date. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: just died

 VAERS ID: 1000624 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-02-04

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Pneumonia

SMQs:, Eosinophilic pneumonia (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Infective pneumonia (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: Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021064098

Write-up: Pneumonia; This is a spontaneous report from a Pfizer-sponsored program via a contactable consumer (patient). A male patient of unspecified age (Age: 63; Unit: Unknown) received the first dose and second dose of BNT162B2, via unspecified routes of administration on unspecified dates at single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. After receiving both vaccines, patient still got pneumonia and he had seen many elderly died from pneumonia even after receiving the vaccine. Outcome of the event was not resolved. No follow-up attempts are possible; information about lot/batch number cannot be obtained.

 VAERS ID: 1001713 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-02-04

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

Allergies:
Diagnostic Lab Data: Test Name: temperature; Result Unstructured Data: 98

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Passed away; A spontaneous report was received from a consumer concerning a patient who received Moderna"s COVID-19 Vaccine (mRNA-1273) and passed away. The patient"s medical history was not provided. No relevant concomitant medications were reported. On an unknown date, approximately 2 hours prior to the onset of the event, the patient received a dose of mRNA-1273 intramuscularly in the for prophylaxis of COVID-19 infection. They were not feeling sick or experiencing any adverse events. Vital signs included temperature 98 degrees Fahrenheit. Approximately two hours after receiving the vaccine, the patient passed away. No treatment information was provided. Action taken with the drug in response to the event was not applicable. The patient died on an undisclosed date. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter"s Comments: This case concerns a patient of unknown age and gender. The medical history and concomitant medication is not provided. The patient experienced Death. The event occurred approximately two hours after receiving their first of two planned doses of mRNA-1273 (Lot unknown). Very limited information regarding this event has been provided at this time. Based on temporal association

between the use of the product and the start date of the event, a causal relationship cannot be excluded. The benefit-risk relationship of Moderna''s COVID-19 vaccine is not affected by this report.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1002052 (history)
 Vaccinated:
 2021-01-19

 Form:
 Version 2.0
 Onset:
 2021-01-20

Age: Days after Sex: Female vaccination:

 Location:
 Ohio
 Submitted:
 0000-00-00

 Entered:
 2021-02-04

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Symptoms: Autopsy, Death

SMQs:

Life Threatening? No Birth Defect? No

Died? Yes Date died: 2021-01-20 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:** 

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

Purchased by: ?

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Passed away yesterday, found deceased in her apartment; This spontaneous report was received from a consumer which refers to a 91-year-old female patient who received the Moderna COVID-19 vaccine (mRNA-1273) and next day the patient passed away. The patient"s medical history was not provided. Concomitant medications were not reported. On 19 Jan 2021, the patient received her first of two planned doses of mRNA-1273 intramuscularly (Lot number: not provided) for prophylaxis of COVID-19 infection. On 20 Jan 2021, the patient passed away and she was found deceased in her apartment. No treatment medication was provided. Action taken with mRNA-1273 in response to the events was not applicable as the patient passed away. On 20 Jan 2021, the patient died, cause of death was unknown. Autopsy result was unknown. The reporter assessed the causality as related between the event and Moderna COVID-19 vaccine.; Reporter's Comments: This case concerns a 91-year old female patient. The medical history and concomitant medication is not provided. The patient experienced Death. The event occurred approximately one day after receiving their first of two planned doses of mRNA-1273 (Lot unknown). Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the onset of the event, a causal relationship cannot be excluded and the event is considered possibly related to the vaccine.; Reported Cause(s) of Death: Unknown Cause of Death

VAERS ID: <u>1004645</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-02-05

Location: Florida

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021096325

Write-up: Pfizer vaccine caused the death; This is a spontaneous report from a non-contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot number and expiration date were not reported), via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The reporter claimed that Pfizer vaccine caused the death of the doctor (patient). No further details reported. No follow-up attempts are possible. Information about lot and batch number cannot be obtained. No further information is expected.; Reported Cause(s) of Death: Pfizer vaccine caused the death

VAERS ID: <u>1005020</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-01-01 Submitted: 0000-00-00 Age: 2021-02-05 Sex: Male Entered:

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-01 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:

Preexisting Conditions: Comments: List of non-encoded Patient Relevant History: Patient Other Relevant History 1: No adverse event, Continue: [UNK], Comment:

No reported adverse events

Allergies: Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Patient took vaccine and died two weeks later; Spontaneous report s were received from consumers via social media posts concerning an 86 year old male patient who received Moderna"s COVID-19 vaccine and died. There was no medical history provided. There were no concomitant medications provided. On approximately 06 Jan 2021, the patient received the first of two planned doses of mRNA-1273 (Batch # unknown), intramuscularly for prophylaxis of COVID-19 infection. All of the social media posts reported the patients death and, according to one post, the patient took two doses of Moderna"s vaccine and died two weeks later. The patient died on or before 23 Jan 2021. No additional information was provided. Very limited information regarding this event has been provided at this time. The benefit-risk relationship of Moderna"s COVID-19 vaccine is not affected by this report.; Reporter"s Comments: This case concerns a 86-year old male patient. The medical history and concomitant medication is not provided. The patient experienced Death. The event occurred approximately two weeks after receiving their second of two planned doses of mRNA-1273 (Lot unknown). Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the onset of the event, a causal relationship cannot be excluded and the event is considered possibly related to the vaccine. The benefit-risk relationship of Moderna"s COVID-19 vaccine is not affected by this report.; Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1005022 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2020-12-26

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-02-05

Location: Unknown

Vaccination / Manufacturer | Lot / Dose | Site / Route | COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1 | -/ OT

Administered by: Unknown Purchased by: ?
Symptoms: Anxiety, Death, Pyrexia, Respiratory distress

**SMQs:**, Anaphylactic reaction (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Acute central respiratory depression (broad), Hypersensitivity (broad), Respiratory failure (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No

Died? Yes Date died: 2020-12-26 Days after onset: 0

Permanent Disability? No

Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Respiratory distress; Anxiety; Fever; Passed away; A spontaneous report was received from a consumer concerning a female patient who received Moderna"s COVID-19 Vaccine (mRNA-1273) and developed fever, respiratory distress, anxiety and passed away. The patient"s medical history was not provided. Concomitant product use was not provided. On an unknown date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, within 24 hours of receiving the vaccine, the patient developed a fever, respiratory distress and anxiety. Treatment for the events included oxygen, morphine, and lorazepam. On the evening of 26 Dec 2020, the patient passed away. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 26 Dec 2020. The cause of death was not reported. Plans for an autopsy were not provided.; Reporter"s Comments: This case concerns a female patient who received their first of two planned doses of mRNA-1273 (Lot unknown), and who experienced the serious unlisted events of death (unknown cause) and respiratory distress, the non-serious listed event of fever, and the non-serious unlisted event of anxiety. The events of respiratory distress, fever, and anxiety occurred within 24 hours of vaccination, while the event of death (unknown cause) occurred an unknown amount of time after vaccination. Very limited information has been provided regarding the circumstances leading to death and additional information has been requested. Based on the current available information and temporal association between the use of the product and the onset of events after vaccination, a causal relationship cannot be excluded.; Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1010899 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Submitted: 0000-00-00

 Sex: Male Entered: 2021-02-08

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021102020

Write-up: On the two people who died, one in (State name) and one in (State name); This is a spontaneous report from a contactable other HCP. This other HCP reported similar events for 2 patients. This is 1 of 2 report. An unknown age male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecific date at single dose for covid-19 immunization. Medical history and concomitant drug were not reported. It was reported that patient was died. Cause of death unknown. Outcome of the event was fatal. Information on the lot/batch number has been requested.; Sender"s Comments: Death with unknown cause is considered related to BNT162B2 for reporting purpose. Information is very limited. Case will be reassessed once receiving additional information, including cause of death. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s): US-PFIZER INC-2021102049 same reporter/drug/event, different patient; Reported Cause(s) of Death: On the two people who died, one in (State name) and one in (State name)

VAERS ID: <u>1010900</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Sex: Male Entered: 2021-02-08

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: 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:

CDC Split Type: USPFIZER INC2021102049

Write-up: patient died; This is a spontaneous report from a contactable Other Healthcare Professional (HCP). This Other HCP reported similar event for 2 patients. This is 2nd of 2 reports. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient"s medical history and concomitant medications were not reported. It was reported that patient died on an unspecified date. Cause of death unknown. Outcome of the event was fatal. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The causal relationship between BNT162B2 and the event death cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s): US-PFIZER INC-2021102020 same reporter/drug/event, different patient; Reported Cause(s) of Death: patient died

VAERS ID: 1016605 (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Age: Submitted: 0000-00-00 Entered: 2021-02-09 Male Sex:

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death, Sepsis

SMQs:, Sepsis (narrow), Opportunistic infections (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: No adverse event (No reported medical history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Sepsis; A spontaneous report was received from a consumer post, concerning an approximately 55-year-old, male physician who received Moderna"s COVID-19 vaccine (mRNA-1273) and developed sepsis, resulting in death. There was no medical history provided. There were no concomitant medications provided. On an unknown date (Thursday), the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. According to the post, two days after vaccine administration, the patient died of sepsis on Saturday. Action taken with mRNA-1273 in response to the event was not applicable. The event, sepsis, was considered fatal. The patient"s date of death was not provided. The cause of death was reported as sepsis.; Reporter"s Comments: This case concerns a 55-year-old, male subject, who experienced a serious unexpected event of Sepsis. Sepsis occurred after first dose of mRNA-1273 vaccine administration. On an unknown date, two days after vaccine administration, the patient died of sepsis. Treatment for the event was not provided. The patient"s medical history was not provided. The patient is a physician. Concomitant product use was not reported. Very limited information regarding this event has been provided at this time and no definite diagnosis or autopsy report have been provided. Based on the current available information and temporal association between the use of the product and the start date of the event of Sepsis, a causal relationship cannot be excluded.; Reported Cause(s) of Death: Sepsis

 VAERS ID: 1017128 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Sex: Female Entered: 2021-02-09

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness: Preexisting Conditions: Allergies:

Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021130110

Write-up: Passed away; This is a spontaneous report from a Pfizer-sponsored program Corporate (Pfizer) Social Media Platforms. This is a spontaneous report from a contactable consumer reporting for friend"s mother. A 50-years-old female patient received the second dose of bnt162b2 (BNT162B2) vaccine, via an unspecified route of administration on an unspecified date at single dose for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient received the first dose of BNT162B2 vaccine on an unknown date. The patient passed away on an unspecified date. The patient was a healthy woman, who just got her 2nd dose of the vaccine a couple of days before. The patient died in her sleep. Doctor labeled her death as "natural causes". It was not reported if an autopsy was performed. No follow-up attempts are Possible. Information on lot/batch cannot be obtained.; Reported Cause(s) of Death: Passed away

 VAERS ID: 1021926 (history)
 Vaccinated:
 2021-01-05

 Form:
 Version 2.0
 Onset:
 2021-01-08

Age: Days after Sex: Female vaccination: 3

 Location:
 Unknown
 Submitted:
 0000-00-00

 Entered:
 2021-02-11

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?
Symptoms: COVID-19, Death, SARS-CoV-2 test positive

SMQs:, Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-18 Days after onset: 10 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: No adverse event (No reported medical history.)

Allergies:

Diagnostic Lab Data: Test Date: 20210108; Test Name: Covid-19 test; Test Result: Positive; Result Unstructured Data: Positive

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Passed away; Positive result; A spontaneous report was received from a consumer concerning a female patient who received Moderna"s COVID-19 Vaccine (mRNA-1273) and developed COVID-19 and passed away. The patient"s medical history was not provided. Concomitant product use was not reported. On 05 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 08 Jan 2021, the patient had a positive COVID-19 test. On 18 Jan 2021, the patient passed away. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 18 Jan 2021. The cause of death was not reported.; Reporter's Comments: This

spontaneous report concerns a female patient who experienced COVID-19 and passed away. The event of COVID-19 occurred 4 days after the first and only dose of the mRNA-1273 vaccine administered and death occurred 14 days after administration of the mRNA-1273 vaccine. Based on the information provided and the known etiology of COVID-19, it is unlikely to be associated with mRNA-1273 vaccine administration. With no definite information on the clinical details of the death, it is difficult to adequately assess a causal association with mRNA vaccine. Main field defaults to ?possibly related"; Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1026021 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-02-12

Location: Maryland

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | -/1        | -/-          |
| PPV: PNEUMO (NO BRAND NAME) / UNKNOWN MANUFACTURER             | - / UNK    | -/-          |

Administered by: Unknown Purchased by: ?

Symptoms: Death, Inappropriate schedule of product administration

SMQs:, Medication errors (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 Visit? No ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness: Preexisting Conditions: Allergies:

Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021120769

Write-up: a male patient received the pneumonia shot 12 days after the first dose of the vaccine; he had died; This is a spontaneous report from a contactable consumer or other non hcp. A 76 years old male patient received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID 19 immunisation and received pneumococcal 13-val conj vac (dipht crm197 protein) (PNEUMOCOCCAL 13-VAL CONJ VAC (DIPHT CRM197 PROTEIN)), via an unspecified route of administration on an unspecified date 12 days after bnt162b2 at single dose for immunisation. The patient medical history and concomitant medications were not reported. The patient died on an unspecified date. It was not reported if an autopsy was performed. Pfizer is Marketing Authorization Holder of pneumococcal 13-val conj vac (dipht crm197 protein) in the reporter"s country. This may be a duplicate report in situations where another Marketing Authorization Holder of pneumococcal 13-val conj vac (dipht crm197 protein) has submitted the same report to the regulatory authorities. Information on lot and batch number has been requested. Follow-up: (08Feb2021): Lot/batch number is not available despite the follow-up attempts made. Follow-up attempts are completed. No further information is expected.; Reported Cause(s) of Death: a male patient received the pneumonia shot 12 days after the first dose of the vaccine; he had died

 VAERS ID: 1030011 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-02-15

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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: ELIQUIS

Current Illness: Preexisting Conditions:

Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021149056

Write-up: taking Eliquis who died after receiving the Pfizer-BioNtech Covid-I9; This is a spontaneous report from a contactable consumer based on information received by Pfizer from Bristol-Myers Squibb (manufacturer control number US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-014171), license party for apixaban (ELIQUIS). This spontaneous case was reported by a non-health professional and describes the occurrence of DEATH (taking Eliquis who died after receiving the Pfizer-BioNtech Covid-I9) in patient of an unknown age and gender who received apixaban (Eliquis) for an unknown indication. CO-SUSPECT PRODUCTS included Covid-19 Vaccine. On an unknown date, the patient started Eliquis (unknown route) and Covid-19 Vaccine (unknown route). DEATH occurred on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. The doctor died after taking Eliquis with Covid-19 Vaccine. For Eliquis(Unknown), the reporter did not provide any causality assessments. This case was linked to US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2021-012621 (Linked Report).; Sender's Comments: BMS Medical Evaluation Comment: This patient died after receiving apixaban therapy. Patient also received COVID-19 vaccine. Based on the limited information available regarding the cause of death and autopsy details, it cannot be ascertained with the reasonable possibility that the apixaban could have caused the event.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1030025</u> (<u>history</u>) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Entered: 2021-02-15 Sex: Male

Location: Oklahoma

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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: No adverse event (No adverse event history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Death; A spontaneous report was received from a consumer concerning a male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and the patient was died. The patient"s medical history was not provided. Concomitant product use was not provided. On an unknown date, the patient received his first dose of mRNA-1273 (Lot number unknown) for prophylaxis of COVID-19 infection. On an unknown date, the patient was died. Treatment of this event was not provided. The patient was died. The cause of death was not provided. Autopsy details were not provided.; Reporter"s Comments: This case concerns a male patient (unknown age), who experienced event of death (cause unknown). The event occurred on an unknown date after the first and last dose of mRNA-1273 vaccine administration. Autopsy and cause of death were not reported. Based on the current available limited information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded and the events are assessed as possibly related.; Reported Cause(s) of Death: Death

VAERS ID: <u>1030132</u> (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-02-15

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Cerebral haemorrhage, Death, Platelet count decreased

SMQs:, Haematopoietic thrombocytopenia (narrow), Haemorrhage terms (excl laboratory terms) (narrow), Systemic lupus erythematosus (broad), Haemorrhagic central nervous system vascular 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: platelet count; Result Unstructured Data: Test Result:low platelet

CDC Split Type: USPFIZER INC2021135267

Write-up: a doctor died of low platelet and brain bleed 16 days after the vaccine; a doctor died of low platelet and brain bleed 16 days after the vaccine; The is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient medical history was not reported. The patient"s concomitant medications were not reported. The patient (doctor) died of low platelet and brain bleed 16 days after the vaccine. It was not reported if an autopsy was performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: a doctor died of low platelet and brain bleed 16 days after the vaccine; a doctor died of low platelet and brain bleed 16 days after the vaccine

VAERS ID: <u>1030273</u> (history) Vaccinated: 2020-12-28 Version 2.0 2020-12-30 Form: Onset: Days after Age: 2 vaccination: Unknown Sex:

Location: Unknown Submitted: 0000-00-00 2021-02-15 Entered:

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA

Administered by: Unknown

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No

Died? Yes Date died: 2020-12-30 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: **Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Death; A spontaneous report was received from a reporter concerning a patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and passed away. The patient"s medical history was not provided. No relevant concomitant medications were reported. The patient received their first of two planned doses of mRNA-1273 on 28 Dec 2020 intramuscularly for prophylaxis of COVID-19 infection. On 30 Dec 2020, 2am the patient passed away. Administrator marked as natural causes. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not applicable. The outcome of the event was fatal. The patient died on 30 Dec 2020. The cause of death was reported as unknown. The reporter did not provide an assessment for the event, passed away.; Reporter"s Comments: This case concerns a patient of unknown age and gender. The medical history and concomitant medication is not provided. The patient experienced Death. The event occurred approximately one day after receiving their first of two planned doses of mRNA-1273 (Lot unknown). Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. The benefit-risk relationship of Moderna"s COVID-19 vaccine is not affected by this report.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1030852</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Entered: 2021-02-15 Sex: Unknown

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / OT

Purchased by: ?

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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: No adverse event (No reported medical history.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Died; A spontaneous report was received from a reporter concerning a unknown patient who received Moderna's COVID-19 Vaccine (mRNA-1273) and passed away. The patient's medical history was not provided. No relevant concomitant medications were reported. On an unknown date, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient passed away. No treatment information was provided. Action taken with RNA-1273 in response to the event was not applicable. The patient died on unknown date. The cause of death was reported as unknown. Autopsy details were unknown.; Reporter"s Comments: This case concerns a patient of unknown age and gender. The patient"s medical history was not provided. The fatal, unexpected event of death occurred on an unknown date after the administration of the first dose of mRNA-1273 on an unknown date. The cause of death was reported as unknown. Autopsy details were unknown. Very limited information regarding this event has been provided at this time. Based on temporal association between the use of the product and the event, a causal relationship cannot be excluded. Additional information regarding the autopsy report, date of the mRNA administration, day of death, medical information and details of concomitant product are all required for further assessment of causality. Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1031494</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2020-12-20 Age: Submitted: 0000-00-00 2021-02-15 Sex: Female Entered:

Location: lowa

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EH9899 / 1

Purchased by: ?

Administered by: Unknown

Symptoms: Death

SMQs: Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-20 Days after onset: 0 Permanent Disability? No Recovered? No

Recovered? No Office Visit? No ER Visit? No

ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021102836

Write-up: Spouse awoke 20Dec and found spouse dead; This is a spontaneous report from a Pfizer sponsored report Corporate (Pfizer) Social Media Platforms. A non-contactable consumer (patient"s husband) reported that a female patient of an unspecified age (Age: 89, Units: Unknown) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Lot number: EH9899, Expiry date: unknown), intramuscular on an unspecified date at a single dose for COVID-19 immunisation. The patient"s medical history and concomitant medications were not reported. It was reported that spouse awoke and found spouse dead on 20Dec2020. Patient was not transferred to hospital. 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: Spouse awoke 20Dec and found spouse dead

 VAERS ID: 1031846 (history)
 Vaccinated:
 2021-02-11

 Form:
 Version 2.0
 Onset:
 2021-02-12

Age: Days after
Sex: Female vaccination:

Location: Washington Submitted: 0000-00-00 Entered: 2021-02-15

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

Administered by: Unknown Purchased by: ?

Symptoms: Autopsy, Cerebral haemorrhage, Condition aggravated, Coronary artery occlusion, Death, Hypertension, Resuscitation

SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Neuroleptic malignant syndrome (broad), Myocardial infarction (narrow), Haemorrhagic central nervous system vascular conditions (narrow), Embolic and thrombotic events, arterial (narrow), Hypertension (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-02-12
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: HTN meds taken "off and on", UNK other medications etc.

Current Illness: UNK

Preexisting Conditions: HTN, other unk

Allergies: UNK

Diagnostic Lab Data: Autopsy ordered by Medical Examiner. Completed on day of death, Friday, Feb 12, 2021 (2/12/21) Findings reported to the family were that she had bleeding in the brain related to hypertension, and "90% of the main coronary artery was occluded" - per family. ME told family that death was unrelated to vaccine. Family believes this, but agreed to let me report this event in case there is a pattern and this data will help advance science.

CDC Split Type:

Write-up: Patient and her husband are elderly, but healthy and live independently. Patient took blood pressure medicine "off and on" according to family. She was 5"2", 120 pounds and slim and healthy and active, so was her husband, though he had pulmonary fibrosis so they had been staying home and not attending church etc, and masking when they did go out to protect against covid disease. They were both vaccinated with covid Pfizer vaccine (dose #1) on Thursday Feb 11. (02/11 /2021) Thursday night as they went to bed they checked in with each other on how they each felt. Patient said she felt totally fine, and her husband said his arm was a bit sore. Patient woke before her husband on Friday Feb 12, went downstairs and, from what the family can tell, fixed herself a snack, then sat on the sofa. Patient"s husband found her deceased on the sofa. He called 911 and they asked him to do CPR until the paramedics arrived. Because of proximity to covid vaccine, the ME wanted to examine the body in the home and also ordered an autopsy. Autopsy was completed on the same day as death, Feb 12, 2021

 VAERS ID: 1033472 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Unknown
 Entered:
 2021-02-16

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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: No adverse event (No reported medical history.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Resident coded and expired; A spontaneous report was received from a consumer concerning a patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and coded and expired. The patient"s medical history was not provided. No concomitant product use was reported. On an undisclosed date, the patient received their first of two planned doses of mRNA-1273 (Lot number: not provided) for prophylaxis of COVID-19 infection. On undisclosed date, the patient coded and expired. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on an undisclosed date. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter"s Comments: MEDICAL COMMENT: MOD 2021 009822 DEATH NOS This case concerns a patient of unknown age and gender who received their first of two planned doses of mRNA-1273 (Lot number: not provided) for prophylaxis of COVID-19 infection and had died. Very limited information regarding this event has been provided at this time to make a proper medical assessment, therefore, the causality is unlikely related to the vaccine in this case of death not otherwise specified. No contact information provided. Follow up is not expected.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1034985 (history)
 Vaccinated: 2021-01-04

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Unknown
 Entered:
 2021-02-17

Location: Kentucky

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA 039K20A / 1 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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

Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: 4 Nurshing home patients Died; A Spontaneous report was received from a pharmacist concerning 4 nursing home patients of unspecified age and gender who received Moderna"s COVID-19 vaccine (mRNA-1273) and died. The patients" medical histories were not provided. No relevant concomitant medications were reported. On unspecified dates, 4 nursing home patients received their first of two planned doses of mRNA-1273 (Lot # 039K20A) for prophylaxis of COVID-19 infection. A pharmacist reported that they just learned 4 nursing home patients died after the first dose of the Modern vaccine. The patients were buried, and no autopsies were conducted. The pharmacist suspected latent Covid-19 on the patients and that the vaccine precipitated this outcome. No treatment information was provided. Action taken with the second dose of mRNA-1273 in response to the event was not applicable. The event 4 nursing home patients died was fatal.; Reporter"s Comments: This case concerns 4 nursing home patients of unspecified age and gender who received their first dose of Moderna"s COVID-19 vaccine (mRNA-1273)Lot # 039K20A) and died. Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: died

 VAERS ID: 1035505 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-02-17

Location: Unknown

Vaccination / Manufacturer | Lot / Dose | Site / Route | COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1 | -/ OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Passed away with an hour to hour and 1/2 of receiving vaccine; A spontaneous report was received from a consumer concerning a patient who received

Moderna"s COVID-19 vaccine (mRNA-1273) and passed away with an hour to hour and 1/2 of receiving vaccine. The patient"s medical history, as provided by the reporter, included COVID-19. No relevant concomitant medications were reported. On unknown date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient passed away within an hour and a 1/2 of receiving the vaccine. Per the nursing home staff, they did not expect the patient to make it many more days. The patient was unresponsive in the room when the shot was given. The patient was 14+ days post COVID. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not applicable. The patient died on an unknown date. The cause of death was unknown.; Reporter"s Comments: This case concerns a patient, who experienced event of death (unknown cause). The event occurred an hour to hour and 1/2 after the first and last dose of mRNA-1273 vaccine administration. Based on the current limited available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded and the event is assessed as possibly related. However, Per the nursing home staff, the patient was 14+ days post COVID and they did not expect the patient to make it many more days. The patient was unresponsive in the room when the shot was given.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: 1035545 (history) Vaccinated: 0000-00-00 Version 2.0 Form: Onset: 0000-00-00 Age: Submitted: 0000-00-00 Sex: Entered: 2021-02-17 Male

Location: New York

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021139379

Write-up: Death; This is a spontaneous report from a contactable consumer. A 42-year-old male patient received Covid 19 Vaccine (UNSPECIFIED TRADE NAME), via an unspecified route of administration from an unspecified date to an unspecified date at single dose for covid-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. The reporter was calling about the Covid 19 Vaccine. Reporter stated that she gets information every day from the nursing home. Reporter stated that she will provide the name of the Nursing home, she just forgot to put it down. The patient, within 2 days dead from it, he was perfectly healthy. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on Lot/batch number has been requested.; Reported Cause(s) of Death: Death

VAERS ID: 1035549 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Entered: 2021-02-17 Sex: Male

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Blood bilirubin, Blood osmolarity, Blood pressure measurement, Blood urea, Monocyte count, Platelet count, Thrombocytopenia

SMQs:, Haematopoietic thrombocytopenia (narrow), Systemic lupus erythematosus (broad), 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 bilirubin; Result Unstructured Data: Test Result:1.50; Test Name: osmolality; Result Unstructured Data: Test Result:297; Test Name: blood pressure; Result Unstructured Data: Test Result:159/106; Test Name: Blood urea (BUN); Result Unstructured Data: Test Result:22.3; Test Name: monocytes; Test Result: 12.1 %; Test Name: platelet count; Result Unstructured Data: Test Result: Thrombocytopenia; Test Date: 20201221; Test Name: platelet count; Result Unstructured Data: Test Result:platelet count decreased again to 0

CDC Split Type: USPFIZER INC2021144615

Write-up: Thrombocytopenia; This is a spontaneous report from a contactable consumer (patient"s wife). A male patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced thrombocytopenia on an unspecified date, the seriousness of the event reported as death. The patient died two weeks after receiving a COVID-19 vaccine. Patient"s wife said that he died from a condition known as thrombocytopenia, marked by a shortage of the blood platelets that help stop bleeding, after he received BNT162B2. The patient underwent lab tests and procedures which included blood bilirubin: 1.50, blood osmolarity: 297, blood pressure measurement: 159/106, blood urea: 22.3, monocyte count: 12.1 %, platelet count: thrombocytopenia,

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platelet count: platelet count decreased again to 0 on 21Dec2020. The patient died on an unspecified date. It was unknown if an autopsy was performed. The outcome of the events was fatal. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Thrombocytopenia

VAERS ID: 1035552 (history) Vaccinated: 2020-12-29 Form: Version 2.0 Onset: 2020-12-29

Days after Age: vaccination: Sex: Female

Submitted: 0000-00-00 Location: Unknown Entered: 2021-02-17

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EL0140 / 1 LA / OT

Administered by: Unknown Purchased by: ?

Symptoms: Body temperature, Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes Date died: 2020-12-29

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: GABAPENTIN; MEMANTINE

Preexisting Conditions: Medical History/Concurrent Conditions: Anxiety; Aphasia; Asthenia; Dementia; Iron deficiency; Major depressive disorder; Osteoporosis;

Penicillin allergy; Polyneuropathy; Type II diabetes mellitus

Diagnostic Lab Data: Test Name: temperature; Result Unstructured Data: Test Result:98 Fahrenheit

CDC Split Type: USPFIZER INC2021146318

Write-up: approxmately 1:30 Pm the resident passed away; This is a spontaneous report from a Pfizer sponsored program. A non-contactable consumer reported that a female patient of an unspecified age (reported as 85 without unit) received the 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number: EL0140), intramuscular at left arm on 29Dec2020 11:29 at single dose for COVID-19 immunization. Medical history included dementia, aphasia, type 2 diabetes mellitus (DM), iron deficiency, asthenia, osteoporosis, polyneuropathy, anxiety, Major depressive disorder (MDD). Concomitant medication included gabapentin, memantine. The patient had allergies to codiene, phenobarbital, penicillin. The vaccine was administrated with no immediate adverse reaction at 11:29. Vaccine screening questions were completed and resident was not feeling sick and temperature was 98F. At approximately 13:30 on 29Dec2020, the resident passed away. It was not reported if an autopsy was performed. No follow-up attempts are possible. No further information is expected. Reported Cause(s) of Death: approxmately 1:30 Pm the resident passed away

VAERS ID: <u>1036480</u> (history) Vaccinated: 2021-01-26 Onset: 2021-02-02 Form: Version 2.0

Age: Days after vaccination: Sex: Male

Location: Illinois Submitted: 0000-00-00 Entered: 2021-02-17

| Vaccination / Manufacturer                     | Lot / Dose  | Site / Route |
|--|-------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | 026L20A / 1 | - / IM       |

Administered by: Public Purchased by: ?

Symptoms: COVID-19, Cough, Death, Endotracheal intubation, SARS-CoV-2 test positive

SMQs:, Anaphylactic reaction (broad), Angioedema (broad), Respiratory failure (broad), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (narrow)

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: amlodipine, aspirin, levothyroxine, losartan, metformin, metoprolol, pravastatin, polyethlyene glycol

Current Illness: had a cough since 2/17/21

Preexisting Conditions: diabetes type 2, hypertension, hypothyroid, hyperlipidemia, MRSA,

Allergies: Sulfa causes a rash

Diagnostic Lab Data: CDC Split Type:

Write-up: Patient passed away on 2/2/21 after being admitted on 1/31/21 after receiving COVID19 Moderna Vaccine on 1/26/21. On initial report to the hospital patient reported having a cough for over 2 weeks (starting approx. 1/17/21). He had a postive COVID19 PCR on 1/31/21. Intubated on 1/31/21 and passed away on 2/2/21

VAERS ID: <u>1037720</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-02-18

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dos | e Site / Route |
|--|-----------|----------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1       | - / OT         |

Administered by: Unknown Purchased by: ?

Symptoms: <u>Completed suicide</u> SMQs:, Suicide/self-injury (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

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Suicide; A spontaneous report was received from a consumer concerning a patient, of unknown age/gender, who received Moderna"s COVID-19 vaccine and experienced suicide. The patient"s medical history was not provided. Concomitant product use was not provided by the reporter. On unknown date, the patient received mRNA-1273 (Lot number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date the patient experienced suicide. Treatment information was not provided. Action taken with the mRNA-1273 in response to the event was not reported. The patient died on unknown date. The cause of death was reported as suicide. Plans for an autopsy were not provided.; Reporter"s Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Suicide

 VAERS ID: 1037867 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-02-18

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021153879

Write-up: Caller"s mother received both doses of the Pfizer covid vaccine; within a month of receiving the vaccine, the caller"s mother died.; This is a spontaneous report from a contactable consumer reported for the mother. A female patient of unknown age received both doses of vaccine BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), on unknown dates at single dose for COVID-19 immunization. Medical history and Concomitant medications were not reported. Within a month of receiving the vaccine, the patient died. It was unknown if an autopsy was performed. Information on the Lot/Batch number has been requested; Reported Cause(s) of Death: within a month of receiving the vaccine, the caller"s mother died

 VAERS ID: 1038253 (history)
 Vaccinated:
 2021-01-12

 Form:
 Version 2.0
 Onset:
 2021-01-13

 Age:
 Days after vaccination:
 1

 Sex:
 Male
 vaccination:

 Location:
 Florida
 Submitted:
 0000-00-00

 Entered:
 2021-02-18

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-13
Days after onset: 0
Permanent Disability? No

Recovered? No

Office Visit? No ER Visit? No ER or Doctor Visit? No

Hospitalized? No Previous Vaccinations:

Previous Vaccinatio Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No medical history reported.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Died the next day; A spontaneous report was received from a consumer concerning a male patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and died the next day. The patient"s medical history was not provided. Concomitant medication use was not provided by the reporter. On 12 Jan 2021, approximately one day prior to the event, the patient received one of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On 13 Jan 2021 the patient died. No additional information was provided in regards to the event. Action taken with mRNA-1273 in response to the event was not applicable. The patient died on 13 Jan 2021. The cause of death was unknown.; Reporter"s Comments: This case concerns a male patient of unknown age. The medical history and concomitant medication were not provided. The patient died approximately one day after receiving their first of two planned doses of mRNA-1273 (Lot unknown). Very limited information regarding this event has been provided at this time.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1039952 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-02-18

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death, Off label use

SMQs

Life Threatening? No Birth Defect? No

Died? Yes
Date died: 0000-00-00
Permanent Disability? No
Recovered? 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:

Allergies:
Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021155151

Write-up: Two report of death related to the vaccine were reported in a young premature baby and 25-year-old young person who dies 15 minutes after receiving the vaccine.; a young premature baby received BNT162B2; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported similar event for 2 patients. This is 1st of 2 reports. A patient of unspecified age and gender (reported as a young premature baby) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The consumer stated his main concern was even though the vaccine had been authorized. The vaccine was only given vaccine on the side of the road. People were dying from the vaccine more than from the virus. He gave out some percentage of people that could die from the virus vs from the vaccine. The percentage of death rate was 0.00045% from the virus. The percentage of death from the vaccine was 6.6%. There were many people reporting side effects such as bell"s palsy, whole body convulsion. Two report of death related to the vaccine were reported in a young premature baby and 25-year-old young person who died 15 minutes after receiving the vaccine. He said it"s sad these were front line worker who were facing all these side effects. The outcome of the event was fatal. Information on the lot/batch number has been requested.; Sender"s Comments: Linked Report(s): US-PFIZER INC-2021157531 same reporter, drug, event, different patient; Reported Cause(s) of Death: Two report of death related to the vaccine were reported in a young premature baby and 25-year-old young person who dies 15 minutes after receiving the vaccine.

 VAERS ID: 1039954 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-02-18

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021157531

Write-up: Two report of death related to the vaccine were reported in a young premature baby and 25-year-old young person who dies 15 minutes after receiving the vaccine.; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported similar event for 2 patients. This is 2nd of 2 reports. A 25-year-old patient of unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The relevant medical history and concomitant medications were not reported. The consumer stated his main concern was even though the vaccine had been authorized. The vaccine was only given vaccine on the side of the road. People were dying from the vaccine more than from the virus. He gave out some percentage of people that could die from the virus vs from the vaccine. The percentage of death rate was 0.00045% from the virus. The percentage of death from the vaccine was 6.6%. There were many people reporting side effects such as bell"s palsy, whole body convulsion. Two report of death related to the vaccine were reported in a young premature baby and 25-year-old young person who died 15 minutes after receiving the vaccine. He said it"s sad these were front line worker who were facing all these side effects. The outcome of the event was fatal. Information on the lot/batch number has been requested.; Sender"s Comments: Linked Report(s): US-PFIZER INC-2021155151 same reporter, drug, event, different patient; Reported Cause(s) of Death: Two report of death related to the vaccine were reported in a young premature baby and 25-year-old young person who dies 15 minutes after receiving the vaccine.

 VAERS ID: 1047571 (history)
 Vaccinated:
 2021-02-10

 Form:
 Version 2.0
 Onset:
 2021-02-11

Age: Days after Sex: Female vaccination:

Location: Washington Submitted: 0000-00-00 Entered: 2021-02-22

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EN6201 / 1 - / IM

Administered by: Other Purchased by: ? Symptoms: Cerebrovascular accident, Death

**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: 2021-02-20 Days after onset: 9 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No ER or Doctor Vis

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness: Preexisting Conditions: Allergies:

Diagnostic Lab Data: CDC Split Type:

Write-up: Death after stroke .

 VAERS ID: 1048665 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-02-23

Location: New York

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death, Internal haemorrhage

SMQs:, Haemorrhage terms (excl laboratory terms) (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: No adverse event (No reported medical history.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Died; Internal bleeding and died; A spontaneous report was received from a nurse concerning a male patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and experienced internal bleeding and died. The patient"s medical history was not provided. No concomitant product use was reported. On unknown date, the patient received their first of two planned doses of mRNA-1273 (Lot number: not provided) intramuscularly for prophylaxis of COVID-19 infection. On unknown date, a nurse reported she read about a doctor who received the COVID-19 vaccine and died 3 days later. She stated she read that the doctor had internal bleeding. It started with bleeding in his hands and feet, then went to his brain and died 3 days later. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not provided. The outcome of the events, internal bleeding and died, was considered fatal.; Reported limited information regarding the events has been provided at this time and is insufficient for causality assessment. Further information has been requested.; Reported

Cause(s) of Death: Internal bleeding

 VAERS ID: 1048686 (history)
 Vaccinated: 2021-01-01

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-02-23

Location: California

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH
 -/1
 -/

Administered by: Unknown Purchased by: ? Symptoms: SARS-CoV-2 antibody test, Sepsis

SMQs:, Sepsis (narrow), Opportunistic infections (broad), COVID-19 (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: Depression; Schizophrenia

Allergies:

Diagnostic Lab Data: Test Date: 202011; Test Name: covid19; Test Result: Positive

CDC Split Type: USPFIZER INC2021166424

Write-up: died just 10 days after being given the vaccine/ put sepsis on her medical records; This is a spontaneous report from a contactable consumer report for Aunt. A 59-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration in Jan2021 at single dose for COVID-19 immunization. Medical history included schizophrenia and depression. The patient's concomitant medications were not reported. Consumer's aunt (patient) was housed in a facility. She was being treated for schizophrenia and depression. This was one of the facilities that chose to house Covid patients during the pandemic. Many of the patients here contracted covid19 during this time and they had to do a full facility lockdown and quarantine. The patient tested positive in Nov2020 and was quarantined to her room for 10 days. 3 weeks ago (in Jan2021), she received the Pfizer vaccine. Consumer's family was not given notice of this and we are sad to report that she died just 10 days after being given the vaccine. They put sepsis on her medical records and have not connected this to the vaccine. Consumer stated aunt was just 59 yrs old, though she was being treated for her mental illness, she was physically healthy. Consumer's family gravely concerned that this facility neglected her health by administering the vaccine without considering possible reactions from the medication she was taking, or the fact she had Covid just months prior. Patient died on an unspecified date. it was unknown if an autopsy performed. Information on Lot/Batch number has been requested.; Reported Cause(s) of Death: died just 10 days after being given the vaccine/ put sepsis on her medical records

 VAERS ID: 1049284 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-02-23

Location: Virginia

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | - / UNK    | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs: 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: Unevaluable event (underlining health issue)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Died; A spontaneous report was received from a consumer concerning a 58-year-old, female patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and patient was died. The patient"s medical history was reported as underlying health issue. Concomitant product use was not provided by the reporter. On an unknown date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: if reported or unknown) intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, patient with underlying health issue died after getting the Moderna COVID-19 vaccine. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on an unknown date. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter"s Comments: This case concerns a 58-year-old female who died on unknown date after first dose of mRNA-1273, lot # unknown. Very limited information regarding this event has been provided at this time, therefore it is difficult to assess a cause and effect relationship. No further information will be available. Of note, patient"s medical history included unknown underlying health issues.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1051451 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-02-24

Location: Unknown

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH
 - / UNK
 - /

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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 VISIT? NO
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:

Preexisting Conditions: Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021179726

Write-up: died 15 min later; This is a spontaneous report from a Pfizer Sponsored Program. A non-contactable consumer reported that a female patient (mother) of an unknown age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose via an unknown route on an unknown date for Covid-19 immunization. Medical history and concomitant drug were not provided. The reporter stated her mother took the vaccine and died 15 min later. No follow-up attempts are possible. Information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: died 15 min later

 VAERS ID: 1056196 (history)
 Vaccinated:
 2021-01-11

 Form:
 Version 2.0
 Onset:
 2021-01-15

Age: Days after Sex: Male vaccination: 4

**Location:** Unknown **Submitted:** 0000-00-00 **Entered:** 2021-02-26

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

Administered by: Unknown Purchased by: ? Symptoms: Arrhythmia, Cardiac arrest, Coma

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (broad), Hyperglycaemia/new onset diabetes mellitus (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), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Cardiomyopathy (broad), Cardiac arrhythmia terms, nonspecific (narrow), Respiratory failure (broad), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-19 Days after onset: 4 Permanent Disability? No Recovered? 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: Congenital cardiovascular disorder (He had been stable and closely monitored for the past 20 years. He had no history of arrhythmia.)

Allergies:

Diagnostic Lab Data:

CDČ Split Type: USPFIZER INC2021188576

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

VAERS ID: <u>1056659</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-02-26

Location: New Jersey

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

Administered by: Unknown Purchased by: ?

Symptoms: Cardiac disorder

SMQs:

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:

CDC Split Type: USPFIZER INC2021186885

Write-up: heart issue; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient passed away after taking the vaccine. He was healthy but developed heart issue after taking vaccine. The patient died on an unspecified date. It was not reported if an autopsy was performed.; Reported Cause(s) of Death: heart issue

VAERS ID: <u>1056669</u> (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Unknown Entered: 2021-02-26 Sex:

Location: Nevada

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021203949

Write-up: She knows one person did die; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2, via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The reporter mentioned that "she knows one person did die" on an unspecified date. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: She knows one person did die

**VAERS ID:** <u>1057547</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Sex: Male Entered: 2021-02-26

Location: Texas

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/2

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs: 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: No adverse event (No medical history reported.)

0

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: 86 year old manager received the two doses of the Moderna vaccine and died; A spontaneous report was received from a consumer, concerning an 86year-old, male patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and passed away. The patient's medical history was not provided. No relevant concomitant medications were reported. On an unspecified date, the patient received their doses of mRNA-1273 (Lot number: unknown) through an unknown route in an unknown arm for prophylaxis of COVID-19 infection. On an unspecified date, it was reported that the patient passed away after receiving both doses. The cause of death was unknown. It was unknown if an autopsy was performed. The patient received both scheduled doses of mRNA-1273 prior to the event; therefore, action taken with the drug in response to the events is not applicable. The outcome of event "86 year old manager received the two doses of the Moderna vaccine and died" was fatal.; Reporter"s Comments: Very limited information regarding this event has been provided at this time. No autopsy report provided. Further information has been requested.; Reported Cause(s) of Death: 86 year old manager received the two doses of the Moderna vaccine and died

**VAERS ID: 1057704** (history) Vaccinated: 2021-01-16 Version 2.0 Onset: Form: 2021-01-16

Age: Days after vaccination: Sex: Female

Submitted: 0000-00-00 Location: Florida Entered: 2021-02-26

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Biopsy bone marrow, Blood test, Body temperature, Chills, Computerised tomogram, Dyspnoea, Fatigue, Inflammatory marker increased, Interleukin level, Laboratory test, Multiple organ dysfunction syndrome, Myelodysplastic syndrome, Pancytopenia, Pyrexia

SMQs:, Anaphylactic reaction (broad), Agranulocytosis (narrow), Haematopoietic cytopenias affecting more than one type of blood cell (narrow), Neuroleptic malignant

syndrome (broad), Anticholinergic syndrome (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (broad), Torsade de pointes, shock-associated conditions (broad), Anaphylactic/anaphylactoid shock conditions (broad), Toxic-septic shock conditions (broad), Anaphylactic/anaphylactoid shock conditions (broad), Hypoglycaemic and neurogenic shock conditions (broad), Blood premalignant disorders (narrow), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Cardiomyopathy (broad), Myelodysplastic syndrome (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (narrow), Sepsis (broad)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-02-12 Days after onset: 27 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: Breast cancer (in the 1990s); Mastectomy

Diagnostic Lab Data: Test Name: bone marrow biopsy; Result Unstructured Data: showed high grade MDS with 19% blasts.; Test Date: 202006; Test Name: blood work; Result Unstructured Data: Normal; Test Name: body temperature; Result Unstructured Data: degrees Fahrenheit; Test Name: CAT scan; Result Unstructured Data: bilateral pleural effusion; Test Name: IL-6; Result Unstructured Data: High; Test Name: lab profile; Result Unstructured Data: elevated d-dimer and ferritin levels; Test Name: Pancytopenia; Result Unstructured Data: abnormal

CDC Split Type: USMODERNATX, INC.MOD20210

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

VAERS ID: <u>1062350</u> (history) Vaccinated: 2021-01-23 2021-01-25 Form: Version 2.0 Onset:

Age: Days after 2 vaccination: Sex: Male

Submitted: 0000-00-00 Location: Unknown Entered: 2021-03-01

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA 013620A / 1

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-25 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:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Death; A spontaneous was received from a consumer concerning a male patient, who received Moderna"s COVID-19 vaccine and who died. The patient's medical history was not provided. No relevant concomitant medications were reported. On 23-Jan-2021, prior to the onset of the event, patient received their first of two planned doses of mRNA-1273 (Lot number:013620A) intramuscularly for prophylaxis of COVID-19 infection. On 25-Jan-2021, approximately 2 days after injection, patient Died. On 26-Jan-2021, neighbor Reporter called in to report a potential AE death. She shared that she lives in a condo building with other elderly. She shared that she and 2 other neighbors went to a vaccination site in Miami at a fire department. She shared that she is fine but that her neighbor died two days after shot. She shared that she didn"t know if he had symptoms and that she knows that he had a lot of medical issues and was on about 15 medicines. She shared that she didn"t know his age but guessed 70. She said we can contact his wife, but it must be a Spanish speaking agent because she speaks little English. She is concerned because they all received the vaccine at the same time. She wanted to reiterate that she was fine but believed we should know about the neighbor"s death. No treatment information was provided. Action taken with the second dose of mRNA-1273 in response to the event death is not applicable. The patient died on 26-Jan-2021. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter"s Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested. The cause of death was not provided.; Reported Cause(s) of Death: Unknown

VAERS ID: <u>1065078</u> (<u>history</u>) Vaccinated: 2020-12-22 Form: Version 2.0 Onset: 2021-01-11 Age: Days after

20 vaccination: Sex: Male

0000-00-00 Submitted: Location: Unknown 2021-03-02 Entered:

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Purchased by: ? Administered by: Unknown

Symptoms: Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (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: No adverse event (no medical history provided)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Unresponsive; A spontaneous report was received from a Reporter concerning a 25 Years-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273). The patient"s medical history was not provided. No relevant concomitant medications were reported. On 22-DEC-2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 01-JAN-2021, The patient became unresponsive and died which is serious. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. On 01-JAN-2021, the outcome of the event unresponsive became fatal. patient died.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: 1065158 (history) Vaccinated: 2021-01-20 Form: Version 2.0 Onset: 2021-01-22 Days after Age:

Sex: Male vaccination: Submitted: 0000-00-00 Location: Florida Entered: 2021-03-02

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EH9899 / 1 | LA / OT      |

Administered by: Unknown Purchased by: ?

Symptoms: Death, Headache

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-28 Days after onset: 6

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: Sulfonamide allergy

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021201124

Write-up: death; severe headache; This is a spontaneous report from a non-contactable consumer from a Pfizer-sponsored program. A male patient of an unspecified age (Age: 83, unit: Unknown; as reported) received the first dose of the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number:EH9899), intramuscularly in the left arm on 20Jan2021 at a single dose for COVID-19 immunisation. The patient"s medical history included sulfonamide allergy from an unknown date and unknown if ongoing. Concomitant medications were not reported. The patient previously took azithromycin [MANUFACTURER UNKNOWN] and experienced allergy on an unspecified date. On 22Jan2021, the patient experienced severe headache (non-serious). On 28Jan2021, the patient experienced death (death, medically significant); 8 days after receiving the vaccine. The patient died on 28Jan2021 due to unknown cause of death. It was unknown if an autopsy was performed. The clinical outcome of the event, death, was fatal. The clinical outcome of the event, severe headache, was not recovered. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: 1065394 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: 2021-03-02 Sex: Female Entered:

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / UNK

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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: No adverse event (No medical history reported.)

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Died; A spontaneous report was received from a consumer on a social media, concerning a 58-years-old female patient, unknown race and ethnicity, who was administered Moderna"s COVID-19 vaccine (mRNA-1273), and died. The patient"s medical history was not provided. No relevant concomitant medications were reported. On an unknown date, prior to the onset of the event, the patient received dose of mRNA-1273 (Lot number: unknown), for the prophylaxis of COVID-19 infection. On 17-Feb-2021, social media interaction was posted concerning a death of a patient on an unknown date after receiving Moderna vaccine. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not applicable. The patient died on an unknown date. The cause of death was not provided. Plans for autopsy were not provided.; Reporter"s Comments: Very limited information regarding the event has been provided at this time and is insufficient for causality assessment. The cause of death was not provided. Plans for autopsy were not provided.; Sender's Comments: US-MODERNATX, INC. MOD-2021-018302: Same Reporter; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1068743 (history)</u> Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-02-09 Age: Submitted: 0000-00-00 2021-03-02 Male Entered: Sex:

Location: Tennessee

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (UNKNOWN)) / UNKNOWN MANUFACTURER - / IM

Administered by: Unknown Purchased by: ? Symptoms: Death, SARS-CoV-2 test positive

SMQs:, Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-02-09 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: Bamlanivimab; Aspirin; Lumigan; Citracal + D3; Chondroitin sulfate a; gabapentin; ipratropium; levothyroxine; losartan; metoprolol; multivitamin; nitroglycerin; fish oil; ranolazine; viagra; simvastatin; maxzide

## **Current Illness:**

**Preexisting Conditions:** allergic to iodine and naproxen. past medical history including hypertension, type 2 diabetes, bladder cancer, hypothyroidism, coronary artery disease, 2 heart attacks, prostrate cancer, and vitamin d deficiency.

Allergies:

Diagnostic Lab Data:

CDC Split Type:

Write-up: Bamlanivimab treatment under Emergency Use Authorization(EUA). Bamlanivimab treatment under Emergency Use Authorization(EUA). Patient received 1st dose of COVID vaccine on 01/28/2021, but he began to have COVID symptoms on 02/04/2021 and tested positive on 02/05/2021. The patient was treated with banlanivimab on 02/08/2021, and he passed away on 02/09/2021.

 VAERS ID: 1068295 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-03-03

Location: Oklahoma

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

Administered by: Unknown Purchased by: ?

Symptoms: COVID-19, Condition aggravated, Death, Illness, Malaise, SARS-CoV-2 test SMQs:, Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Lupus syndrome

Allergies:

Diagnostic Lab Data: Test Name: COVID-19; Test Result: Negative; Comments: tested negative 2 times over the following 10 day while deteriorating.; Test Name: COVID-19; Test Result: Negative; Comments: tested negative 2 times over the following 10 day while deteriorating.; Test Name: COVID-19; Test Result: Positive; Comments: Was admitted and tested positive and put on ventilator

CDC Split Type: USPFIZER INC2021201566

Write-up: Was admitted and tested positive and put on ventilator; She felt slightly ill the day of vaccine; 2 days later patient become ill; tested negative 2 times over the following 10 day while deteriorating; Patient died 10 days later; This is a spontaneous report from a contactable consumer via Pfizer Sales Representative. This consumer (daughter) was reported for a female patient (mother). A 76-year-old female patient received first dose of bnt162b2 (Pfizer), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunization. Medical history included lupus from an unknown date and unknown if ongoing. The patient"s concomitant medications were not reported. The patient with lupus received 1st dose of vaccine. She felt slightly ill the day of vaccine. 2 days later patient become ill, tested negative 2 times over the following 10 day while deteriorating. Was admitted and tested positive and put on ventilator. Patient died 10 days later. Daughter thought she had COVID before vaccination. Event took place after use of product. The patient underwent lab tests and procedures which included COVID-19: negative (tested negative 2 times over the following 10 day while deteriorating), COVID-19: positive (Was admitted and tested positive and put on ventilator) all on an unspecified date. The patient died on an unspecified date. It was not reported if an autopsy was performed. The outcome of other events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Patient died 10 days later

 VAERS ID: 1068304 (history)
 Vaccinated:
 2021-02-10

 Form:
 Version 2.0
 Onset:
 2021-02-17

 Age:
 Days after
 7

Sex: Male vaccination:

Location: Connecticut Submitted: 0000-00-00 Entered: 2021-03-03

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-02-17 Days after onset: 0 Permanent Disability? No Recovered? No

Office Visit? No ER Visit? No ER or Doctor Visit? No Hospitalized? No Previous Vaccinations:

Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Bacterial infection (Patient was being treated for bacterial infection and had spent 1 week in hospital within one month prior to being dosed with vaccine.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021209258

Write-up: died; This is a spontaneous report from a contactable consumer reporting for a patient. An 86-year-old male patient received the first dose of BNT162B2

(PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), on 10Feb2021 at single dose for COVID-19 immunization. Concomitant medications were not reported. Relevant medical history included bacterial infection, the patient was being treated for bacterial infection and had spent 1 week in hospital within one month prior to being dosed with vaccine. On 17Feb2021 the patient died. The cause of death was unknown. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: death

 VAERS ID: 1068306 (history)
 Vaccinated:
 2021-02-18

 Form:
 Version 2.0
 Onset:
 2021-02-18

Age: Days after Sex: Male vaccination:

**Location:** Unknown **Submitted:** 0000-00-00 **Entered:** 2021-03-03

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

Administered by: Unknown Purchased by: ?

Symptoms: Blue toe syndrome, Body temperature, Death, Feeling cold, Heart rate, Heart rate increased, Myocardial infarction, Nasopharyngitis, Peripheral swelling, Pneumothorax, Pyrexia, Skin discolouration, Tremor

SMQs:, Cardiac failure (broad), Angioedema (broad), Neuroleptic malignant syndrome (broad), Myocardial infarction (narrow), Anticholinergic syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Embolic and thrombotic events, arterial (narrow), Parkinson-like events (broad), Noninfectious encephalopathy/delirium (broad), Extravasation events (injections, infusions and implants) (broad), Haemodynamic oedema, effusions and fluid overload (narrow), Hypotonic-hyporesponsive episode (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Hypoglycaemia (broad), Dehydration (broad)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-02-23 Days after onset: 5 Permanent Disability? No Recovered? No

Office Visit? Yes ER Visit? No

ER or Doctor Visit? No Hospitalized? Yes, ? days Extended hospital stay? Yes

Previous Vaccinations: Other Medications:

Current Illness: Magnesium low (went to the hospital on 17Feb2021)

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: Test Name: Body temperature; Result Unstructured Data: Test Result:normal; Test Date: 20210218; Test Name: Body temperature; Result Unstructured Data: Test Result:low grade fever; Test Date: 20210219; Test Name: Body temperature; Result Unstructured Data: Test Result:fever increased; Test Date: 20210219; Test Name: Heart rate; Result Unstructured Data: Test Result:130/140 seconds

CDC Split Type: USPFIZER INC2021211484

Write-up: heart attacks; Collapse of lung; pulse was in the 130s/140s; passed away; nose and fingers turned gray and were cold to the touch; nose and fingers turned gray and were cold to the touch; his big toe had turned gray; his right foot was swollen; low grade fever; Shaking; extremely cold; This is a spontaneous report from a contactable consumer. An elderly male patient received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 18Feb2021, at single dose, for COVID-19 immunisation. Medical history included ongoing blood magnesium decreased (went to the hospital on 17Feb2021). Concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), on 27Jan2021, for COVID-19 immunisation and experienced arm soreness. The patient experienced passed away (death, hospitalization, medically significant) on 23Feb2021, heart attacks (caused hospitalization, medically significant) on 20Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, pulse was in the 130s/140s (caused hospitalization) on 19Feb2021 with outcome of unknown, low grade fever on 18Feb2021 with outcome of recovered on 23Feb2021, shaking on 18Feb2021 with outcome of unknown, extremely cold on 18Feb2021 with outcome of unknown, nose and fingers turned gray and were cold to the touch on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown, his right foot was swollen on 19Feb2021 with outcome of unknown, his right foot was swollen required physician visit on 19Feb2021. They were reported as a result of the magnesium deficiency. On 19Feb2021 evening his fever increased and his nose and fingers turned gray and were cold to the touch. On 20Feb2021 he collapsed at home and was taken to the hospital by ambulance. He had several heart attacks prior to the collapse. They decided to put him in a medically induced com

 VAERS ID: 1068307 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-03-03

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death, Haemorrhage

SMQs:, Haemorrhage terms (excl laboratory terms) (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:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021213418

Write-up: died; bled out; This is a spontaneous report from a contactable nurse. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient had bled out on an unspecified date with outcome of unknown. The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: The limited information provided precludes a full clinical assessment of the case. As a cautionary measure and for reporting purposes, and assuming a drug-event temporal association, the Company cannot completely exclude a causal association between the reported events "bled out" and "died" (death of unknown cause) and BNT162B2 administration, until sufficient information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s): US-PFIZER INC-2021210582 Same reporter/drug, different patient; Reported Cause(s) of Death: died

 VAERS ID: 1070765 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-03-03

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death
SMQs:
Life Threatening? No
Right Defect? 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:

CDC Split Type: USPFIZER INC2021215418

Write-up: died 2 days after the second vaccine; This is a spontaneous report from a contactable consumer reporting for his/her father. An 87-year-old male patient received the second dose of bht162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number unknown) via unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient"s medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162B2 on a unspecified date for COVID-19 immunisation and was fine. The patient died 2 days after the second vaccine. The reporter stated patient death due to the Pfizer Covid vaccine. The patient had autopsy. The outcome of event was fatal. Information about lot/batch number has been requested.; Reported Cause(s) of Death: died 2 days after the second vaccine

 VAERS ID: 1070769 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-03-03

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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: Diabetes; Heart disorder; Hospitalization; Pacemaker insertion (cardiac)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021224736

Write-up: then died within 24 hours afterwards; This is a spontaneous report from a contactable consumer. This consumer reported that a 74-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number unknown), via an unspecified route of administration an unspecified date at single dose for COVID-19 immunization. Concomitant medications were not reported. The patient with a host of health issues (heart issues/had a pace maker, diabetes, among others) was in a rehabilitation center following a hospital stay and was given the second dose of vaccine. It was reported that the patient died within 24 hours afterwards. It was not reported if an autopsy was performed. Information on batch/lot number was requested.; Reported Cause(s) of Death: then died within 24 hours afterwards

 VAERS ID: 1070770 (history)
 Vaccinated: 2021-02-04

 Form:
 Version 2.0
 Onset: 2021-02-01

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-03-03

Location: Texas

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH
 EL9269 / 1
 - / OT

Administered by: Public Purchased by: ?

Symptoms: Foetal heart rate abnormal, Heart rate, Maternal exposure during pregnancy, Ultrasound scan

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Foetal disorders (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-02-22 Days after onset: 21 Permanent Disability? No Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? Yes Hospitalized? No Previous Vaccinations:

Other Medications: VIT D; FOLATE; PRENATAL VITAMINS [ASCORBIC ACID;BETACAROTENE;CALCIUM

SULFATE; COLECAL CIFEROL; CYANOCOBALAMIN; FERROUS; ZOLOFT

Current Illness:

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: Test Date: 20210203; Test Name: heartbeat; Result Unstructured Data: Test Result:152 bpm; Test Date: 20210220; Test Name: heartbeat; Result Unstructured Data: Test Result:no heartbeat; Test Date: 20210203; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result Unstructured Data: Test Result:no abnormalities; Test Date: 20210220; Test Name: ultrasound; Result:no abn

CDC Split Type: USPFIZER INC2021225027

Write-up: Maternal exposure during pregnancy; Fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected; This is a spontaneous report from a contactable consumer (parent). This consumer reported information for both mother and fetus. This is a fetus report. A patient of unspecified age and gender (fetus) received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269), transplacental on 04Feb2021 at 14:00 at single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medication included ergocalciferol (VIT D), folic acid (FOLATE), ascorbic acid/betacarotene /calcium sulfate/colecalciferol/cyanocobalamin/ferrous fumarate/folic acid/ nicotinamide/pyridoxine hydrochloride/retinol acetate/riboflavin/thiamine mononitrate/tocopheryl acetate/zinc oxide (PRENATAL VITAMINS) and sertraline hydrochloride (ZOLOFT) at 25 mg, all transplacental. It was reported that OB exam on 03Feb21 showed healthy baby at 7weeks 5days heartbeat detected 152 bpm; no abnormalities identified via ultrasound; labs and hormone levels all within normal ranges. No issues detected. Mother received 1st dose of vaccine on 04Feb2021. Per ultrasound on 20Feb2021, fetus stopped growing on 09Feb2021 (8 weeks 4 days); no heartbeat detected. Miscarriage occurred on 22Feb2021. The fetus died on 22Feb2021. It was not reported if an autopsy was performed.; Sender"s Comments: Linked Report(s): US-PFIZER INC-2021204433 same drug and reporter, different patient and event; Reported Cause(s) of Death: Fetus stopped growing on 09Feb21 (8w4d); no heartbeat detected. Miscarriage occurred 22Feb21.

**VAERS ID:** <u>1071117</u> (history) **Vaccinated:** 2021-01-31 **Form:** Version 2.0 **Onset:** 2021-02-07

Age: Days after 7
Sex: Unknown vaccination: 7

 Location:
 Unknown
 Submitted:
 0000-00-00

 Entered:
 2021-03-04

Vaccination / Manufacturer | Lot / Dose | Site / Route | COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1 | -/ OT

Administered by: Unknown Purchased by: ?

Symptoms: Death, Haemorrhage, International normalised ratio, Urinary tract infection, Urine analysis

SMQs:, Haemorrhage terms (excl laboratory terms) (narrow)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-02-12

Days after onset: 5
Permanent Disability? No
Recovered? No
Office Visit? No

Office Visit? No ER Visit? No ER or Doctor Visit? No Hospitalized? No Previous Vaccinations:

Other Medications: ANTICOAGULATION

Current Illness: Anticoagulant therapy (Long term history of anticoagulation therapy.)

Preexisting Conditions:

Allergies:

Diagnostic Lab Data: Test Date: 20210210; Test Name: INR; Test Date: 20210210; Test Name: urine analysis; Result Unstructured Data: diagnosed with a UTI CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Passed away; UTI; Abnormal bleeding; A spontaneous report was received from a healthcare professional concerning a patient who received the Moderna COVID-19 Vaccine (mRNA-1273) and experienced abnormal bleeding, UTI, and passed away. The patient's medical history included a long term history of anticoagulation therapy. Concomitant product use included anticoagulation therapy. On 31Jan2021 prior to the onset of the events the patient recieved their first dose of mRNA-1273 (Lot number:not reported) intramuscularly for prophylaxis of COVID-19 infection. On 07Feb2021, the patient complained of abnormal bleeding. Patient was seen at clinic on 10Feb2021 and was diagnosed with a UTI and given antibiotics. An INR was also completed that day due to patient having a long term history of anticoagulation therapy. Results of that showed the INR to be 12. Prior to vaccination, patient's INR was normal and no changes to medications and diet were made after vaccination and prior to complaint starting. On 12Feb2021 the patient passed away. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12Feb2021. The cause of death was unknown. Plans for an autopsy were not provided.; Reporter's Comments: This case concerns an 82 year

old male patient, with history of long term anticoagulation therapy (unknown indication), who experienced a fatal event of death and abnormal hemorrhage, 13 days after receiving second dose of mRNA- 1273 (Lot# Unknown). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1071128</u> (history) Vaccinated: 2020-12-28 Form: Version 2.0 Onset: 2021-01-04

Age: Davs after vaccination: Sex: Female

Submitted: 0000-00-00 Location: Unknown Entered: 2021-03-04

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-04 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:** 

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Unresponsive; A spontaneous report was received from Pfizer concerning a 32-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had a sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 28 DEC 2020, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 04 JAN 2021, at 7:20 am, the patient died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 04 Jan 2021. The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter"s Comments: This case concerns a 32-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had a sudden death. The cause of death was unknown. Plans for an autopsy were not provided. Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1071129</u> (history) Vaccinated: 2021-01-08 Version 2.0 Onset: 2021-01-09 Form:

Age: Days after vaccination:

Sex: Male Location: Unknown Submitted: 0000-00-00 Entered: 2021-03-04

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-09 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:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (no reported medical history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Unresponsive; A spontaneous report was received from Pfizer concerning a 43-year old, male patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and had a sudden death. The patient"s medical history was not provided. No relevant concomitant medications were reported. On 08 Jan 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 09 JAN 2021, the patient died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 08 Jan 2021. The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: 1071130 (history) Vaccinated: 2020-12-28 Form: Version 2.0 Onset: 2020-12-29

Age: Days after vaccination: Sex: Male

Submitted: 0000-00-00 Location: Unknown Entered: 2021-03-04

Vaccination / Manufacturer Lot / Dose Site / Route

COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad) Life Threatening? No

Birth Defect? No Died? Yes

Date died: 2020-12-29 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: **Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Unresponsive; A spontaneous report was received from Pfizer concerning a 45-year old, male patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and had a sudden death. The patient"s medical history was not provided. No relevant concomitant medications were reported. On 28 Dec 2020, approximately 24 hours prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 29 Dec 2020, the patient was found deceased at home. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 29 Dec 2020. The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter"s Comments: Very limited information regarding this event has been provided at this time.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1071131</u> (history) 2020-12-31 Vaccinated: Version 2.0 2020-12-31 Form: Onset:

Age: Days after vaccination: Sex: Female

Submitted: 0000-00-00 Location: Unknown Entered: 2021-03-04

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-31 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:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

Allergies:

Diagnostic Lab Data:

CDČ Split Type: USMODERNATX, INC.MOD20210

Write-up: Unresponsive; A spontaneous report was received from Pfizer concerning a 50-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and had a sudden death. The patient"s medical history was not provided. No relevant concomitant medications were reported. On 31 Dec 2020, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) intramuscular for prophylaxis of COVID-19 infection. On 31 Dec 2020, the patient died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 31 Dec 2020. The cause of death was unknown. Plans for an autopsy were unknown.; Reporter"s Comments: This case concerns a 51 year old, female patient, who experienced an unexpected event of Death, after receiving 1st dose of mRNA- 1273 (Lot# unknown). Very limited information regarding this event has been provided at this time. There is no contact information and no further follow up information is expected.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1071132</u> (history) Vaccinated: 2021-01-07 2021-01-07 Form: Version 2.0 Onset:

Age: Days after vaccination: Sex: Male

Submitted: 0000-00-00 Location: Unknown Entered: 2021-03-04

Vaccination / Manufacturer Lot / Dose Site / Route

COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / OT

Administered by: Unknown Purchased by: ? Symptoms: Acute respiratory failure, Death

SMQs:, Anaphylactic reaction (broad), 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), Acute central respiratory depression (narrow), Hypersensitivity (broad), Respiratory failure (narrow)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-01-12

Days after onset: 5 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:

**Current Illness:** Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No Reported medical history)

Allergies: Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: chronic hypoxia respiratory failure; Unresponsive; A spontaneous report was received from Pfizer concerning a 51-year old, male patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and had developed hypoxia a sudden death. The patient"s medical history was not provided. No relevant concomitant medications were reported. On 07 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 07 Jan 2021, around 6:00 pm, the patient became increasingly hypoxic. He was transported to the hospital for acute on chronic hypoxia respiratory failure. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 12 Jan 2021 at 11:25pm. The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1071133</u> (history) Vaccinated: 2021-01-08 2021-01-08 Version 2.0 Onset: Form:

Age: Days after 0 vaccination: Sex: Female

Submitted: 0000-00-00 Location: Unknown Entered: 2021-03-04

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / OT -/1

Administered by: Unknown Purchased by: ?

Symptoms: Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-01-08

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:** 

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (no reported medical history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Unresponsive; A spontaneous report was received from Pfizer concerning a 52-year old, female patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and had a sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 08 Jan 2021, approximately 2 hours prior to the onset of event, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 08 Jan 2021, the patient was monitored for the appropriate amount of time by nursing staff, following vaccination. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 08 Jan 2021 at 2:15pm. The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter"s Comments: This case concerns a 52-year old, female patient, who experienced a sudden death 1 day after administration of first dose of mRNA-1273. The cause of death was not provided. Plans for an autopsy were unknown. Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1071134</u> (history) Vaccinated: 2020-12-23 Form: Version 2.0 Onset: 2021-01-08 Days after Age: 16 vaccination: Sex: Female Submitted: 0000-00-00 Location: Unknown

Entered: 2021-03-04 Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-08 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:
Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (no reported medical history)

1

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Death; A spontaneous report was received from a reporter concerning a 56-year old female patient, who received Moderna"s COVID-19 vaccine (mRNA-1273) and had experienced death. The patient"s medical history was not provided. No relevant concomitant medications were reported. On 23 Dec 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 08 Jan 2021, the patient died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 08 Jan 2021. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter"s Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1071135 (history)
 Vaccinated:
 2021-01-08

 Form:
 Version 2.0
 Onset:
 2021-01-09

Age: Days after
Sex: Female vaccination:

 Location:
 Unknown
 Submitted:
 0000-00-00

 Entered:
 2021-03-04

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-01-09

Days after onset: 0
Permanent Disability? No
Recovered? No

Recovered? No Office Visit? No ER Visit? No ER or Doctor Vis

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

2021-03-04

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Unresponsive; A spontaneous report was received from Pfizer concerning a 56-year old, female patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and had a sudden death. The patient "s medical history was not provided. No relevant concomitant medications were reported. On 08 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 09 Jan 2021, the patient was found deceased in her home. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 09 Jan 2021. The cause of death was not provided/unknown. Plans for an autopsy were unknown/not provided.; Reporter"s Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

**VAERS ID:** <u>1071136</u> (history) Vaccinated: 2021-01-04 Version 2.0 Onset: 2021-01-11 Form: Age: Days after 7 vaccination: Sex: Female Submitted: 0000-00-00 Location: Unknown

Entered:

 Vaccination / Manufacturer
 Lot / Dose Site / Route

 COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA
 -/1
 -/OT

Administered by: Unknown Purchased by: ?

Symptoms: Pyrexia, Respiratory failure, Sepsis, Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), 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), Acute central respiratory depression (narrow), Guillain-Barre syndrome (broad), Cardiomyopathy (broad), Hypersensitivity (broad), Respiratory failure (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Hypokalaemia (broad), Sepsis (narrow), Opportunistic infections (broad)

Life Threatening? Yes Birth Defect? No

Died? Yes

**Date died:** 2021-01-11

Days after onset: 0 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: **Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: sepsis; respiratory failure; Fever; Unresponsive; A spontaneous report was received from Pfizer concerning a 56-year old, female patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and experienced respiratory failure, sepsis, fever and sudden death. The patient"s medical history was not provided. No relevant concomitant medications were reported. On 04 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 11 Jan 2021, the patient began to have a fever. She was sent to the emergency room for evaluation. That evening, she died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 11 Jan 2021. The cause of death was reported as respiratory failure and sepsis. Plans for an autopsy were unknown/not provided.; Reporter"s Comments: This is a case of 56-year old, female patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and experienced sepsis, fever, respiratory failure and sudden death. Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Respirtory Failure; Sepsis

VAERS ID: <u>1071137</u> (history) Vaccinated: 2020-12-30 Version 2.0 Onset: 2021-01-04 Form:

Days after Age: Sex: Female vaccination:

Submitted: 0000-00-00 Location: Unknown Entered: 2021-03-04

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: Life Threatening? No

Birth Defect? No Died? Yes

Date died: 2021-01-04

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:** 

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No Reported Medical History)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Unresponsive; A spontaneous report was received from Pfizer concerning a 58-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 30 Dec 2020, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 04 Jan 2021, the patient died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 04 Jan 2021. The cause of death was unknown/not reported. Plans for an autopsy were unknown/not provided.; Reporter"s Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

**VAERS ID:** <u>1071138</u> (history) Vaccinated: 2021-01-05 Form: Version 2.0 Onset: 2021-01-08

Age: Days after vaccination: Sex: Male

Submitted: 0000-00-00 Location: Unknown Entered: 2021-03-04

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-08 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:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Sudden death; A spontaneous report was received from Pfizer concerning a 60-year old, male patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and experienced sudden death. The patient"s medical history was not provided. No relevant concomitant medications were reported. On 05 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 08 Jan 2021, the patient died. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 08 Jan 2021. The cause of death was unknown/not reported. Plans for an autopsy were unknown/not provided.; Reporter"s Comments: Very limited information regarding the event has been provided at this time and is insufficient for causality assessment. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1071139 (history)
 Vaccinated:
 2021-01-12

 Form:
 Version 2.0
 Onset:
 2021-01-13

Age: Days after
Sex: Female vaccination:

Location: Unknown Submitted: 0000-00-00 Entered: 2021-03-04

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death
SMQs:
Life Threatening? No

Birth Defect? No Died? Yes Date died: 2021-01-13

Days after onset: 0
Permanent Disability? No
Recovered? No

Office Visit? No ER Visit? No ER or Doctor Vis

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations:

Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (no reported medical history)

Allergies:

Diagnostic Lab Data:

 $\textbf{CD\bar{C} Split Type:} \ \textbf{USMODERNATX}, \ \textbf{INC.MOD20210}$ 

Write-up: Sudden death; A spontaneous report was received from Pfizer concerning a 60-year old, female patient who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced sudden death. The patient's medical history was not provided. No relevant concomitant medications were reported. On 12 Jan 2021, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) for prophylaxis of COVID-19 infection. On 13 Jan 2021, the patient was found to be deceased at 3:00 am. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The patient died on 13 Jan 2021. The cause of death was unknown/not reported. Plans for an autopsy were unknown/not provided. ; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1071300 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-03-04

Location: Ohio

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | - / UNK    | -/-          |

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs: 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: No adverse event (No reported medical history.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Died; A spontaneous report, was received from a consumer on a social media, concerning a 38-years-old female patient, unknown race and ethnicity, who was administered Moderna's COVID-19 vaccine (mRNA-1273), and died. The patient's medical history was not provided. No relevant concomitant medications were reported. On an unknown date, prior to the onset of the event, the patient received dose of mRNA-1273 (Lot number: unknown), for the prophylaxis of COVID-19 infection. On 17-Feb-2021, social media interaction was posted concerning a death of a patient on an unknown date after receiving Moderna vaccine. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not applicable. The patient died on an unknown date. The cause of death was

not provided. Plans for autopsy were not provided.; Reporter"s Comments: Very limited information regarding the event of death has been provided at this time. No further information will be available.; Sender"s Comments: MODERNA, INC.-MOD-2021-018380:Same reporter; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1073471 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Sex: Male Entered: 2021-03-04

Location: Unknown

 Vaccination / Manufacturer
 Lot / Dose Site / Route

 COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA
 -/1
 -/OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness: Hospice care Preexisting Conditions: Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Was found deceased a little less than 12 hours following COVID vaccination; A spontaneous report was received from a reporter concerning a 96-year-old, male patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and was found deceased a little less than 12 hours following COVID vaccination. The patient sectived their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, the patient was found deceased a little less than 12 hours following COVID vaccination, and he had had some changes over the last two days. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. On an unknown date the patient died. The cause of death was unknown. Plans for an autopsy were not provided.; Reporter"s Comments: This case concerns a 96 year old male patient, who was on hospice care experienced a fatal event of death, after receiving mRNA-1273 (Lot# Unknown). Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1074599 (history)
 Vaccinated:
 2021-02-02

 Form:
 Version 2.0
 Onset:
 2021-02-03

Age: Days after
Sex: Male vaccination:

Location: Minnesota Submitted: 0000-00-00 Entered: 2021-03-05

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA 043L20A / 1 LA / -

1

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs: 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:

Current Illness: COPD
Preexisting Conditions: Medical History/Concurrent Conditions: Hospice care

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Death; A spontaneous report was received from a other health care professional concerning a 57-year-old, male patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and died. The patient"s medical history included chronic obstructive pulmonary disease (COPD). Concomitant product use was not provided. On 02 Feb 2021, prior to onset of the events, the patient received his first of two planned doses of mRNA-1273 (Lot number: 043L20A) in the left arm for prophylaxis of Covid-19 infection. 03 Feb 2021, it was reported that the patient died. The patient was not experiencing any symptoms prior to death. He was on hospice care, not hospitalized. No further information was provided. Treatment information was unknown. The cause of death was not reported. Plans for an autopsy were unknown. Action taken with the mRNA-1273 in response to the event was not applicable.; Reporter"s Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown

 VAERS ID: 1076912 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-03-05

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: COVID-19, Drug ineffective

SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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: Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021224962

Write-up: died from COVID after receiving the two doses of the vaccine; COVID; This is a spontaneous report from a contactable consumer report for a friend. A patient of unspecified age and gender received first dose and second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE) both via an unspecified route of administration on unspecified dates at single doses for covid-19 immunisation. The patient"s medical history and concomitant medications were not reported. The consumer mentioned her friend died from COVID after receiving the two doses of the vaccine. The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: died from COVID after receiving the two doses of the vaccine

 VAERS ID: 1076915 (history)
 Vaccinated:
 2021-01-19

 Form:
 Version 2.0
 Onset:
 2021-01-21

Age: Days after Sex: Female vaccination: 2

 Location:
 Unknown
 Submitted:
 0000-00-00

 Entered:
 2021-03-05

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No

Died? Yes Date died: 2021-01-21 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: Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021228157

Write-up: (name) is now dead 2 days after receiving a COVID mRN shot; This is a spontaneous report from a non-contactable other non HCP. A 28-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 19Jan2021 at single dose for Covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient is now dead 2 days after receiving a Covid mrn (as reported) shot in Jan2021. She died two days later, according to her mother. 28 year old daughter took the vaccine on a Tuesday (on 19Jan2021) and was dead by Thursday (on 21Jan2021). Outcome of event was fatal. Autopsy shows no other red flags (as reported). The reporter has assured us he will get to the bottom of this vaccine crap. Anything attached should be red flag (as reported). No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: (name) is now dead 2 days after receiving a COVID mRN shot

 VAERS ID: 1076917 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Sex: Female
 Submitted: 0000-00-00

 Entered: 2021-03-05

Location: Pennsylvania

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021229958

Write-up: one died after the vaccine; This is a spontaneous report from a Pfizer-sponsored program. This contactable consumer reported that a female patient of an unspecified age received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The reporter reported 3 females died post vaccination with the Pfizer-BioNTech COVID-19 vaccine. She explained one died after the vaccine on an unspecified date. She explained she had no additional details on the adverse event. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: one died after the vaccine

Vaccinated: 0000-00-00 VAERS ID: <u>1076918</u> (history) Version 2.0 0000-00-00 Form: Onset: Submitted: 0000-00-00 Age: 2021-03-05 Sex: Female Entered:

Location: Pennsylvania

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

Administered by: Unknown Purchased by: ?

Symptoms: Chest pain SMQs:, Gastrointestinal nonspecific symptoms and therapeutic procedures (broad), Cardiomyopathy (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:

CDC Split Type: USPFIZER INC2021229959

Write-up: chest pain; This is a spontaneous report from a contactable consumer from a Pfizer-sponsored program. A female patient in her 50s received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose for COVID-19 immunisation on unknown date. Relevant history and concomitant drug was unknown. The patient died after experiencing chest pain for 2 weeks post vaccination. The outcome of event was fatal. It was unknown if autopsy done or not. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Chest pain

**VAERS ID:** <u>1076919</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-03-05

Location: Pennsylvania

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Rout |
|--|------------|-------------|
| COVID19: COVID19 (COVID19 (PEIZER-BIONTECH)) / PEIZER/BIONTECH | - / UNK    | -/-         |

Administered by: Unknown Purchased by: ?

SMQs:, Myocardial Infarction
SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (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:** 

Allergies:

Diagnostic Lab Data:

CDČ Split Type: USPFIZER INC2021229960

Write-up: died of an heart after the vaccine/Heart attack; This is a spontaneous report from a contactable consumer received from a Pfizer-sponsored program. This consumer reported similar events for 3 patients. This report is the 1st of 3. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced heart attack on an unspecified date. The patient died of an heart attack after the vaccine on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: died of an heart after the vaccine/Heart attack

VAERS ID: <u>1080335</u> (history) Vaccinated: 0000-00-00 Version 2.0 0000-00-00 Onset: Form: Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-03-08

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / UNK -/-

Administered by: Unknown Purchased by: ?

Symptoms: Anaphylactic reaction

SMQs:, Anaphylactic reaction (narrow), Anaphylactic/anaphylactoid shock conditions (narrow), Hypersensitivity (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: No adverse event (No reported medical history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Anaphylaxis; A spontaneous report was received from a physician assistant concerning a patient of unspecified age and gender, who received Moderna"s COVID-19 vaccine (mRNA-1273) and experienced anaphylaxis. The patient"s medical history was not provided. No relevant Concomitant medications were reported. On an unknown date, prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) for prophylaxis of COVID-19 infection. On an unknown date, after receiving vaccine, the patient died due to anaphylaxis. No further details were available at the time of this report. Treatment for the event was not provided. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the event anaphylaxis was fatal .The patient died on an unspecified due to anaphylaxis. Autopsy details were not provided.; Reporter's Comments: Very limited information regarding the event of anaphylaxis has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Anaphylaxis

VAERS ID: <u>1083754</u> (<u>history</u>) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-03-09

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Asymptomatic COVID-19, Drug ineffective, Systemic inflammatory response syndrome

SMQs:, Lack of efficacy/effect (narrow), Tumour lysis syndrome (broad), Sepsis (broad), Opportunistic infections (broad), COVID-19 (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:** 

Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021239063

Write-up: systemic inflammatory; asymptomatic COVID-19 infection; asymptomatic COVID-19 infection; This is a spontaneous report from a non-contactable consumer. A male patient of an unspecified age received the second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient"s medical history and concomitant medications were not reported. On an unspecified date, the patient developed a devastating systemic inflammatory response within 36 hours of receiving his second Pfizer vaccine shot. Patient's deadly inflammatory state followed his vaccination. Administration of the Pfizer vaccine ignited a deadly inflammatory response in patient's body acutely, in a setting where he had a recent asymptomatic COVID-19 infection. The patient died on an unspecified date. It was not reported if an autopsy was performed. Outcome of all events were fatal. No follow-up attempts are possible, information about lot/batch number cannot be obtained. No further information is expected.; Reported Cause(s) of Death: asymptomatic COVID-19 infection; asymptomatic COVID-19 infection; systemic inflammatory

VAERS ID: 1085185 (history) Vaccinated: 2021-01-05 Form: Version 2.0 Onset: 2021-01-05

Days after Age: vaccination: Sex: Female

0000-00-00 Submitted: Location: Virginia Entered: 2021-03-09

| Vaccination / Manufacturer                     | Lot / Dose  | Site / Route |
|--|-------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | 026L20A / 1 | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Arthralgia, Back pain, Body temperature, COVID-19, Coronavirus test positive, Headache, Pyrexia

SMQs:, Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Retroperitoneal fibrosis (broad), Arthritis (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: 2021-02-02 Days after onset: 28 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: TRULICITY; METFORMIN; JARDIANCE; LOSARTAN; AMLODIPINE; SYNTHROID; SIMVASTATIN; ALLOPURINOL; ESTROGEN;

COLCHICINE; CALCIUM; ZINC; VITAMIN C ACID

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

Allergies:

Diagnostic Lab Data: Test Date: 20210105; Test Name: Body temperature measurment; Result Unstructured Data: High; Test Date: 20210109; Test Name:

COVID-19; Test Result: Positive ; Result Unstructured Data: Positive CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: testing positive for COVID; Fever for 3 hours after the vaccine/ High temperature; Joint pain; Severe upper back pain; Headache; A spontaneous report was received from a nurse concerning a 44-year-old female patient who experienced fever for 3 hours after vaccination, headache, joint pain, and severe upper back pain. The patient"s medical history was not provided. Products known to have been used by the patient, within two weeks prior to the event, included dulaglutide, metformin, empagliflozin, losartan, amlodipine, levothyroxine, simvastatin, allopurinol, estrogen, colchicine, calcium, zinc, multivitamin and vitamin C. On 05 Jan 2021, the patient received mRNA-1273 (Lot number 026L20A) intramuscularly for prophylaxis of COVID-19 infection. On 05 Jan 2021, patient experienced fever for 3 hours after vaccination. The patient also experienced headache, joint pain, and severe upper back pain. The patient stated her temperature was high from 05 Jan 2021 until 09 Jan 2021 when it went down. Treatment information was not provided. Follow-up received on 21 Feb 2021, from the patient"s husband, included that the patient tested positive for Covid-19 on 09 Jan 2021 and was hospitalized on 11 Jan 2021. The patient never recovered from her symptoms and the patient died on 02 Feb 2021. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events Coronavirus test positive was fatal and for headache, joint pain, severe upper back pain and temperature were unknown. The cause of death was reported as Coronavirus test positive and autopsy details was unknown.; Reporter"s Comments: This case concerns a 44-year-old female who was hospitalized with a serious unexpected event of COVID-19 with fatal outcome along with NS unexpected back pain and NS expected fever, headache, arthralgia. Event onset was 5 days after the first dose of mRNA-1273. Treatment not reported. Event outcomes fatal. Autopsy results unknown. Based on current available information and temporal association between use of the product and the start date of the event, a causal relationship cannot be excluded.; Reported Cause(s) of Death: Testing positive for COVID

VAERS ID: <u>1085865</u> (<u>history</u>) Vaccinated: 2021-01-29 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: 2021-03-09 Sex: Male Entered:

Location: Ohio

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA 007M20A / 1 LA / IM

Administered by: Public Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-02-23 Permanent Disability? No Recovered? No

Office Visit? No ER Visit? No ER or Doctor Visit? No Hospitalized? No **Previous Vaccinations:** Other Medications: Unknown

**Current Illness:** Preexisting Conditions: unknown

Allergies: Unknown

Diagnostic Lab Data: Unknown

CDC Split Type:

Write-up: DEATH 2/23/21

 VAERS ID: 1090182 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Male
 Entered:
 2021-03-11

Location: Tennessee

 Vaccination / Manufacturer
 Lot / Dose Site / Route

 COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA
 -/1
 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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: No adverse event (No medical history reported.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Passed away; A spontaneous report was received from a consumer concerning a male patient of unknown age, who was received Moderna"s COVID-19 vaccine (mRNA-1273) and died. The patient"s medical history was not provided. No concomitant medications were reported. On an unknown date, prior to the onset of event, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) intramuscularly for prophylaxis of COVID-19 infection. It was reported by the patient"s wife that the patient died. She was calling to cancel his second dose of mRNA-1273. No additional details, including the date of death, were reported. Treatment information was not provided. Action taken with the mRNA-1273 was not applicable as the patient died. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter"s Comments: Very limited information regarding this event has been provided at this time. No further information is expected.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1106175 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-03-16

Location: Kentucky

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | LA / OT      |

Administered by: Unknown Purchased by: ?

Symptoms: Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (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:

Previous Vaccination Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: a friend died from the vaccine; A spontaneous report was received from a non health care professional, concerning her friend, who was administered Moderna"s COVID-19 vaccine (mRNA-1273) and died from the vaccine. The patient"s medical history, concomitant history, and lab data was not provided by the reporter. On an unknown date, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. The patient experienced death after receiving the moderna mRNA1273 vaccine. No further details were provided. The action taken with the second dose of mRNA-1273 in response to the event was not applicable. The outcome of the events, died from the vaccine, were considered as fatal:; Reporter"s Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1106349 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-03-16

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021259374

Write-up: Resulted in the death; This is a spontaneous report from a Pfizer sponsored program: A contactable consumer reporting on behalf of the sister reported that a female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unknown date, at single dose, for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient experienced an adverse effect that resulted in death on an unspecified date. Cause of death was unknown. It was unknown if an autopsy was done. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Resulted in the death

**VAERS ID:** <u>1108473</u> (history) Vaccinated: 0000-00-00 Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-03-16

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Arrhythmia, Cardiac failure congestive, Condition aggravated, Death, Diabetes mellitus, Fall
SMQs:, Cardiac failure (narrow), Hyperglycaemia/new onset diabetes mellitus (narrow), Accidents and injuries (narrow), Cardiomyopathy (broad), Cardiac arrhythmia terms, nonspecific (narrow), Immune-mediated/autoimmune disorders (broad) Life Threatening? No

Birth Defect? No Died? Yes

Date died: 2021-03-08 Permanent Disability? No

Recovered? No Office Visit? Yes ER Visit? No ER or Doctor Visit? Yes Hospitalized? No Previous Vaccinations: Other Medications:

**Current Illness: Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: CDČ Split Type:

Write-up: death Narrative: Patient received 1st dose of Moderna COVID-19 vaccine on 03/08/2021. Patient died 03/09/2021. Medical examiner received report that patient was alert before a fall on the night of 03/08/2021. Death certificate will report death likely due to arrhythmia due to underlying CHF. Contributing factors include

VAERS ID: <u>1108474</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-03-16

Location: Unknown

| Vaccination / Manufacturer                                  | Lot / Dose | Site / Route |
|---|------------|--------------|
| COVID19: COVID19 (COVID19 (UNKNOWN)) / UNKNOWN MANUFACTURER | - / UNK    | -/-          |

Administered by: Unknown Purchased by: ?

Symptoms: Cardiac failure, Cardiac failure congestive, Confusional state, Death, Dyspnoea, General physical health deterioration, Generalised oedema, Increased upper airway secretion, Insomnia, Nausea, Pulse absent, Respiratory arrest, Tachypnoea, Unresponsive to stimuli

SMQs:, Cardiac failure (narrow), Anaphylactic reaction (broad), Acute pancreatitis (broad), Angioedema (broad), Asthma/bronchospasm (broad), Hyperglycaemia/new

onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Dementia (broad), Acute central respiratory depression (narrow), Pulmonary hypertension (broad), Guillain-Barre syndrome (broad), Noninfectious encephalitis (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Haemodynamic oedema, effusions and fluid overload (narrow), Cardiomyopathy (broad), Eosinophilic pneumonia (broad), Hypotonichyporesponsive episode (broad), Hypersensitivity (broad), Respiratory failure (narrow), Hypoglycaemia (broad), Infective pneumonia (broad)

Life Threatening? No Birth Defect? No

Died? Yes Date died: 2021-01-10

Permanent Disability? No Recovered? No Office Visit? Yes ER Visit? No

ER or Doctor Visit? Yes Hospitalized? No **Previous Vaccinations:** 

Other Medications: **Current Illness:** 

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type:

Write-up: death Narrative: Patient was admitted to the ER on 12/26/20 with worsening shortness of breath and was admitted to acute care services. On 12/29/20, a hospice consult was placed for end stage CHF, EF 20%. On 12/30/20, he transferred to the facility and was a DNR. On 1/7/21, he was noted to have increased secretions in throat and was given atropine gtts sublingual and ondansetron for nausea. He also had issues with insomnia and was given trials of hydroxyzine, trazodone and melatonin. Lorazepam remained on profile as well as part of hospice care. On 1/9/21, he was noted to be more confused, tachypneic and had anasarca (furosemide was ordered). Later on that same day he began to decline rapidly to the point of unresponsiveness other than to verbal stimuli and was determined to be imminent. On 1/10/21, he remained unresponsive and not able to tolerate oral meds. That same day at 1020 when nursing did rounds, he was found to be pulseless and without respirations. An autopsy was declined.

VAERS ID: <u>1107188 (history)</u> Vaccinated: 0000-00-00 Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Entered: 2021-03-17 Sex: Female

Location: Missouri

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ? Symptoms: Death

SMOs:

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: No adverse event (No medical history reported.)

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: death after second dose; A spontaneous report was received from a consumer concerning a female patient of unknown age, who experienced severe symptoms post first dose of Moderna's Covid-19 vaccine (mRNA-1273) and death shortly after her second dose. The patient's medical history was not provided. Concombined the reporter. No lab data was not provided On unspecified date, the patient received her second of two planned doses of mRNA-1273 (Batch number not provided) intramuscularly for prophylaxis of COVID-19 infection. It was reported that shortly after receiving the second dose of mRNA-1273, the patient died. Treatment information was not provided/unknown. Action taken with the drug in response to the events is not applicable. The patient died on an unknown date. Plans for an autopsy were not reported; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: death

VAERS ID: 1112825 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Entered: 2021-03-18 Sex: Unknown

Location: Arkansas

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | LA / IM      |

Administered by: Pharmacy Purchased by: ?

Symptoms: Abdominal pain, Arthralgia, Death, Epistaxis, Fatigue, Feeling abnormal, Mouth haemorrhage, Nausea, Pain, Pain in extremity, Pyrexia, Vomiting SMQs:, Acute pancreatitis (broad), Haemorrhage terms (excl laboratory terms) (narrow), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Retroperitoneal fibrosis (broad), Dementia (broad), Oropharyngeal conditions (excl neoplasms, infections and allergies) (narrow), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Arthritis (broad), Tendinopathies and ligament disorders (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-17 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: None

CDC Split Type:

Write-up: Received vaccine on afternoon of 3/15/2021 and began experiencing nausea and vomiting, left arm and shoulder pain, fever, body aches, fatigue, and abdominal pain the morning of 3/16/20. He notified the pharmacy that administered the vaccine to him and they told him that some people have those symptoms with it. On 3/16/21 he went to bed around 11:30 PM feeling terrible and was found dead in his bed the next day (3/17/21) with dried blood coming out of his nose and

mouth.

 VAERS ID: 1114256 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Submitted: 0000-00-00

 Sex: Male Entered: 2021-03-19

Location: Florida

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Aneurysm, Erythema

SMQs:, Anaphylactic reaction (broad), Hypersensitivity (broad), 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 Provious Vaccinations:

Previous Vaccinations:
Other Medications:
Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Aneurysm; red splotches on arm skin; A spontaneous report was received from a Consumer concerning a HCP, male patient of unknown age who received Moderna"s COVID-19 vaccine (mRNA-1273) and experienced developed red splotches on his arm skin and patient died from an aneurysm. The patient"s medical history was not provided. No concomitant medications were reported. On an unknown date, prior to the onset of the events, the patient received their unknown of the two planned doses of mRNA-1273 (lot/batch: unknown) via unknown route for prophylaxis of COVID-19 infection. On an unspecified date, after vaccination the patient had a reaction and developed red splotches on his arm skin. Then four to five days, later in the hospital the patient died from an aneurysm (Seriousness criteria: death). The cause of death was aneurysm. No autopsy details reported No Laboratory investigations were provided. No Treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of aneurysm was fatal and for erythema was unknown.; Reporter"s Comments: Very limited information regarding these events has been provided at this time. Further information has been requested; Reported Cause(s) of Death: Aneurysm

 VAERS ID: 1114257 (history)
 Vaccinated:
 2021-01-28

 Form:
 Version 2.0
 Onset:
 2021-03-06

 Age:
 Days after vaccination:
 37

 Location:
 Illinois
 Submitted:
 0000-00-00

 Entered:
 2021-03-19

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Angiogram, Chills, Death, Headache, Myalgia, Nausea, Pyrexia

SMQs:, Rhabdomyolysis/myopathy (broad), Acute pancreatitis (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Eosinophilic pneumonia (broad), Tendinopathies and ligament disorders (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-03-06 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:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse reaction (no adverse events reported.)

Allergies:

Diagnostic Lab Data: Test Date: 20210224; Test Name: cardiac angiography; Test Result: Inconclusive; Result Unstructured Data: unknown

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: fever; chills; headaches, excruciating generalized body aches like he had just be ran over by a truck; nausea; patient has passed away; A spontaneous report from was received from a Consumer concerning a 74 Years-old male patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and experienced nausea, headaches, chills, fever, excruciating generalized body aches like he had just be ran over by a truck, patient has passed away. The patient"s medical history was not provided. No relevant concomitant medications were reported. On 23-02-2021, prior to the onset of the events, the patient received the second of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, The patient experienced nausea, headaches, chills, fever, excruciating generalized body aches like he had just be ran over by a truck. The patient had a cardiac angiography on 24-02-2021. The result was unknown. The patient was found dead on 06-03-2021. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the events nausea, headaches, chills, fever, excruciating generalized body aches like he had just be ran over by a truck was recovering. The patient died on 06-03-2021. The information about the autopsy was unknown. The cause of the death was unknown.; Reporter"s Comments: Very limited information regarding this events has been provided at this time. The patient must have been in some form of cardiac issues before death, that"s reason why cardiac angiography was done. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

**VAERS ID: 1114382** (history) Vaccinated: 2021-02-20 Form: Version 2.0 Onset: 2021-02-24

Days after Age: vaccination: Sex: Unknown

Submitted: 0000-00-00 Location: Texas Entered: 2021-03-19

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EL9266 / 2 | LA / OT

Administered by: Private Purchased by: ?

Symptoms: Exposure during pregnancy, Foetal death

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Termination of pregnancy and risk of abortion (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-02-24 Days after onset: 0 Permanent Disability? No Recovered? No Office Visit? Yes ER Visit? No

ER or Doctor Visit? Yes Hospitalized? No

Previous Vaccinations: Other Medications: PRENATAL VITAMINS [ASCORBIC ACID;BETACAROTENE;CALCIUM SULFATE;COLECALCIFEROL;CYANOCOBALAMIN;FERROUS

**Current Illness: Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021278790

Write-up: Baby stop growing 3 days later (7 weeks 3 days per sono); Baby stop growing 3 days later (7 weeks 3 days per sono); This is a spontaneous report from a contactable Other HCP. This Other HCP reported events for herself and fetus. This is a fetus report. A 40-year-old mother received bnt162b2 (BNT162b2), dose 2 administered in Arm Left on 20Feb2021 (Batch/Lot Number: El9266) as SINGLE DOSE, dose 1 administered in Arm Left on 27Jan2021 (Batch/Lot Number: El3248) as SINGLE DOSE for covid-19 immunisation. The mother medical history included allergies: Shellfish. No other vaccine in four weeks. No COVID prior vaccination. Concomitant medication included ascorbic acid, betacarotene, calcium sulfate, colecalciferol, cyanocobalamin, ferrous fumarate, folic acid, nicotinamide, pyridoxine hydrochloride, retinol acetate, riboflavin, thiamine mononitrate, tocopheryl acetate, zinc oxide (PRENATAL VITAMINS). The mother was pregnant. Last menstrual date: 04Jan2021. Due Date: 11Oct2021. The mother was 7 weeks pregnant at time of 2nd vaccine. Baby stop growing 3 days later (7 weeks 3 days per sono) on 24Feb2021 08:00 AM. AE resulted in: Doctor or other healthcare professional office/clinic visit, Emergency room/department or urgent care. The patient died on 24Feb2021 08:00 AM. It was not reported if an autopsy was performed.; Sender"s Comments: Based on provided information and temporal association the reported events causal relationship with the suspect drug cannot be excluded. However there is very limited information provided in this report. Additional information is needed to better assess the case, including complete medical history and diagnostics workup. This case will be reassessed upon receipt of follow-up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of rise review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s): US-PFIZER INC-2021277400 Same reporter/drug, different patient /event (mother case); Reported Cause(s) of Death: Baby stop growing 3 days later (7 weeks 3 days per sono); Baby stop growing 3 days later (7 weeks 3 days per

VAERS ID: <u>1114383</u> (<u>history</u>) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 **Submitted:** 0000-00-00 Age: 2021-03-19 Sex: Female Entered:

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Liver disorder

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:

CDC Split Type: USPFIZER INC2021284281

Write-up: The patient had liver problems and died; This is a spontaneous report from a contactable consumer. A 39-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient had liver problems and died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: The patient had liver problems and died

 VAERS ID: 1114894 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Submitted: 0000-00-00

 Sex: Unknown
 Entered: 2021-03-19

Location: Massachusetts

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA
 - / UNK
 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Product administered at inappropriate site, Thrombocytopenia

SMQs:, Haematopoietic thrombocytopenia (narrow), Systemic lupus erythematosus (broad), Drug abuse and dependence (broad), Medication errors (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: Medical History/Concurrent Conditions: No adverse event (No medical history reported.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Thrombocytopenia; Vaccinators are vaccinating very high up on the shoulder; A spontaneous report was received from a nurse concerning a patient, who received Moderna"s COVID-19 vaccine (mRNA-1273) and experienced Vaccinators are vaccinating very high up on the shoulder, thrombocytopenia. The patient"s medical history, was not provided by the reporter.No Concomitant medications were reported. On an unknown date, the patient received their planned dose of mRNA-1273 (Lot number: unknown) for prophylaxis of COVID-19 infection. The reporter stated that Vaccinators are vaccinating very high up on the shoulder. They need to go down on the deltoid. She also reported the event of thrombocytopenia of which one involved a doctor who died. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the event, vaccinators are vaccinating very high up on the shoulder was resolved. The outcome of the events thrombocytopenia is fatal.; Reporter"s Comments: This report refers to a patient who experienced non-serious of vaccinating very high up on the shoulder, (Vaccine administered at inappropriate site.) There were no reported AEs associated with this case of vaccine administered at inappropriate site.; Reported Cause(s) of Death: Thrombocytopenia

 VAERS ID: 1115348 (history)
 Vaccinated:
 2021-03-05

 Form:
 Version 2.0
 Onset:
 2021-03-06

 Age:
 Days after
 4

Age: Days after Sex: Female vaccination:

**Location:** North Carolina **Submitted:** 0000-00-00 **Entered:** 2021-03-19

Vaccination / Manufacturer | Lot / Dose | Site / Route | COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | 026A21A / 1 | LA / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No

**Died?** Yes **Date died:** 2021-03-06

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:

Preexisting Conditions: Comments: List of non-encoded Patient Relevant History: Patient Other Relevant History 1: no adverse event, Continue: [UNK], Comment: No medical history reported

Allergies:

Diagnostic Lab Data:

CDČ Split Type: USMODERNATX, INC.MOD20210

Write-up: death; A spontaneous report was received from a HCP concerning about a 86 years old female patient, who received Moderna's COVID-19 vaccine (mRNA-1273) and died. The patient's medical history was not reported. Concomitant medications were not reported. On 05 Mar 2021, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Batch number: 026A21A) via intramuscular in left deltoid for prophylaxis of COVID-19 infection. On 06 Mar 2021 the patient died next day after vaccination, who left quite well after vaccination from the facility, the reason for death is not known. Treatment information was not provided. Action taken with mRNA-1273 in response to the event is not applicable. The outcomes of all the event is not applicable.; Reporter's Comments: This is a case of death in a 86 years old female patient, with unknown past medical hx or current co morbid conditions and concomitant medications, who died one day after receiving first dose of vaccine. Very limited information has been provided at this time: Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1116259 (history)
 Vaccinated:
 2021-01-21

 Form:
 Version 2.0
 Onset:
 2021-01-21

Age: Days after Sex: Male vaccination:

Location: California Submitted: 0000-00-00 Entered: 2021-03-19

Vaccination / Manufacturer | Lot / Dose | Site / Route | COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | 029L20A / 1 | LA / OT

Administered by: Unknown Purchased by: ?

Symptoms: Asthenia, Death, Dysstasia, Gait inability, Malaise

SMQs:, Anticholinergic syndrome (broad), Dystonia (broad), Guillain-Barre syndrome (broad), Noninfectious encephalitis (broad), Noninfectious

encephalopathy/delirium (broad), Noninfectious meningitis (broad)

Life Threatening? No Birth Defect? No

Died? Yes
Date died: 2021-02-13
Days after onset: 23
Permanent Disability? No

Recovered? No Office Visit? Yes ER Visit? No

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications:

Current Illness: Lung disease (on oxygen support prior to vaccination)

Preexisting Conditions: Allergies: Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Death; not able to stand up or walk; extreme weakness; he did not feel well; not able to stand up or walk; A spontaneous report was received from the patient"s wife concerning a male (age not provided) who experienced extreme weakness/asthenia, did not feel well/malaise, unable to walk/gait inability, and unable to stand/dysstasia. The patient"s medical history included lung disease which required oxygen support. Per patient"s wife, no concomitant products were in use within two weeks of the event. The patient"s wife also stated he does not take any daily medications. On 21 Jan 2021, prior to the onset of events, the patient received the first of two planned doses of mRNA-1273 (Batch number 029L20A) by injection into his left arm for prophylaxis of Covid-19 infection. After receiving the vaccine, the patient"s wife stated he did not feel well. He experienced extreme weakness. He was not able to stand up or walk for the first few days after getting the shot. "He could not walk even 3 steps and get in the car". On 09 Feb 2021, the patient felt a little bit better and could walk from one bedroom to another. No Medications were used to treat the patient"s symptoms. No relevant medical tests were provided. The patient had an appointment with his healthcare provider (date and time not provided) and was told he could not get the second dose of vaccine unless he got better. The patient"s wife stated she is not blaming the vaccine because her husband had a lung disease prior to getting the vaccine. His doctor said, (per his wife) this lung disease had weakened him to the point he could not drive his car anymore. His brain was fine before the vaccine. On 03 Mar 2021, the patient"s wife called to say that the patient had finally passed away on 13 Feb 2021. The second dose of mRNA-1273 was withheld in response to the events while waiting for the patient"s condition to improve however; it was never given due to the patient"s death. The events of did not feel well, extreme weakness, unable to walk, and unable to st

 VAERS ID: 1121585 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Sex: Female Entered: 2021-03-22

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | A -/1      | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death
SMQs:
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:

Previous Vaccinations
Other Medications:
Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (no adverse event reported)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: died; A spontaneous report from was received from a Consumer concerning a female patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and mentioned that a patient who had received the Moderna vaccine had died, and so they were concerned about getting the second dose. The patient"s medical history was not provided. No relevant concomitant medications were reported. On unknown date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 intramuscularly for prophylaxis of COVID-19 infection. On an unknown date, The patient mentioned that a patient who had received the Moderna vaccine had died, and so they were concerned about getting the second dose. Laboratory details are not provided. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the events was considered Fatal.; Reporter"s Comments: This is a case of death of an unknown age female subject with unknown medical history, who died on an unknown day after receiving first dose of vaccine. Very limited information has

been provided at this time. No follow up is possible.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1121622 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00

Sex: Unknown Entered: 2021-03-22

Location: Unknown

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH
 - / UNK
 - /

Administered by: Unknown Purchased by: ? Symptoms: Death

SMQs: Life Threatening? No Birth Defect? No

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:

Died? Yes

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021288934

Write-up: my friend just died after taking your shot; This is a spontaneous report from a Pfizer sponsored program. A non-contactable consumer reported a patient (friend) of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. His/her friend just died after taking your shot (And he/she know of more.) He/she will just keep his/her immune system high. They didn"t need a vaccine. The patient died on an unspecified date. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained; Reported Cause(s) of Death: my friend just died after taking your shot

 VAERS ID: 1125070 (history)
 Vaccinated:
 2021-01-21

 Form:
 Version 2.0
 Onset:
 2021-02-28

Age: Days after Sex: Male vaccination: 38

Location: Louisiana Submitted: 0000-00-00 Entered: 2021-03-23

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA 025L20A / 2 RA / OT

Administered by: Unknown Purchased by: ?

Symptoms: Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (narrow)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-02-28

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:

Preexisting Conditions: Medical History/Concurrent Conditions: Congestive heart failure; Diabetes; High cholesterol; Hypertension

Allergies:

Diagnostic Lab Data

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: He past away on 28Feb2021 from a heart attack; A spontaneous report was received from a consumer concerning a 80 year old male patient who received Moderna"s COVID-19 vaccine and the patient died due to heart attack. The patient"s medical history, as provided by the reporter, included diabetes, congestive heart failure, hypertension and high cholesterol. Concomitant product use was not provided by the reporter. The patient received their first of two planned doses of mRNA-1273 (Batch number: 025L20A) intramuscularly in the right arm on 21 Jan 2021. On 26 Feb 2021, the patient received their second of two planned doses of mRNA-1273 (Batch number: 024M20A) intramuscularly in the left arm for prophylaxis of COVID-19 infection. On 28 Feb 2021 the patient passed away due to heart attack. No treatment information was provided. The seriousness criteria for the event passed away from a heart attack were death and medically significant. Action taken with mRNA-1273 in response to the event was not applicable. The outcome for the event, he passed away from a heart attack was fatal.; Reporter's Comments: This case concerns a 80 year old, male patient. Who died due to myocardial infarction. Very limited information regarding this event has been provided at this time. The patient"s medical history of diabetes, congestive heart failure, hypertension and high cholesterol remains the risk factor for myocardial infarction. Further information has been requested. The cause of death is Myocardial infarction.; Reported Cause(s) of Death: Heart Attack

VAERS ID: <u>1125079</u> (history) Vaccinated: 2021-02-02 Form: Version 2.0 Onset: 2021-03-03

Days after Age: 29 vaccination: Sex: Male

Submitted: 0000-00-00 Location: Michigan Entered: 2021-03-23

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/2        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death, Unresponsive to stimuli

SMQs:, Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Guillain-Barre syndrome (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Hypotonic-hyporesponsive episode (broad), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-03 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: **Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19 (Patient was diagnosed with Covid-19 prior to first dose.); Dehydration (The patient was reported to be dehydrated prior to testing positive for Covid-19)

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Patient passed away; Found him non-responsive; A spontaneous report was received from a consumer concerning a male patient of an unknown age who received Moderna"s COVID-19 vaccine (mRNA-1273) and experienced unresponsiveness to stimulus. The event was followed by his death. The patient"s medical history included Covid-19 and experienced dehydration prior to testing positive for Covid-19. Concomitant product use was not provided by the reporter. The patient was diagnosed with COVID-19 at the skilled facility after becoming dehydrated. He was transported to Hospital on 23 Dec 2020 then discharged to skilled facility on 03 Jan 2021 for physical therapy. On 02 Feb 2021, the patient received their first of two planned doses of mRNA-1273 (Batch number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 02 Mar 2021, the patient received their second of two planned doses of mRNA-1273 (Batch number: unknown) intramuscularly for prophylaxis of COVID-19 infection. The anatomical location were not reported. On 03 Mar 2021, the patient was found non-responsive and the staff at skilled rehabilitation tried to resuscitate. Death was the outcome. Treatment information was not provided. Action taken with mRNA-1273 in response to the event(s) was not applicable. The outcome of the event non responsive to stimuli was fatal. The patient died-on 03 Mar 2021 and the cause of death was not provided. It is not known whether autopsy done on this individual. No results were provided.; Reporter"s Comments: This is a case of death in an unknown aged male subject with unknown medical history of recently recovered covid-19 infection before first dose, who died one day after receiving second dose of vaccine. Very limited information has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

**VAERS ID:** <u>1126560</u> (history) Vaccinated: 0000-00-00 Version 2.0 Onset: 0000-00-00 Form: Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-03-23

Location: New Hampshire

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

Administered by: Unknown Purchased by: ?

Symptoms: Chest pain, Death, Dyspnoea

SMQs:, Anaphylactic reaction (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (broad), Cardiomyopathy (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? Yes, ? days
Extended hospital stay? No Previous Vaccinations: Other Medications

Current Illness: **Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: CDC Split Type: USPFIZER INC2021281269

Write-up: passed away; chest pain; trouble breathing; This is a spontaneous report from a contactable physician and from three non-contactable consumers from a Pfizer-sponsored program. A 66-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection; lot number and expiry date not reported), via an unspecified route of administration, on an unspecified date, as SINGLE DOSE for covid-19 immunisation. The patient had just taken the COVID-19 vaccine and he was hospitalized due to the effects. The patient was rushed to hospital with chest pains and was experiencing trouble breathing. The patient was in the ICU fighting the effects of the vaccine. The patient passed away four hours late on an unspecified date. The outcome of chest pains and trouble breathing was unknown. Cause of death was unknown. It was unknown if an autopsy was performed. Information on the lot/Batch number has been requested.; Sender"s Comments: Based on temporal association, the causal relationship between BNT162B2 and the events death, chest pain and dyspnea cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review

and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: passed away

 VAERS ID: 1130148 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-03-24

Location: Missouri

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/2        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Liver disorder

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:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

Allergies:

**Current Illness:** 

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: something wrong with the liver; A spontaneous report was received from a consumer concerning patients of unspecified age and gender who received Moderna"s COVID-19 vaccine (mRNA-1273) and were dying after second shot and something wrong with the liver (liver disorder). The patients" medical histories were not provided. No relevant concomitant medications were reported. Dates of vaccination were not reported. The reported heard on the news that "people are dying after the second shot" and apparently one of the patients had something wrong with the liver after getting the shot. The reporter said the patients received Moderna"s mRNA-vaccine. On an unknown date, the patient experienced the event(s) people are dying after second shot, No treatment information was provided. The action taken with the vaccine in response to the events was not applicable. The cause of death for "one of the patients was had something wrong with the liver".; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested; Reported Cause(s) of Death: liver disorder; death unknown cause

 VAERS ID: 1133038 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-03-25

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Cardiac arrest, Death, Malaise

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (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), Respiratory failure (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? Yes, ? days Extended hospital stay? No

Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021296570

Write-up: died after receiving the first dose of a COVID-19 vaccine; cardiac arrest; fell ill; This is a spontaneous report from a non-contactable consumer reported for a patient (friend"s cousin). A male patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, batch/lot number and expiration date not provided), via an unspecified route of administration, on an unspecified date, at single dose, for COVID-19 immunization. Medical history included patient was infected with the virus in 2020 (reported as "over six months ago"), but not in the current time. Concomitant medications were not reported. The patient died after receiving the first dose of a COVID-19 vaccine on an unknown date. Patient felt ill that evening a few hours after receiving the shot, followed by cardiac arrest. Patient was taken to the hospital, where he died the next day. The outcome of the event "unknown cause of death" was fatal, of other events was unknown. The cause of death was not reported. It was unknown if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: died after receiving the first dose of a COVID-19 vaccine

 VAERS ID: 1133039 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2021-03-01

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-03-25

Location: Tennessee

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH
 EN6201 / 2
 RA /

Administered by: Unknown Purchased by: ?

Symptoms: Diarrhoea, Movement disorder, Renal impairment, Tremor

SMQs:, Rhabdomyolysis/myopathy (broad), Acute renal failure (narrow), Neuroleptic malignant syndrome (broad), Retroperitoneal fibrosis (broad), Pseudomembranous colitis (broad), Akathisia (broad), Dyskinesia (broad), Dystonia (broad), Parkinson-like events (broad), Noninfectious encephalopathy/delirium (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Noninfectious diarrhoea (narrow), Tumour lysis syndrome (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-16
Days after onset: 14
Permanent Disability? No
Recovered? No
Office Visit? No

ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:

Current Illness: Glomerulonephritis

Preexisting Conditions: Medical History/Concurrent Conditions: Dementia (He had dementia prior to getting the vaccine); Walking aid user

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021296708

Write-up: kidneys were unable to support life; Diarrhea; unable to get up without assistance; shaking so bad; This is a spontaneous report from a contactable consumer (Patient"s wife). An 80-year-old male patient received second dose of BNT162B2 (BNT162B2) via an unspecified route of administration, administered in Arm Right on an unspecified date (Batch/Lot Number: EN6201, expiry date not reported) as single dose for covid-19 immunization. Medical history included ongoing glomerulonephritis, dementia (He had dementia prior to getting the vaccine) and walking aid user. The patient experienced kidneys were unable to support life on an unspecified date and was reported as fatal, shaking so bad on 01Mar2021, diarrhea on 02Mar2021, unable to get up without assistance on 01Mar2021. Patient"s wife reports that her husband didn"t have any reactions until the third day. He was shaking so bad that the car seat was vibrating. He also had diarrhea. He had dementia prior to getting the vaccine. After getting the vaccine he was unable to get out of the chair without physically being helped out of the chair. He was able to use his walker before getting the vaccine but was not able to after getting the vaccine. Her husband passed away yesterday. He was shaking so bad on 01Mar2021. It lasted for 12-24 hours and then it was not as spasmodic. He had diarrhea from 02Mar - 03Mar2021. He recovered completely from it. He was unable to get up without assistance on 01Mar2021. That did not change. He required assistance until he died. He was unable to use his walker staring on 01Mar2021. His kidneys were unable to support life. Two weeks before he received the vaccine her husband was up and walking. After he received the second dose this happened. Caller is unsure if this caused kidney failure. An autopsy is not being performed. Her husband died yesterday. He had kidney problems that he lived with for 58 years. After receiving the vaccine his kidney functions took a nose dive. She was told by some of the people taking care of him that

 VAERS ID: 1133040 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Sex: Male Entered: 2021-03-25

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (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 Vis

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness: Preexisting Conditions: Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021297473

Write-up: died from heart attack; This is a spontaneous report from a contactable consumer via a Pfizer Sponsored reported for a male patient (Husband). A male patient of an unspecified age received first dose of COVID-19 vaccine (UNSPECIFIED TRADE NAME), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient died from heart attack exactly 1 week later after vaccine on an unspecified date. Never had any heart issues or anything. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: died from heart attack

VAERS ID: 1135281 (history) Vaccinated: 2021-01-21 Form: Version 2.0 Onset: 2021-01-22

Age: Days after vaccination: Sex: Male

Submitted: 0000-00-00 Location: Arizona Entered: 2021-03-25

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA LOT: 011L20A EX / 1 LA / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-22 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:** 

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Passed away; A spontaneous report was received from a Healthcare Professional concerning a 57-years-old male patient who received Moderna's COVID-19 vaccine (mRNA-1273) and passed away/death. The patient's medical history was not provided. However, the patient had some serious chronic health condition. No relevant concomitant medications were reported. On 21 Jan 2021, prior to the onset of the event, the patient received their first of two planned doses of mRNA-1273 (lot/batch: LOT: 011L20A Exp: 03July2021) intramuscularly in the left deltoid for prophylaxis of COVID-19 infection. He did not experience any symptoms right away and nothing within the next 15 mins under observation. On 22 Jan 2021, the patient passed away. Treatment details was not reported. Action taken with mRNA-1273 in response to the event passed away, was not applicable. On 22 Jan 2021, the patient died. It was unknown if an autopsy was performed.; Reporter's Comments: Very limited information regarding the event of death has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Passed away

Vaccinated: 2021-03-17 **VAERS ID:** <u>1135587</u> (history) Form: Version 2.0 Onset: 2021-03-01 Age: Submitted: 0000-00-00 Male Entered: 2021-03-25 Sex:

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-01 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: Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021305669

Write-up: died yesterday; This is a spontaneous report received from Medical Information from a contactable other health professional. A 57-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on 17Mar2021, at single dose, for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient died in Mar2021 (reported as "yesterday"). The outcome of the event was fatal. The cause of death was not reported. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Sender"s Comments: Event unknown cause of death is assessed as related until sufficient information is available to confirm an unrelated cause of death. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: died yesterday

VAERS ID: 1135589 (history) Vaccinated: 0000-00-00 Version 2.0 Onset: 0000-00-00 Form: Submitted: 0000-00-00 Age: Male Entered: 2021-03-25 Sex: Location: Texas

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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 Vis

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness: Preexisting Conditions: Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021308003

Write-up: Death; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date (batch/lot number was not reported) as single dose for COVID-19 immunization. The patient"s medical history and concomitant medications were not reported. The patient got a steroid shot in between his 2 doses of the vaccine and he fell dead the next day. The reporter stated that the reporter didn"t know what manufacturer he received, but that he took steroids all the time. The patient died on an unspecified date. The cause of death was unknown. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1140697 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-03-28

Location: Virginia

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021321350

Write-up: She passed one to two days after the shot; This is a spontaneous report from a contactable consumer. A female patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Patient died after receiving the COVID vaccine. She passed one to two days after the shot. It was not expected. Waiting on the autopsy. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: She passed one to two days after the shot

 VAERS ID: 1145721 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 1.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-03-30

Location: Unknown

Vaccination / Manufacturer | Lot / Dose | Site / Route | COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | - / UNK | UN / UN

Administered by: Unknown Purchased by: Unknown

Symptoms: COVID-19, Death

SMQs:, Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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: Unknown

Allergies:

Diagnostic Lab Data: CDC Split Type: 2021028911

Write-up: COVID-19 INFECTION (COVID-19, COVID-19) This spontaneous report received from a consumer via a company representative and concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. We are unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient developed covid-10 infection. On an unspecified date, the patient died from covid-19. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).

**VAERS ID:** <u>1146779</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 2021-03-30 Sex: Male Entered:

Location: Mississippi

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: 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:

CDC Split Type: USPFIZER INC2021321304

Write-up: passed away; This is a spontaneous report received from a contactable consumer reporting for a male patient of unspecified age that received second dose of BNT162B2 via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. It was reported that the patient passed away late Saturday night after receiving his second COVID-19 Vaccine on Friday. An autopsy was not performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained; Reported Cause(s) of Death: passed away

VAERS ID: <u>1146785</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 0000-00-00 Onset: Submitted: 0000-00-00 Age: 2021-03-30 Female Entered: Sex:

Location: Virginia

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021321442

Write-up: She died in the bathroom on the second day.; This is a spontaneous report from a contactable consumer. This reporter reported similar events for 3 patients. This is 2nd of 3 patients. A female patient of an unspecified age received bnt162b2 (BNT162B2, PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation. The patient medical history was not reported. The patient"s concomitant medications were not reported. It is reported the patient died in upstate. Waiting on the autopsy. She died in the bathroom on the second day. It was not expected. The patient died on an unspecified date. It was not reported if an autopsy was performed. The outcome of the event was fatal. Information on Lot/Batch has been requested.; Reported Cause(s) of Death: She died in the bathroom on the second day.

 VAERS ID: 1149905 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-03-31

Location: New Jersey

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/UNK -/OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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: No adverse event (No reported medical history)

Allergies:

niergies. Diagnostic I ah Data

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Died; A spontaneous report was received from a Consumer concerning a patient where age and gender unspecified who received Moderna's COVID-19 vaccine (mRNA-1273) and experienced event Death. The patient's medical history was not provided. No relevant concomitant medications were reported. On unknown date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (lot/batch: unknown) in the Anatomical location unspecified for prophylaxis of COVID-19 infection. On unknown date, The patient experienced the event Death. Laboratory details were not provided. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not reported. The outcome of the event was Fatal. The reporter assessed the event Death related to the study drug was unknown:; Reporter's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1153088 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-03-31

Location: California

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | - / UNK    | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210331140

Write-up: MAJOR HEART ATTACK; This spontaneous report received from a consumer concerned a 50 year old female. The patient "s weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, she had major heart attack and died. It was unknown if an autopsy was performed. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The reporter and company provided causality between Covid-19 vaccine ad26.cov2.s and major heart attack as possible. This report was serious (Death).; Sender"s Comments: - covid-19 vaccine ad26.cov2.s -Heart attack. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: MAJOR HEART ATTACK

 VAERS ID: 1153527 (history)
 Vaccinated:
 2021-01-29

 Form:
 Version 2.0
 Onset:
 2021-01-30

Age: Days after Sex: Female vaccination:

 Location:
 Minnesota
 Submitted:
 0000-00-00

 Entered:
 2021-03-31

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

1

Purchased by: ? Administered by: Private

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? Yes Birth Defect? No Died? Yes

Date died: 2021-03-18 Davs after onset: 46 Permanent Disability? Yes

Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? Yes Hospitalized? Yes, 27 days Extended hospital stay? No Previous Vaccinations: Other Medications:

**Current Illness:** 

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021315468

Write-up: Suffered massive stroke 24 hours after Pfizer vaccine; This is a spontaneous report from a contactable consumer. This consumer reported for a (age- 86; unit- unknown) female elderly patient with no pregnant received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 29Jan2021 13:45 PM at single dose for covid-19 immunisation. No pregnant at time of vaccination. No illnesses or chronic health conditions, no family history of strokes, heart disease or high blood pressure, very healthy prior to vaccine. No other vaccine in four weeks. She suffered massive stroke 24 hours after Pfizer vaccine on 30Jan2021 13:00 PM. Event resulted in Emergency room/department or urgent care, Hospitalization for 27 days, Life threatening illness (immediate risk of death from the event), Disability or permanent damage, Patient died on 18Mar2021. Treatments were received for the event. Outcome of the event was fatal. No autopsy was done. lot/batch number has been requested.; Reported Cause(s) of Death: Suffered massive stroke 24 hours after Pfizer vaccine

2021-03-01 VAERS ID: 1153540 (history) Vaccinated: Form: Version 2.0 Onset: 2021-03-01

Age: Days after 0 vaccination: Sex: Male

Submitted: 0000-00-00 Location: Michigan Entered: 2021-03-31

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

Administered by: Unknown Purchased by: ?

Symptoms: Cardiac failure congestive

SMQs:, Cardiac failure (narrow), Cardiomyopathy (broad)

Life Threatening? Yes Birth Defect? No Died? Yes

Date died: 2021-03-01 Days after onset: 0 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? Yes Hospitalized? Yes, 1 days Extended hospital stay? No Previous Vaccinations:

Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Chronic kidney disease; Congestive heart failure; Diabetes; Hypertension

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021319461

Write-up: He had not been experiencing any issues or symptoms of his chronic illnesses, but within 1 day had CHF symptoms and died; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration in Mar2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included chronic kidney disease, Congestive heart failure (CHF), hypertension, diabetes mellitus. The concomitant drugs included other unspecified medications in two weeks. There were no covid prior vaccination, and no covid tested post vaccination. The patient had not been experiencing any issues or symptoms of his chronic illnesses, but within 1 day had CHF symptoms and died in Mar2021, which resulted in Emergency room/department or urgent care, Hospitalization, Life threatening illness (immediate risk of death from the event), died. The patient was hospitalized for 1 days. Treatment was received. The patient died in Mar2021. The event was listed as complication of Covid 19 vaccination. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: He had not been experiencing any issues or symptoms of his chronic illnesses, but within 1 day had CHF symptoms and died

Vaccinated: 0000-00-00 VAERS ID: <u>1153885</u> (history) Form: Version 2.0 Onset: 2021-03-11 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-04-01

Location: New York

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Cardiac arrest, Death

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (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), Respiratory failure (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-13 Days after onset: 2 Permanent Disability? No Recovered? No

Recovered? No Office Visit? Yes ER Visit? No

ER or Doctor Visit? No Hospitalized? Yes, 2 days Extended hospital stay? No Previous Vaccinations: Other Medications:

Current Illness:
Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210329515

Write-up: ASYSTOLE; PASSED AWAY; This spontaneous report received from a physician concerned their mother-in-law, an female of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 11-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient was in a nursing home, but was hospitalized for pyelonephritis. The patient was not allowed back into the nursing home without a negative COVID test and the vaccine. After discharge from the hospital, the patient"s COVID test came back negative, and upon arrival to the nursing home, the patient received the Janssen COVID-19 vaccine. Within 30 minutes, the patient was unresponsive and transported back to the hospital. On arrival to the hospital, the patient was asystole. She was treated at the hospital until 13-MAR-2021, when she passed away. Asystole was reported as fatal. Additionally, cause of death was reported as "cause unknown", therefore, an additional serious adverse event of "passed away" was captured. An autopsy was not performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died on 13-MAR-2021. This report was serious (Death and Hospitalization).; Sender"s Comments: V0: An female of unknown age became unresponsive 30 minutes after, experienced asystole on the same day as, and died of unknown causes 2 days after receiving Janssen COVID-19 Vaccine Ad26.COV2.S (suspension for injection; route of administration and batch number unknown) for prophylactic vaccination while in a nursing home. Medical history and concomitant medications were not reported. The patient was the mother-in-law of the reporter, an internal medicine physician. The patient had no complaints for 30 minutes after receiving the vaccine, then became un

 VAERS ID: 1153902 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Sex: Female Entered: 2021-04-01

Location: Mississippi

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | - / UNK    | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death, Pain in extremity

SMQs:, Tendinopathies and ligament disorders (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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210353764

Write-up: DIED; SORE ARM/ARM PAIN; This spontaneous report received from a consumer concerned a female of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient had a sore arm/arm pain, and later on died. On an unspecified date, the patient died from unknown cause of death. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died on an unspecified date, and the outcome of sore arm/arm pain was not reported. This report was serious (Death). This case, from the same reporter is linked to 20210329044.; Sender"s Comments: V0: 20210353764 - COVID-19 VACCINE AD26.COV2.S - Died. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1153994 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Sex: Unknown

 Entered: 2021-04-01

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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: No adverse event (No medical history reported.)

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Died from the Moderna vaccine; A spontaneous report was received from a consumer concerning a patient who received Moderna score a consumer concerning a patient who received Moderna consumer concerning a patient consumer consumer concerning a patient consumer (mRNA-1273) and died from the Moderna vaccine/death. The patient"s medical history was not provided. No concomitant product use was reported. On unknown date, the patient received their first of two planned doses of mRNA-1273 (Lot number: not provided) intramuscularly for prophylaxis of COVID-19 infection. On unknown date, the patient died after receiving the Moderna vaccine (Seriousness criteria: death, medically significant). The date of death was unknown. Autopsy results not provided. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not applicable. The outcome of the event, died from the Moderna vaccine/death, was considered fatal. .; Reporter's Comments: Very limited information regarding the event of death has been provided at this time. No further information has been requested.; Reported Cause(s) of Death: Died from the Moderna vaccine

VAERS ID: <u>1157484 (history)</u> Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 2021-04-01 Unknown Entered: Sex:

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: COVID-19

SMQs:, Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210328911

Write-up: COVID-19 INFECTION; This spontaneous report received from a consumer via a company representative and concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. We are unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient developed covid-19 infection. On an unspecified date, the patient died from covid-19. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: A patient of unknown age and gender died an unknown time after receiving Janssen COVID-19 Vaccine Ad26.COV2.S (suspension for injection, route of administration not reported) for prophylactic vaccination. Medical history, concomitant medications, and details of the event were not reported. It was unknown if an autopsy was performed. This case has insufficient information to make a meaningful medical assessment.; Reported Cause(s) of Death: COVID-19

VAERS ID: <u>1157491</u> (history) Vaccinated: 0000-00-00 Onset: 2021-03-10 Form: Version 2.0 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-04-01

Location: Alabama

Vaccination / Manufacturer Lot / Dose | Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN 1802070 / UNK

Administered by: Other Purchased by: ?

Symptoms: Blood pressure measurement, Circulatory collapse, Headache, Oxygen therapy

SMQs:, Anaphylactic reaction (narrow), 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), Acute central respiratory depression (broad), Hypersensitivity (narrow), Respiratory failure (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-10 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:** Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data: Test Date: 202103101400; Test Name: Oxygen supplementation; Result Unstructured Data: 90"s; Test Date: 202103101400; Test Name: BP;

Result Unstructured Data: 145/75 CDC Split Type: USJNJFOC20210341940

Write-up: COLLAPSED; HEADACHE; This spontaneous report received from a consumer concerned a 70 year old male. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 1802070 expiry: UNKNOWN) dose was not reported, administered on 10-MAR-2021 11:00 for prophylactic vaccination. No concomitant medications were reported. On 10-MAR-2021, the patient experienced headache, was clammy to the touch. On same day at 14:00, checked blood pressure (BP) and it was 145/75 and his oxygen level read in the 90"s. At 18:00, he collapsed while getting up out of his chair and emergency medical services (EMS) was called performed cardiopulmonary resuscitation (CPR) but never got him back. On 10-MAR-2021, the patient died from cause unknown. An autopsy was not performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of collapsed on 10-MAR-2021, and the outcome of headache was not reported. This report was serious (Death, and Other Medically Important Condition). The suspected product quality complaint has been confirmed to be no product quality complaint identified within the reported. Complaint is approved for void, based on the PQC evaluation/investigation performed. This report was associated with product quality complaint :90000173895.; Sender"s Comments: V0: 20210341940-COVID-19 VACCINE AD26.COV2.S- COLLAPSED. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: Cause unknown

VAERS ID: <u>1157506</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-03-10 Age: Submitted: 0000-00-00 2021-04-01 Sex: Female Entered:

Location: Connecticut

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | - / UNK    | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Abdominal pain upper, Death, Ear pain, Fatigue, Headache, Pain in extremity, Pallor, Pre-existing condition improved SMQs:, Acute pancreatitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Hypotonic-hyporesponsive episode (broad),

Tendinopathies and ligament disorders (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-17 Days after onset: 6 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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210347684

Write-up: FEELING BETTER FOR THE MOST PART; DEATH; LOOKED PALE; STOMACH CRAMPS; EAR ACHES; ARM HURTS; BEYOND EXHAUSTED; HEADACHE; This spontaneous report received from physician via social media post and concerned a 25 year old female. The patient"s weight, height and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration, and batch number were not reported) dose was not reported, administered on 09-MAR-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 10-MAR-2021, the patient felt "the vaccine is killing me today" and "its taking it"s toll on me". The patient was told that she looked pale on an unspecified date in MAR-2021. On 10-MAR-2021, the patient developed stomach cramps, ear aches, arm hurt, was beyond exhausted, and headache. On an unspecified date, the patient had reported feeling better for the most part. On 17-MAR-2021, the patient died from an unknown cause. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome for looked pale, stomach cramps, ear aches, feeling better for the most part, arm hurts, beyond exhausted and headache was unknown. This report was serious (Death).; Sender"s Comments: v0 This spontaneous report from a physician reporting a social media post involved a 25-year-old female who received the Janssen COVID-19 Vaccine for prevention of COVID-19 infection and died approximately one week later. Medical history and concomitant medications were not reported. The patient reported no adverse effect on the day of the vaccination. The next day, she reported that "The vaccine is killing me today. My arm hurts, beyond exhausted, headache, stomach cramps and earaches." She also reported that people told her she looked pale. The following day, the patient reported that she was feeling better "for the most part". The patient died approximately 6 days later. No information was provided regarding the cause of death. There is insufficient information provided in this case to make a meaningful medical assessment.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

**VAERS ID:** <u>1157515</u> (history) Vaccinated: 0000-00-00 Version 2.0 0000-00-00 Form: Onset: Age: Submitted: 0000-00-00 Unknown Entered: 2021-04-01 Sex:

Location: Pennsylvania

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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: Unknown cause of death; Comments: Unknown

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210350272

Write-up: DEATH; This spontaneous report received from a consumer concerned multiple patients. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported, per procedure no follow up will be requested for this case. No concomitant medications were reported. The reported called for an agency, during call she had mentioned "several deaths were reported with the vaccine". She read it on a website. The cause of the deaths was not reported. It was unknown if autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: 20210350272-covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

VAERS ID: 1157534 (history) Vaccinated: 0000-00-00 Version 2.0 Onset: Form: 2021-03-28 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-04-01

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death SMOs:

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: Comments: Unknown

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210356482

Write-up: DEATH; This spontaneous report received from a consumer via a company representative concerned a female of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry date: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 28-MAR-2021, the patient received vaccine shot and she died on the same day. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death and Other Medically Important Condition).; Sender's Comments: 20210356482 - Covid-19 Vaccine Ad26.Cov2.S - Death. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

VAERS ID: <u>1157561</u> (history) Vaccinated: 2021-02-11 Form: Version 2.0 2021-02-11

Age: Days after 0 vaccination: Sex: Female

Submitted: 0000-00-00 Location: Michigan 2021-04-01 Entered:

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Blood glucose increased, Death, Dyspnoea, Loss of consciousness, Unresponsive to stimuli, Vomiting

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (broad), Acute pancreatitis (broad), Hyperglycaemia/new onset diabetes mellitus (narrow), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Guillain-Barre syndrome (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Cardiomyopathy (broad), Hypotonichyporesponsive episode (broad), Generalised convulsive seizures following immunisation (broad), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-02-19 Days after onset: 8 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: INSULIN

Current Illness: Diabetes (Unspecified type of diabetes.)

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: Test Name: blood sugar; Result Unstructured Data: blood sugar 208, 212, 199 up until her bedtime of 9:45PM; Test Name: blood sugar; Result Unstructured Data: blood sugar 304 9am, 260 10:30AM then stayed over 200/280 all day even with insulin; Test Name: blood sugar; Result Unstructured Data: Blood sugar was between 144-179 all day even with insulin; Test Name: blood sugar; Result Unstructured Data: Blood sugar was between 144-179 all day even with insulin; Test Name: blood sugar; Result Unstructured Data: Blood sugar range 87-102

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Died; Unresponsive; Shortness of breath; Not able to eat; Sick; Nauseous; Vomiting; Passed out on kitchen floor; Blood sugar increased; A spontaneous report was received from a consumer concerning an unspecified age, female patient who received Moderna"s COVID-19 vaccine (mRNA-1273) and experienced raised blood sugar/blood sugar increased, passed out on kitchen floor/loss of consciousness, nausea, vomiting, sick/illness, not being able to eat/decreased appetite, shortness of breath/dyspnea, unresponsive/unresponsive to stimuli and died/death. The patient's medical history included diabetes. Products known to have been used by the patient, within two weeks prior to the event, included unspecified insulin. On 11 Feb 2021, the patient received their first planned doses of mRNA-1273 (Batch number: unknown) intramuscularly for prophylaxis of COVID-19 infection. On 11 Feb 2021, the patient had a rise in her blood sugar (blood sugar 208, 212, 199 up until her bedtime of 9:45PM). On 12 Feb 2021, the patient passed out on the kitchen floor and the patient"s blood sugar took a dive (blood sugar was 304 9:00AM, blood sugar was 260 10:30AM then stayed over 200/280 all day even with insulin). That evening, the patient experienced nausea and vomiting. On 13 Feb 2021, the patient sblood sugar was up and had nausea and vomiting throughout the night. The patient spoke with her doctor, who told her to regulate it with insulin if she needed too. Per the report, the doctor informed the patient that there have been studies that say the vaccine has shown to mess with blood sugars. The patient"s blood sugar remained between 144-179 all day even with insulin. The patient had nausea and vomiting. On 14 Feb 2021, the patient reported still being sick. The patient reported a weight loss of 5 pounds and reported not being able to eat. Blood sugar was 174-292 all day even with insulin. On 17 Feb 2021, the patient s blood sugar was bouncing between 53-151 all day even with insulin. On 18 Feb 2021, the patient reported shortness of breath and was using Vicks to help clear the nasal passage. On 19 Feb 2021, approximately at 6:00AM, the patient spouse found patient breathing but unresponsive. At approximately 7:25AM, the patient died. Treatment information included, unspecified insulin and Vicks. Action taken with the drug in response to the event is not applicable. The outcome of event, passed out on kitchen floor/loss of consciousness, was considered resolved on 12 Feb 2021. The outcome of events, raised blood sugar/blood sugar increased, passed out on kitchen floor/loss of consciousness, nausea, vomiting, sick/illness, not being able to eat/decreased appetite, shortness of breath/dyspnea, were considered unknown. The outcome of events, unresponsive/unresponsive to stimuli and died/death, were considered fatal. The cause of death was not provided. Plans for autopsy was not provided.; Reporter"s Comments: Very limited information regarding these events has been provided at this time. Patient"s history of uncontrolled diabetes with recent fluctuations may have been contributory for the occurrence of the death. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1157604 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 2021-03-21

 Age: Submitted: 0000-00-00
 Sex: Female Entered: 2021-04-01

Location: California

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | - / UNK    | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death, Pneumonia

SMQs:, Eosinophilic pneumonia (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Infective pneumonia (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-21 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: Stomach cancer (Medical history reported as diagnosis of stage four stomach cancer)

Preexisting Conditions: Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Pneumonia; Stage four stomach cancer; Parent died after receiving both doses; A spontaneous report was received from a consumer concerning a female patient, who received Moderna"s COVID-19 vaccine (mRNA-1273) and experienced stage four stomach cancer/gastric cancer stage IV, pneumonia and parent died after receiving both doses. The patient"s medical history, as provided by the reporter, included stomach cancer. Concomitant product use was not provided by the reporter. On an unspecified date, prior to the onset of the events, the patient received their first of two planned doses of mRNA-1273 (Lot number: unknown) via unknown route of administration for prophylaxis of COVID-19 infection. On an unspecified date, prior to the onset of the events, the patient received their second of two planned doses of mRNA-1273 (Lot number: unknown) via unknown route of administration for prophylaxis of COVID-19 infection. On an unspecified date, patient was diagnosed of stage four stomach cancer and developed pneumonia after both doses of vaccine with seriousness criteria as medically significant. The patient died on 21 Mar 2021. Treatment information was not provided. The patient received both scheduled doses of mRNA-1273 prior to the events, therefore action taken with the drug in response to the events were not applicable. The outcome of the events, stage four stomach cancer and pneumonia were fatal. The patient died on 21 Mar 2021. The cause of death was reported as stage four stomach cancer and pneumonia. Plans for an autopsy were unknown.; Reporter"s Comments: This patient"s stage IVgastric cancer is unlikely due to the Moderna"s mRNA-1273 vaccine due to the latency of gastric cancer. Very limited information regarding these events have been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1161961 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

Sex: Unknown Entered: 2021-04-02

Location: Unknown

Lot / Dose Site / Route Vaccination / Manufacturer COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN - / UNK

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs: 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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210356723

Write-up: DEATH; This spontaneous report received from a patient via a company representative concerned a patient of unspecified age and sex. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin)total 1 dose, start therapy date were not reported for prophylactic vaccination. The Batch number was not reported. The Company is unable to perform follow-up to request batch/lot number. No concomitant medications were reported. On an unspecified date, the patient experienced death. On an unspecified date, the patient died from unknown cause of death. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: 20210356723-Covid-19 vaccine ad26.cov2.s-Death. This event is considered unassessable. The event has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF

VAERS ID: <u>1161963</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-03-01 Submitted: 0000-00-00 Age: Entered: 2021-04-02 Sex: Male

Location: New York

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: COVID-19, Death, SARS-CoV-2 test

SMQs:, Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (narrow)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-03-29

Days after onset: 27 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: Comments: Unknown

Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Result Unstructured Data: Positive CDC Split Type: USJNJFOC20210358262

Write-up: DEATH; CONFIRMED COVID-19 INFECTION; This spontaneous report received from a patient via a company representative concerned a male of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN, expiry: ÚNKNOWN) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On MAR-2021, the subject experienced confirmed covid-19 infection. On 29-MAR-2021, the subject experienced death. Laboratory data (dates unspecified) included: COVID-19 virus test (NR: not provided) Positive. On 29-MAR-2021, the subject died from unknown cause of death. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. On an unspecified date, the patient died from unknown cause of death, and the outcome of confirmed covid-19 infection was not reported. It was unknown if an autopsy was performed This report was serious (Death, and Other Medically Important Condition).; Sender"s Comments: V0: 20210358262-COVID-19 VACCINE AD26.COV2.S- Death, Confirmed Covid-19 Infection. This event(s) is considered Unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1162137</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 **Submitted:** 0000-00-00 Age: Sex: Unknown Entered: 2021-04-02

Location: Pennsylvania

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021340045

Write-up: when the patient got really bad the patient died; This is a spontaneous report from a contactable consumer. A 92-year-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced when the patient got really bad the patient died. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: when the patient got really bad the patient died

VAERS ID: <u>1166023</u> (history) Vaccinated: 0000-00-00 Version 2.0 Onset: 0000-00-00 Form: Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-04-04

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: COVID-19, Completed suicide, Drug ineffective, Tinnitus
SMQs:, Lack of efficacy/effect (narrow), Suicide/self-injury (narrow), Hearing impairment (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021344589

Write-up: killed himself; tinnitus; contracted the virus; Contracted the virus; This is a spontaneous report from a non-contactable nurse. A male patient of an unspecified age received BNT162B2 (Pfizer-BioNTech COVID-19 vaccine, lot number and expiry date unknown), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization. Medical history included COVID-19 on an unknown date. The patient's concomitant medications were not reported. It was reported that the patient, contracted the virus and developed tinnitus after receiving the vaccine and killed himself. The outcome of the event tinnitus and contracted the virus was unknown. The patient died on an unspecified date. It was not reported if an autopsy was performed. No follow up attempts are possible; information about lot number/batch number cannot be obtained.; Sender"s Comments: Based on the information currently available, a causal association between the reported event tinnitus and BNT162B2 cannot be excluded. Drug ineffective depends on many fators including pharmacokinetics, patient general health condition and immunity system function. However on conservative basis, the possible causality cannot be excluded. The event "killed himself" is not related to BNT162B2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and investigators, as appropriate.; Reported Cause(s) of Death: killed himself

VAERS ID: 1166062 (history) Vaccinated: 2021-03-17 Form: Version 2.0 Onset: 2021-03-18

Age: 0.42 Days after Male vaccination: Sex:

0000-00-00 Submitted: Location: Unknown Entered: 2021-04-04

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | -/2        | LA / SYR     |

Administered by: Work Purchased by: ?

Symptoms: Death, Diet refusal, Emotional distress, Exposure via breast milk, Failure to thrive, Hepatic enzyme increased, Pyrexia, Rash, Thrombotic thrombocytopenic purpura

SMQs:, Liver related investigations, signs and symptoms (narrow), Anaphylactic reaction (broad), Haemorrhage terms (excl laboratory terms) (narrow), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Embolic and thrombotic events, arterial (narrow), Depression (excl suicide and self injury) (broad), Renovascular disorders (broad), Neonatal exposures via breast milk (narrow), Neonatal disorders (broad), Hypersensitivity (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Immune-mediated/autoimmune disorders (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-20 Days after onset: 2 Permanent Disability? No Recovered? No

Office Visit? No ER Visit? No

ER or Doctor Visit? Yes Hospitalized? Yes, 2 days Extended hospital stay? No

**Previous Vaccinations:** Other Medications:

Current Illness: **Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type:

Write-up: Patient received second dose of Pfizer vaccine on March 17, 2020 while at work. March 18, 2020 her 5 month old breastfed infant developed a rash and within 24 hours was inconsolable, refusing to eat, and developed a fever. Patient brought baby to local ER where assessments were performed, blood analysis revealed elevated liver enzymes. Infant was hospitalized but continued to decline and passed away. Diagnosis of TTP. No known allergies. No new exposures aside from the mother"s vaccination the previous day.

**VAERS ID: 1168960** (history) Vaccinated: 0000-00-00 Version 2.0 Form: Onset: 0000-00-00 Age: Submitted: 0000-00-00 Sex: Unknown Entered: 2021-04-05

Location: New York

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210350465

Write-up: GOT THE VACCINE AND DIED 24 HOURS LATER; This spontaneous report received from a consumer concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient died 24 hours later vaccination. Cause of death was not reported. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0:20210350465-covid-19 vaccine ad26.cov2.s-Got the vaccine and died 24 hours later. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s); Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1169011</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-04-05

Location: Florida

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / OT

Administered by: Unknown Purchased by: ?

Symptoms: COVID-19

SMQs:, Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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: No adverse event (No reported medical history.)

Allergies:

Diagnostic Lab Data:

CDČ Split Type: USMODERNATX, INC.MOD20210

Write-up: one friend got COVID after the shot and has passed away; A spontaneous report was received from a consumer concerning a female patient of an unknown age who received Moderna"s COVID-19 vaccine and got COVID after the shot and has died/COVID-19. The patient"s medical history was not provided. Concomitant product use was not provided by reporter. On an unknown date the patient received their first of two planned doses of mRNA-1273 (Batch number not provided) for prophylaxis of COVID-19 infection. Reporter mentioned that her friend got COVID after the shot and has died. No treatment information was provided. Action taken with the second dose of mRNA-1273 in response to the event death is not applicable. The patient died on an unknown date. The cause of death was not provided. Plans for an autopsy were not provided.; Reporter"s Comments: A case of death of female patient of an unknown age who developed COVI on an unknown date post mRNA-1273 (vaccination (lot unknown) and died. Very limited information regarding this event/s has been provided at this time. However, based on the known etiology of COVID and the established profile of mRNA-1273, the event is assessed as unlikely related to mRNA-1273 administration. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1173591</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-04-06

Location: Ohio

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs: 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: No adverse event (No medical history reported)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Died; A spontaneus report was received from a consumer concerning a male patient of an unknown age who received Moderna"s COVID-19 vaccine (mRNA-1273) and died. The patient's medical history was not provided. No relevant concomitant medications were reported. On an unknown date, prior to onset of the event, the patient received their dose of mRNA-1273 (lot/batch number: unknown) for prophylaxis of COVID-19 infection. On an unknown date, the patient died. Action taken with mRNA-1273 in response to the event was not applicable. The patient died on an unspecified date. The cause of death was unknown. Plans for an autopsy were unknown.; Reporter's Comments: Very limited information regarding the event has been provided at this time and is insufficient for causality assessment. The cause of death was unknown. Plans for an autopsy were unknown. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1174358</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-04-07

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021352130

Write-up: Pfizer vaccination killed patient; This is a spontaneous report from a Pfizer-sponsored program, Corporate (Pfizer) Social Media Platforms. A contactable consumer reported for mother (patient) that a female patient of unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient"s medical history and concomitant medications were not reported. The reporter reported that Pfizer vaccination killed reporter"s mom (patient) on an unspecified date. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Pfizer vaccination killed patient

 VAERS ID: 1178144 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Submitted: 0000-00-00

 Sex: Unknown
 Entered: 2021-04-07

Location: Oregon

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: <u>Drug interaction</u>

SMQs:

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: RISPERDAL

**Current Illness:** 

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210403502

Write-up: DIED FROM THE INTERACTION OF THE TWO PRODUCTS RISPERDAL AND COVID VACCINE; This spontaneous report received from a consumer who had heard that two people who took Risperdal and got a COVID vaccine died from the interaction of the two products. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, beatch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. The patient received risperidone (form of admin, route of admin, and batch number were not reported) dose, frequency, and therapy dates were not reported for an unspecified indication. No concomitant medications were reported. On an unspecified date, consumer heard that a few people who took Risperdal and got a COVID vaccine died from the interaction of the two products. The action taken with covid-19 vaccine ad26.cov2.s, and risperidone was not applicable. This report was serious (Death).; Sender"s Comments: A report received from a consumer who had heard that "a few people who took Risperdal and got a COVID vaccine died from the interaction of the two products." The patients past medical history, concomitant medications were not reported. COVID-19 vaccine ad26.cov2.s date and dose administered were not reported. Risperidone dose, frequency, therapy dates and indication were not reported. There is insufficient information provided in this case to make a meaningful medical assessment.

 VAERS ID: 1178152 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-04-07

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (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:

Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210403505

Write-up: HEART ATTACK; This spontaneous report received from a consumer via a company concerned a 40 year old male. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow up to request batch/lot number. No concomitant medications were reported. About 7 days after receiving the vaccine, the patient went to hospital regarding shortness of breath. On an unspecified date, the patient experienced heart attack and was hospitalized (date unspecified) and was later sent to intensive care unit (ICU). On an unspecified date, the patient died from heart attack. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, and Hospitalization Caused / Prolonged).; Sender"s Comments: 20210403505 -Covid-19 vaccine ad26.cov2.s -Heart attack. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: HEART ATTACK

 VAERS ID: 1178296 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-04-07

Location: North Carolina

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

Administered by: Unknown Purchased by: ?

Symptoms: Cardiac arrest

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (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), Respiratory failure (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:

CDC Split Type: USPFIZER INC2021347629

Write-up: cardiac arrest; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient experienced cardiac arrest 20 hours after receiving BNT162B2 on an unspecified date. The patient passed away due to cardiac arrest. The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: cardiac arrest

2021-02-27 VAERS ID: <u>1178307</u> (history) Vaccinated: Form: Version 2.0 Onset: 2021-02-28 Age: Days after vaccination: Sex: Female

Submitted: 0000-00-00 Location: Washington Entered: 2021-04-07

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

Administered by: Unknown Purchased by: ?

Symptoms: Cardiac arrest

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (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), Respiratory failure (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-02-28 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:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Heart disorder

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021364871

Write-up: She died 23 hours later on 28Feb/Her cause of death on her death certificate was stated to be cardiac arrest; This is a spontaneous report from a contactable consumer (patient's husband). A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, lot number and expiry date were not reported), via an unspecified route of administration on 27Feb2021 at a single dose for COVID-19 immunisation. Medical history included heart disease from an unknown date and unknown if ongoing. The patient"s concomitant medications were not reported. Patient died 23 hours later on 28Feb2021 after first dose on 27Feb2021. She did not show any adverse symptoms after being vaccinated. The questionnaire before the vaccination asked "if you have a chronic health condition such as heart disease". It was stated that she has heart disease; still the vaccination was given. Her cause of death on her death certificate was stated to be cardiac arrest. The patient died on 28Feb2021. It was unknown if an autopsy was performed. Information about Batch/Lot number has been requested.; Reported Cause(s) of Death. She died 23 hours later on 28Feb/Her cause of death on her death certificate was stated to be cardiac arrest

VAERS ID: <u>1178308</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-04-07

Location: Washington

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

Administered by: Unknown

Symptoms: Death SMQs:

Life Threatening? No

Purchased by: ?

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:

CDC Split Type: USPFIZER INC2021371687

Write-up: two deaths in her state from vaccine; This is a spontaneous report received from a contactable consumer. This consumer reported similar events for two patients. This the first of two reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not provided), on unspecified date at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. Reporter was concerned because there had been two deaths in her state from vaccine and thought Pfizer might be curious in how their product was being handled. The patient died on unspecified date. It was unknown if autopsy was performed. The outcome of the event was fatal. Information on lot/batch number has been requested.; Sender's Comments: Linked Report(s): US-PFIZER INC-2021371688 same reporter/event, different patient; Reported Cause(s) of Death: two deaths in her state from vaccine

VAERS ID: <u>1182765</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-04-08

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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: Cardiovascular disease, unspecified

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021352646

Write-up: died approximately one week after receiving the Pfizer vaccine; This is a spontaneous report from a non-contactable consumer. A 94-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not reported), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. Medical history included cardiovascular disease and other conditions (could not name). The patient"s concomitant medications were not reported. The patient was ill but was able to walk around on own and found pretty weak for age. It was reported that the patient died approximately one week after receiving the vaccine on an unspecified date. It was unknown if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: died approximately one week after receiving the Pfizer vaccine

VAERS ID: <u>1183985</u> (history) 2020-09-18 Vaccinated: Form: Version 2.0 2020-09-19

Age: Days after 1 vaccination: Male Sex:

Submitted: 0000-00-00 Location: New York Entered: 2021-04-09

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

Administered by: Unknown Purchased by: ?

Symptoms: Blood pressure fluctuation, Blood pressure measurement, Death, Dysphonia, Fatigue, Headache, Heart rate, Illness, Muscular weakness, Pneumonitis, Pulmonary oedema, Pulmonary thrombosis, Pulse abnormal, Vaccination complication

SMQs:, Rhabdomyolysis/myopathy (broad), Cardiac failure (narrow), Peripheral neuropathy (broad), Interstitial lung disease (narrow), Neuroleptic malignant

syndrome (broad), Embolic and thrombotic events, venous (narrow), Parkinson-like events (broad), Guillain-Barre syndrome (broad), Noninfectious encephalopathy/delirium (broad), Haemodynamic oedema, effusions and fluid overload (narrow), Hypertension (broad), Cardiomyopathy (broad), Eosinophilic pneumonia (narrow), Hypersensitivity (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-02-01 Davs after onset: 135 Permanent Disability? No Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? Yes Hospitalized? Yes, ? days Extended hospital stay? No

Previous Vaccinations:

Other Medications: PANTOPRAZOLE; ASPIRIN (E.C.); FUROSEMIDE; FIRDAPSE

Preexisting Conditions: Medical History/Concurrent Conditions: Brain metastases; Gait disturbance; Lambert-Eaton myasthenic syndrome (Cannot walk without FIRDAPSE); Metastases to liver; Metastases to lymph nodes; Migraine (Ever since he was a kid); Muscular weakness; Radiotherapy (of his head and lung for his cancer); Small cell lung cancer (In liver and lymph nodes; brain metastases)

Allergies:

Diagnostic Lab Data: Test Name: Blood pressure; Result Unstructured Data: Test Result:not stable; going up and down; Test Name: pulse; Result Unstructured Data: Test Result:pulse incomplete

CDC Split Type: USPFIZER INC2021368470

Write-up: Fluid in his bottom right lobe of his lung where the cancer is; Inflammation in the bottom of his lung; in lower right lobe of lung; Blood pressure isn"t stable; going up and down; Blood pressure issues; Exhausted; fatigue; Trying to control his blood pressure and his pulse issues, pulse incomplete; Muscle weakness was severely progressing; Bad reaction to the Covid vaccine; Blood clot on his lung; Raspy voice; the patient had been sick; Moderate headaches; Passed away; This is a spontaneous report from a contactable consumer (patient) based on the information received by Pfizer from Pharmaceuticals (Manufacturer control number 2020CAT00505). A 74-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date at single dose for COVID-19 to an unspecified date at 20 mg thrice daily, for Lambert-Eaton myasthenic syndrome. Medical history included Lambert-Eaton myasthenic syndrome. Medical history included Lambert-Eaton myasthenic syndrome (he could not walk without FIRDAPSE), migraine ever since he was a kid, small cell lung cancer (in liver and lymph nodes; brain metastases to liver, metastases to lymph nodes, radiotherapy of his head and lung for his cancer, gait disturbance from an unknown date and unknown if ongoing, muscular weakness from an unknown date and unknown if ongoing. Concomitant medications included pantoprazole, acetylsalicylic acid (ASPIRIN (E.C.), furosemide. The patient experienced blood clot on his lung in Jan2021 with outcome of unknown, fluid in his bottom right lobe of his lung where the cancer was on an unspecified date with outcome of not recovered, inflammation in the bottom of his lung; in lower right lobe of lung on an unspecified date with outcome of not recovered, raspy voice in 2021 with outcome of recovered, blood pressure not stable; going up and down; blood pressure issues on an unspecified date with outcome of not recovered, exhausted; fatigue on an unspecified date with outcome of not recovered, sick in 2021 with outcome of unknown, trying to control his blood pressure and his pulse issues, pulse incomplete on an unspecified date with outcome of unknown, moderate headaches from 19Sep2020 with outcome of recovered, muscle weakness severely progressing on an unspecified date with outcome of unknown, 10 mg 3 times a day wasn"t enough (therapeutic product effect incomplete), on an unspecified date with outcome of unknown, he"d switch and do a couple doses of 15 mg and it was better but not enough (intentional product use issue) on an unspecified date with outcome of unknown, after he received the COVID vaccine, he experienced a bad reaction (unspecified) on an unspecified date with outcome of unknown. The events were reported as serious as involved hospitalization. The patient passed away on an unspecified date in Feb2021. It was not reported if an autopsy was performed. The clinical course of the events included the following information. On 21Sep2020, a spontaneous report was received from a consumer, via a company representative, regarding a 74-year-old male who was being treated with FIRDAPSE 10 MG (amifampridine). On 22Sep2020, additional information was received from a consumer. On 02Oct2020, additional information was received from a consumer and chemotherapy was added as a co-suspect. On 01Feb2021, additional information was received from a consumer via a company representative. On 09Feb2021, additional information was received from a consumer, and this case was determined to be the master case for cases 2021CAT00039 and 2021CAT00052 (both invalid, duplicate cases) and the information was merged into this case (2020CAT00505). This case was re-assessed as serious/unexpected, and COVID vaccine was added as co-suspect. On 18Feb2021, additional information was received from a consumer via a company representative. On 19Feb2021, additional information was received from a patient ambassador via a company representative. Medical history included LEMS (Lambert-Eaton myasthenic syndrome) and migraines. Concomitant products included: an unknown statin, pantoprazole, and acetylsalicylic acid (ASPIRIN) 81 mg. On 18Sep2020, the patient started treatment with FIRDAPSE 10 mg at 10 mg, 3x/day orally for LEMS. On 19Sep2020 and 20Sep2020, after starting the product, the patient experienced moderate headaches. On 21Sep2020, the patient did not experience a headache. On 22Sep2020, the patient experienced a headache that was "4/10." He had taken acetaminophen; aspirin; caffeine (EXCEDRIN) and ibuprofen as treatment and it "helped." The patient had not spoken to his HCP (health care provider) about the event but was going to call his HCP and ask to increase his dose of FIRDAPSE. The product was working and he was walking better, but he had heard people taking up to 80 mg a day. As of 22Sep2020, product use was ongoing and headaches were improved. On 02Oct2020, it was learned that his medical history included being prone to headaches (also reported as migraines ever since he was a kid) and "chemo" for small cell lung cancer stage 4 which was in his liver and lymph nodes. Concomitant products included furosemide. It was noted that the patient had been on the product for 4 to 5 days when he experienced his moderate headaches. He had the headaches for just a couple days, but he wasn"t sure if it was due to the FIRDAPSE or it was the chemo. He took "a couple" of ibuprofen and he was "alright." On an unspecified date, the patient was in contact with his HCP and he was told to "keep an eye on it" (presumed headaches) and see if it got worse. They agreed that it could have been the chemo or a "fluke" thing. He also spoke to his HCP about his FIRDAPSE dose of 10 mg, 3x/day not being enough. He would switch and do a couple doses of 15 mg and it was better, but not enough. His HCP thought he should be taking 20 mg 3x/day, so he was working with the patient's insurance and pharmacy to get it changed. As of 02Oct2020, FIRDAPSE and chemo treatment were ongoing and moderate headaches were resolved (reported as he"d been good for a few days). On 01Feb2021 and 09Feb2021, it was learned that on 02Oct2020, the patient"s FIRDAPSE dose increased to 20 mg, 3x/day. On an unspecified date, the patient received the COVID vaccine at an unreported dose, route, and frequency of administration for an unreported indication. After the patient received the COVID vaccine, he experienced a bad reaction (unspecified). Since 27Jan2021 (reported as since Wednesday, relative to 01Feb2021), the patient had been sick. On 31Jan2021, the patient went to the emergency room, and they thought he had a blood clot on his lung. Subsequently, he was admitted to the hospital. Initially, when the patient was in the hospital, they took all his medications away, including his FIRDAPSE, as the pharmacy was managing his medication. The patient wife was able to get the doctors to let the patient keep his FIRDAPSE in his room with him before he missed any doses because he could not walk without his FIRDAPSE. On an unspecified date in 2021, the patient had radiation of his head and lung for his cancer (previously reported medical history), and "they" (presumed his medical provider) said he could have a raspy voice and headache, which he did experience but then resolved. While in the hospital, the patient"s blood pressure was not stable. It went "up and down, up and down." He had fluid in the bottom right lobe of his lung, where the cancer was, and they could not "tap it" due to the blood pressure issues. They were trying to get the fluid out every other way they could. The doctors said he had inflammation in the bottom of his lung. He was given a "good dose" of prednisone, but he was just exhausted. They were trying to control his blood pressure and his pulse. When they got one of them "up," the other went "down." The doctors said that the patient"s LEMS had nothing to do with why he was in the hospital. His wife expressed her gratitude for the FIRDAPSE and how it had helped him. As of 09Feb2021, treatment with FIRDAPSE was ongoing. The patient was still in the hospital and not doing well, also reported that he was still the same, he had not improved but he had not worsened. The blood clot on his lung, blood pressure fluctuation and pulse issues, fluid in the bottom right lobe of his lung, inflammation in the bottom of his lung, and exhaustion were not resolved. The status of the bad reaction to the COVID vaccine was not reported. No additional information was provided. On 18Feb2021 and 19Feb2021, it was learned that the patient"s medical history included: muscle weakness and lung cancer with brain metastases. On unspecified dates, after starting FIRDAPSE, the patient"s muscle weakness began severely progressing, and he experienced fatigue. The weakness was worsening significantly, even after being on the medication (presumed FIRDAPSE). On 14Feb2021 or 15Feb2021, the patient was discharged from the hospital. On 18Feb2021, the patient took his last dose of FIRDAPSE. On 18Feb2021 (reported as last night, relative to 19Feb2021), the patient passed away. The cause of death was unknown. A 74-year-old male, with a history of migraines and chemotherapy for metastatic small cell lung cancer, was taking an unknown statin, furosemide, pantoprazole, and Aspirin. He added FIRDAPSE for LEMS on 18Sep2020 and experienced headaches for a couple days, but he wasn"t sure if it was due to the FIRDAPSE or chemo. After COVID vaccine, he experienced a bad reaction (unspecified). Since 27Jan2021, he was hospitalized with a blood clot on his lung. He had brain and lung radiation for cancer. While in the hospital, he had fluid and inflammation in the bottom right lobe of his lung, where the cancer was, which count not be drained due to labile blood pressure. His muscle weakness began progressing and he experienced fatique. In Feb2021, he was discharged on FIRDAPSE. A few days post-discharge, he died. Based on the information provided, the events were assessed as unrelated. Information on the batch/lot number has been requested.; Reported Cause(s) of Death: Passed away

VAERS ID: <u>1192044 (history)</u> Vaccinated: 0000-00-00 Form: Version 2.0 0000-00-00 Onset: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-04-10

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route

COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH -/1 -/-

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No

Birth Defect? No Died? Yes

Date died: 0000-00-00 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No

ER Visit? No ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness: Preexisting Conditions:

Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021369331

Write-up: died; This is a spontaneous report from a contactable consumer. A 30-year-old female patient received her first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiry date were not reported), via an unspecified route of administration on an unspecified date as a single dose for COVID-19 immunization. The patient"s medical history and concomitant medications were not reported. It was reported that the patient who was completely healthy died on an unspecified date. Reporter stated that she had "great concerns about the Pfizer COVID 19 vaccine and actually all three of the vaccines on the market. She had been so distraught over the last couple of weeks since she found out that they are wanting to start experimentations on babies and that the babies can not handle this. She wanted to ask someone how does this fit in with the Nuremberg code since the babies have no awareness of what is going on since they are 6 months or less? She stated experiments should be based on animal experimentation but by the way all the companies skip animal testing. 15 years ago all the animals tested for the coronavirus vaccine died. The 30 year old mother that died bothered her completely and she never even met that person. The reporter stated people should have survived and that people do not need vaccine junk science and that it is making them into some operating system. She stated the vaccine is not helping and this was created just to create more fear." It was not reported if an autopsy was performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: Died

 VAERS ID: 1192062 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-04-10

Location: Washington

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

Administered by: Unknown Purchased by: ?

Symptoms: Death
SMQs:
Life Threatening? No
Birth Defect? No
Died? Yes

Died? Yes
Date died: 0000-00-00
Pormanont Disability? No

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:

CDC Split Type: USPFIZER INC2021371688

Write-up: death; This is a spontaneous report received from a contactable consumer. This consumer reported similar events for two patients. This the second of two reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number not provided) via an unspecified route of administration, on unspecified date at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced death on an unspecified date. It was unknown if autopsy was performed. Information on lot/batch number has been requested.; Sender's Comments: Linked Report(s): US-PFIZER INC-2021371687 same reporter/event, different patient; Reported Cause(s) of Death: death

 VAERS ID: 1192078 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Sex: Male Entered: 2021-04-10

Location: Washington

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: Life Threatening? N

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: Cancer

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021372641

Write-up: Passed away; This is a spontaneous report from a contactable consumer received via a Pfizer-sponsored program, Pfizer RXPathways. A male patient of an unspecified age received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunisation. Medical history included stage 4 cancer. The patient's concomitant medications were not reported. The patient passed away on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Passed away

 VAERS ID: 1192116 (history)
 Vaccinated:
 2021-03-20

 Form:
 Version 2.0
 Onset:
 2021-03-28

Age: Days after Sex: Male vaccination:

 Location:
 Unknown
 Submitted:
 0000-00-00

 Entered:
 2021-04-10

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

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Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-03-28

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: Preexisting Conditions: Allergies:

Diagnostic Lab Data:

CDČ Split Type: USPFIZER INC2021385447

Write-up: Had his first vaccination of the Pfizer and 8 days later he passed away; This is a spontaneous report from a contactable consumer. A male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 20Mar2021 at single dose for COVID-19 immunisation. Medical history and concomitant medications were unknown. It was reported that the patient had his first vaccination on 20Mar2021 and 8 days later (on 28Mar2021) the patient passed away. It was unknown if an autopsy was performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: Had his first vaccination of the Pfizer and 8 days later he passed away

 VAERS ID: 1192117 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Submitted: 0000-00-00

 Sex: Unknown
 Entered: 2021-04-10

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Cerebral haemorrhage

SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Haemorrhagic central nervous system vascular conditions (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: Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021385762

Write-up: Brain bleed; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender (physician) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date (at an

unspecified age) at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The consumer reported that a perfectly healthy physician who died after receiving the vaccine actually dying from a brain bleed. The outcome of the event was fatal. The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Brain bleed

 VAERS ID: 1194127 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-04-11

Location: Unknown

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19:
 COVID19 (MODERNA)) / MODERNA
 -/1
 -/OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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: No adverse event (No reported medical history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Died; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Died) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient"s past medical history included No adverse event (No reported medical history). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. No treatment information was provided. Very limited information regarding the event of death has been provided at this time. Further information has been requested.; Sender"s Comments: Very limited information regarding the event of death has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1197611 (history)
 Vaccinated:
 2021-02-05

 Form:
 Version 2.0
 Onset:
 2021-03-01

 Age:
 Days after vaccination:
 24

Location: Washington Submitted: 0000-00-00 Entered: 2021-04-12

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA 011M20A / 2 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Cerebrovascular accident, Death, Echocardiogram, Myocardial infarction, Vomiting

**SMQs:**, Acute pancreatitis (broad), Myocardial infarction (narrow), 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), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow)

Life Threatening? Yes Birth Defect? No Died? Yes Date died: 2021-03-11

Days after onset: 10 Permanent Disability? No Recovered? No

Office Visit? No ER Visit? No ER or Doctor Visit? No Hospitalized? Yes,? da

Hospitalized? Yes, ? days Extended hospital stay? No Previous Vaccinations: Other Medications: COZAAR

**Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event

Allergies:

Diagnostic Lab Data: Test Date: 20210305; Test Name: Echocardiogram; Test Result: Inconclusive; Result Unstructured Data: unknown

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Massive heart attack; Death; vomiting; Stroke; This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (Massive heart attack), CEREBROVASCULAR ACCIDENT (Stroke) and DEATH (Death) in a 73-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch nos. 011m20a and 013a21a) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient"s past medical history included No adverse event. Concomitant products included LOSARTAN POTASSIUM (COZAAR) for an unknown indication. On 05-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 05-Mar-2021, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On 11-Mar-2021, the patient experienced DEATH (Death) (seriousness criterion death) and VOMITING (vomiting). In March 2021, the patient experienced MYOCARDIAL INFARCTION (Massive heart attack) (seriousness criteria hospitalization and life threatening) and CEREBROVASCULAR ACCIDENT (Stroke) (seriousness criterion medically significant). On 11-Mar-2021, MYOCARDIAL INFARCTION (Massive heart attack), CEREBROVASCULAR ACCIDENT (Stroke) and VOMITING (vomiting) had resolved. The patient died on 11-Mar-2021. The cause of death was not reported. It is unknown if an autopsy was performed. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 05-Mar-2021, Echocardiogram: unknown (Inconclusive) unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not

provide any causality assessments. No concomitant medication information also included inhalers, non specified and eye drops non specified. No treatment information was reported. Based on the current available information and temporal association between the use of the product and the start dates of the events, a causal relationship cannot be excluded.; Sender"s Comments: Based on the current available information and temporal association between the use of the product and the start dates of the events, a causal relationship cannot be excluded.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1198107 (history)</u> Vaccinated: 1968-02-10 Version 2.0 2021-04-12 Age: Days after 19420 vaccination: Sex: Female Submitted: 0000-00-00 Location: Unknown Entered: 2021-04-12

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN 1805031 / 1 RA / IM

Administered by: Private Purchased by: ?

Symptoms: Bradycardia, Death, Disseminated intravascular coagulation, Endotracheal intubation, Haemodialysis, Hypotension, Intensive care, Liver function test increased, Mental status changes, Metabolic acidosis, Pyrexia, Respiratory failure, SARS-CoV-2 test positive, Sepsis, Shock, Transfusion

SMQs:, Acute renal failure (narrow), Liver related investigations, signs and symptoms (narrow), Anaphylactic reaction (narrow), Angioedema (broad), Lactic acidosis

(broad), Haemorrhage terms (excl laboratory terms) (narrow), Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Torsade de pointes, shock-associated conditions (broad), Hypovolaemic shock conditions (narrow), Toxic-septic shock conditions (narrow), Anaphylactic/anaphylactoid shock conditions (narrow), Hypoglycaemic and neurogenic shock conditions (narrow), Dementia (broad), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Acute central respiratory depression (narrow), Guillain-Barre syndrome (broad), Noninfectious vesser type unispeciment and mixed anternal and verticular (larrow), Acute Certical respinatory depletes and mixed and mixed anternal and verticular respinatory depletes and mixed and mixed anternal respinatory depletes and mixed and mi COVID-19 (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-12 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:** 

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

**CDC** Split Type:

Write-up: 53 y.o. female with a PMhx of asthma, CHF, CKD (not on HD), DM, HTN, hypothyroidism, methadone dependence for back pain, chronic bilateral foot ulcers presents with c/o one day of fever and admitted for sepsis of unknown origin on 3/9. Patient tested negative for SARSCOV2 on admission on 3/9. She was deemed a candidate for the vaccine and it was administered on 3/10 (Janssen Lot 1805031). On 3/19, she tested positive for SARSCOV2. She developed worsening respiratory failure and required oxygen supplementation with gradual escalation until she was intubated on 3/29. She received 5 days of remdesivir and steroid therapy. She developed DIC for which she received supportive care (vitamin K, transfusions, etc) and an HLH-type picture for which the steroids treatment was prolonged. She was not a candidate for tocilizumab given the elevated LFTs \$q 5x the upper limit of normal. During the ICU course patient was started on hemodialysis. Patient gradually started improving around 4/5 with planning for spontaneous breathing trials in attempts to extubate after weaning of sedatives. On 4/8, during a dialysis session patient became hypotensive and bradycardic. After this episode, patient"s mental status worsened and developed worsening metabolic acidosis and worsening shock refractory to vasopressors. Family decided for DNR and transition to comfort care. Patient expired on 4/12.

VAERS ID: 1205260 (history) Vaccinated: 0000-00-00 2021-03-22 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: 2021-04-13 Sex: Female Entered:

Location: California

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

Administered by: Unknown Purchased by: ? Symptoms: Death, Dementia

SMQs:, Dementia (narrow), Noninfectious encephalopathy/delirium (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? Yes

Hospitalized? No **Previous Vaccinations:** 

Other Medications: Current Illness:

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021382963

Write-up: died; Dementia; This is a spontaneous report from a contactable consumer. This consumer reported similar event for two patients. This is the first of two

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reports. This is a spontaneous report from a contactable consumer. This consumer reported similar event for two patients. This is the second of two reports. A 91-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunisation. The patient"s medical history and concomitant medications were not reported. The patient had no known allergies. The patient had no other vaccines in four weeks. The patient was not pregnant ("AS REPORTED"). It was reported that the patient at the board and care developed dementia like side effects on 22Mar2021 that didn"t exist prior. It was also reported that the patient died on an unspecified date. T events required emergency room/department or urgent care and reported as life-threatening illness (immediate risk of death from the event). The patient had no COVID prior the vaccination and was not tested for COVID post vaccination. Therapeutic measures were taken as a result of the events which included hospice. The outcome of the event dementia was not recovered. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Sender"s Comments: Linked Report(s): US-PFIZER INC-2021383789 Same reporter/drug/event, different patient.; Reported Cause(s) of Death: died

VAERS ID: <u>1205264</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-04-13

Location: Connecticut

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

Administered by: Unknown Purchased by: ?

Symptoms: Death, Malaise

SMQs:

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:

CDC Split Type: USPFIZER INC2021390868

Write-up: person didn"t get the second shot, got sick and died; person didn"t get the second shot, got sick and died; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first dose via an unspecified route of administration on an unspecified date (batch/lot number and expiration date was not reported) as single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The consumer stated that they had a case where a person didn"t get the second shot, got sick and died (pending confirmation). The patient died on an unspecified date. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: person didn"t got the second shot got sick and died

VAERS ID: <u>1216626</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-04-16

Location: Unknown

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | -/2        | RA / IM      |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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: CDC Split Type: Write-up: None stated.

VAERS ID: <u>1217480</u> (<u>history</u>) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-04-01 Age: Submitted: 0000-00-00 2021-04-16 Sex: Male Entered:

Location: New Jersey

Vaccination / Manufacturer Lot / Dose Site / Route

COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ? Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-04-01 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:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210416142

Write-up: DEATH; This spontaneous report received from a consumer concerned a 60 year old African American, Not Hispanic or Latino male. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, 1 total administered as approximately on 26-Mar-2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 01-APR-2021, the patient died from unknown cause of death. It was reported that, the patient death occurred about 6-7 days after receiving the vaccine. It was unknown, if an autopsy was performed. The patient death occurred about 6-7 days after receiving the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender''s Comments: 20210416142-covid-19 vaccine ad26.cov2.s -Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1220913</u> (<u>history</u>) Vaccinated: 2021-02-03 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Entered: 2021-04-16 Sex: Male

Location: Texas

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA 012M20A / 1 - / OT

Administered by: Unknown Purchased by: ? Symptoms: Pancreatic carcinoma, Vaccination site pain SMQs:, Non-haematological malignant tumours (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-02-23 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: Cancer (NOS) (for 30 years); Diabetes; Pancreatic cancer

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Husband died because of terminal pancreatic cancer; Sore arm; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of PANCREATIC CARCINOMA (Husband died because of terminal pancreatic cancer) in a 74-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 012M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient"s past medical history included Diabetes. Concurrent medical conditions included Pancreatic cancer and Cancer (NOS) (for 30 years). On 03-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced PANCREATIC CARCINOMA (Husband died because of terminal pancreatic cancer) (seriousness criteria death and medically significant) and VACCINATION SITE PAIN (Sore arm). On 23-Feb-2021, VACCINATION SITE PAIN (Sore arm) outcome was unknown. The patient died on 23-Feb-2021. The reported cause of death was Pancreatic cancer. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. He was on loads of different medication for cancer which the wife did not know about. Treatment information was not provided. As per the patient"s wife on 23Feb2021, her husband died because of terminal pancreatic cancer which she thinks is not related to the vaccine This case was linked to US-MODERNATX, INC.-MOD-2021-069647 (Linked Report); Sender"s Comments: Based on the current available information and the temporal association between the product use and the start date of the event a causal relationship cannot be ruled out. US-MODERNATX, INC.-MOD-2021-069647; Reported Cause(s) of Death: Pancreatic cancer

VAERS ID: <u>1220979</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-04-16

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA

Administered by: Unknown Symptoms: Death

SMQs:

Purchased by: ?

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: No adverse event

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Death; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Death) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient"s past medical history included No adverse event. Concurrent medical conditions included No adverse event. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant medication list was not provided. Treatment information was not provided.; Sender"s Comments: Limited information regarding the event has been provided at this time and a causal relationship cannot be excluded; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1221106 (history)
 Vaccinated:
 2021-02-10

 Form:
 Version 2.0
 Onset:
 2021-02-21

 Age:
 Days after
 11

Sex: Male vaccination:

 Location:
 Tennessee
 Submitted:
 0000-00-00

 Entered:
 2021-04-16

| Vaccina              | tion / Manufacturer         | Lot / Dose  | Site / Route |
|----------------------|-----------------------------|-------------|--------------|
| COVID19: COVID19 (Co | OVID19 (MODERNA)) / MODERNA | 011L20A / 1 | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: Life Threatening? No

Birth Defect? No Died? Yes

Date died: 2021-02-21 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:

Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Eleven days after receiving the dose, he died; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Eleven days after receiving the dose, he died) in a 79-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 011L20A) for COVID-19 vaccination. The patient"s past medical history included COVID-19. On 10-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on 21-Feb-2021 The patient died on 21-Feb-2021. The cause of death was not reported. It is unknown if an autopsy was performed. Unknown Action taken with mRNA-1273 in response to the event was not applicable. Prior to the patient"s receiving his first dose of the Moderna Covid-19 vaccine series, wife reported that he was hospitalized for Covid-19 infection for three weeks. While hospitalized, he was treated for Covid-19 infection with medications unknown to her and was very sick on a ventilator in the ICU. He was then discharged to a rehab facility for several weeks and moved to a nursing home for additional rehab. Eleven days after receiving the dose, he died on 21 Feb 2021. He had been getting along well and working on coming home prior to receiving the first dose. Limited information regarding the patient"s death has been provided at this time and a causal relationship cannot be excluded; Sender"s Comments: Limited information regarding the patient"s death has been provided at this time and a causal relationship cannot be excluded; Neported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1221127 (history)
 Vaccinated:
 2021-01-22

 Form:
 Version 2.0
 Onset:
 2021-01-29

Age: Days after Sex: Female vaccination:

 Location:
 Texas
 Submitted:
 0000-00-00

 Entered:
 2021-04-16

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA
 -/1
 LA / OT

Administered by: Unknown Purchased by: ?

Symptoms: Brain stem thrombosis

SMQs:, Ischaemic 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: 2021-01-30 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:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No medically reported history)

Allergies: Diagnostic Lab Data:

**Current Illness:** 

CDČ Split Type: USMODERNATX, INC.MOD20210

Write-up: Died of clots in brain; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of BRAIN STEM THROMBOSIS (Died of clots in brain) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient"s past medical history included No adverse event (No medically reported history). On 22-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 29-Jan-2021, the patient experienced BRAIN STEM THROMBOSIS (Died of clots in brain) (seriousness criteria death and medically significant). The patient died on 30-Jan-2021. The reported cause of death was Brain stem thrombosis. It is unknown if an autopsy was performed. This is a 76 year-old, who received mRNA-1273 Vaccine) and died 8 days after receiving first dose of vaccine and subsequently experienced brain stem thrombosis. No medical hx or conmeds were provided. The reported cause of death was brain stem thrombosis. Very limited information has been reported at this time. Further information is expected. This case was linked to MOD21-075103, US-MODERNATX, INC.-MOD-2021-075124 (Linked Report).; Sender's Comments: This is a 76 year-old, who received mRNA-1273 Vaccine) and died 8 days after receiving first dose of vaccine and subsequently experienced brain stem thrombosis. No medical hx or conmeds were provided. The reported cause of death was brain stem thrombosis. Very limited information has been reported at this time. Further information is expected. MOD21-075103: US-MODERNATX, INC.-MOD-2021-075124: Patient''s brother in law case; Reported Cause(s) of Death: brain stem thrombosis

VAERS ID: <u>1224535</u> (history) 2021-03-16 Vaccinated: 2021-03-16 Form: Version 2.0

Age: Days after vaccination: Unknown Sex:

Location: Illinois Submitted: 0000-00-00 Entered: 2021-04-18

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

0

Purchased by: ? Administered by: Unknown

Symptoms: Apgar score, Foetal heart rate decreased, Foetal hypokinesia, Maternal exposure during pregnancy

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Foetal disorders (narrow)

Life Threatening? No Birth Defect? No Died? Yes Date died: 0000-00-00

Permanent Disability? No Recovered? No Office Visit? Yes ER Visit? No

ER or Doctor Visit? No Hospitalized? Yes, 3 days Extended hospital stay? No Previous Vaccinations:

Other Medications: **Current Illness: Preexisting Conditions:** Allergies:

CDC Split Type: USPFIZER INC2021363057

Diagnostic Lab Data: Test Date: 2021; Test Name: apgars; Result Unstructured Data: Test Result:0

Write-up: decreased fetal movement; decreased fetal heart tones; 34 weeks pregnant; This is a spontaneous report from a contactable pharmacist. This pharmacist reported information for both mother and fetus. This is a fetus report. A fetus patient of an unspecified gender received the first dose of bnt162b2, transplacental on 16Mar2021 (Lot Number: Unknown) as single dose for covid-19 immunisation. The 31-year-old mother received this vaccine via Intramuscular. The patient medical history and concomitant medications were not reported. The mother presented to obstetrician office 2 weeks after covid vaccine with complaints of decreased fetal movement. Mother was taken to emergency c-section due to decreased fetal heart tones in the office. Baby was delivered with appars of 0 and ultimately fetal demise. Mother was 34 weeks pregnant and had an otherwise uncomplicated pregnancy. The onset date of events decreased fetal movement and decreased fetal heart tones was 30Mar2021. The events were result in Doctor or other healthcare professional office/clinic visit and hospitalization for 3 days. The outcome of the events was fatal. The patient died on an unspecified date in 2021 due to events. It was not reported if an autopsy was performed. Information on the Lot/Batch number has been requested.; Sender's Comments: The reported events are likely due to an intercurrent condition and not related to BNT162B2 .,Linked Report(s): US-PFIZER INC-2021359597 Mother case; Reported Cause(s) of Death: 34 weeks pregnant; decreased fetal movement; decreased fetal heart tones

**VAERS ID: 1224836** (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-04-06 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-04-18

Location: Florida

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

Administered by: Unknown Purchased by: ?

Symptoms: Confusional state, Death, Dehydration, Guillain-Barre syndrome, Laboratory test, Lethargy, Lumbar puncture, Urinary incontinence

SMQs:, Peripheral neuropathy (narrow), Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Dementia (broad), Guillain-Barre syndrome (narrow), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Demyelination (narrow), Hypoglycaemia (broad), Dehydration (narrow), Immune-mediated/autoimmune disorders (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-06

Days after onset: 0 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: **Current Illness:** 

**Preexisting Conditions:** Allergies:

Diagnostic Lab Data: Test Name: tests; Result Unstructured Data: Test Result:diagnosed with Guillain-Barre Syndrome; Test Name: lumbar puncture; Result Unstructured Data: Test Result:diagnosed with Guillain-Barre Syndrome

CDC Split Type: USPFIZER INC2021381625

Write-up: Guillain-Barre Syndrome; urinary incontinence; confusion; lethargy; dehydration; expired; This is a spontaneous report from a contactable physician. A 76-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot and expiry were not reported), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation. The patient received first dose of bnt162b2 on an unspecified date for Covid-19 immunization. The patient's medical history and concomitant medications were not reported. The physician reported that the patient received his second Pfizer vaccine dose and 2 weeks after receiving the vaccine he presented to her office with urinary incontinence, confusion and lethargy. He was admitted to the hospital and within a few days later, day 5, he was diagnosed with Guillain-Barre Syndrome. Following tests and a lumbar puncture. He was hospitalized x2 weeks, received IVIG x 5days. He was then transferred to a Nursing Home. He was readmitted to the hospital with dehydration and expired 2 days later (last night). The physician asked, "have you seen this type of thing before, with GBS?" The physician considered the case as non-serious. The outcome of the events was unknown except for expired. The patient died on 06Apr2021 as he expired. There was no autopsy done. Information on the lot/batch number has been requested.; Sender"s Comments: Limited information precludes a medically meaningful assessment of the case. Based on the current available information, a possible contributory role of the suspect product to the development of events cannot be totally excluded. Additional information including relevant medical history, detailed clinical course, and specified concomitant medications is required to better assess the case. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: expired

VAERS ID: <u>1224919</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-04-08 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-04-18

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-08 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: Preexisting Conditions:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021392222

Write-up: the client died yesterday; This is a spontaneous report from a non-contactable other healthcare professional (hcp) from a Pfizer-sponsored program. A patient of unspecified age and gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, Solution for injection, lot number and expiry date were not reported) via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient died on 08Apr2021. The cause of death was unknown. It was unknown if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot been obtained.; Sender"s Comments: Death of unknown cause is assessed related as a cautionary measure and for reporting purposes. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: the client died yesterday

**VAERS ID:** <u>1227130</u> (history) Vaccinated: 0000-00-00 Version 2.0 2021-03-12 Form: Onset: Age: Submitted: 0000-00-00 Male 2021-04-18 Sex: Entered:

Location: Ohio

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Computerised tomogram, Pneumonia, Thrombosis, X-ray

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (broad), Eosinophilic pneumonia (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Infective pneumonia (narrow)

Life Threatening? No

Birth Defect? No

Died? Yes

Date died: 2021-03-25 Days after onset: 12 Permanent Disability? No

Search Results from the VAERS Database

Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? No Hospitalized? Yes, 1 days Extended hospital stay? No Previous Vaccinations: Other Medications: ELIQUIS

**Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Atrial fibrillation; Congestive heart failure; Dementia; Groin hernia

Diagnostic Lab Data: Test Date: 20210314; Test Name: CAT scan; Result Unstructured Data: Saddle PE; Test Date: 20210314; Test Name: X-ray; Result

Unstructured Data: Saddle PE

CDC Split Type: USJNJFOC20210424686

Write-up: PNEUMONIA; BLOOD CLOTS; This spontaneous report received from a consumer concerned an 89 year old male. Initial information was received on 13-APR-2021 and processed with additional information received on 15-APR-2021. The patient"s height, and weight were not reported. The patient"s past medical history included congestive heart failure (ejection fraction 20%), large lower left groin hernia, atrial fibrillation, and dementia. No known drug allergies was reported. There was no history of blood clots. The patient received vaccination with covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose was not reported, administered on 04-MAR-2021 for prophylactic vaccination. Vaccination site was not reported. Batch number was not reported, will be requested. Concomitant medications included apixaban twice a day for atrial fibrillation. On 11-MAR-2021, the patient was taken to Emergency Room (ER) and diagnosed with pneumonia. Patient was awake over 48 hours "felt due to dementia and illness". On 14-MAR-2021, the patient was taken back to hospital and X-ray and CAT scan showed saddle pulmonary embolism. On 15-MAR-2021, the patient was discharged to a home with hospice. On 23-MAR-2021, the patient deceased. It was unknown if autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, Hospitalization Caused / Prolonged).; Sender's Comments: V0: An 89-year old man experienced fatal saddle pulmonary embolism 10 days after vaccine. Relevant medical history included congestive heart failure with ejection fraction 20%, atrial fibrillation (A Fib), and dementia. Relevant concomitant medication (others not reported) included Eliquis for A fib. The patient was diagnosed with pneumonia in the Emergency Department 7 days after vaccine, and 3 days later was brought back to the hospital and diagnosed with saddle pulmonary embolus. He was discharged home on hospice the next day and died 19 days after vaccine. There was no reported thrombocytopenia. The patient"s age, concurrent pneumonia, and complicated past medical history are confounders. There is insufficient information to make a meaningful medical assessment. Additional information has been requested, including attempts to contact the patient"s treating physicians.; Reported Cause(s) of Death: PNEUMONIA; **BLOOD CLOTS** 

Vaccinated: 0000-00-00 VAERS ID: <u>1227282</u> (<u>history</u>) Version 2.0 Onset: 0000-00-00 Form: Submitted: 0000-00-00 Age: Entered: 2021-04-18 Sex: Unknown

Location: Georgia

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021404175
Write-up: I know a physician in died afterwards; This is a spontaneous report from a Pfizer-sponsored programs from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Lot number was not reported) as single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient knows a physician and died afterwards on an unspecified date. It was unknown if an autopsy was performed. Information about lot/batch number has been requested.; Reported

Cause(s) of Death: I know a physician in (name) died afterwards

VAERS ID: <u>1227286</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 2021-04-18 Male Entered: Sex:

Location: Unknown

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

Administered by: Unknown

Symptoms: Death

SMQs: Life Threatening? No Birth Defect? No Died? Yes

Purchased by: ?

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:

CDC Split Type: USPFIZER INC2021416933

Write-up: within two weeks of receiving the vaccine the patient died; This is a spontaneous report based on information received by Pfizer from Merck & Co., Inc. A contactable Consumer reported for a male patient of an unspecified age that received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation. The patient medical history and the patient"s concomitant medications were not reported. The patient died within two weeks of receiving the vaccine on an unspecified date. It was not reported if an autopsy was performed. No follow-up attempts are possible, information about lot/batch number cannot been obtained.; Reported Cause(s) of Death: within two weeks of receiving the vaccine both family members died

 VAERS ID: 1227287 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Male
 Entered:
 2021-04-18

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

Other Medications Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021416943

Write-up: within two weeks of receiving the vaccine both family members died; This is a spontaneous report based on information received by Pfizer (Case Number: 01903495). A contactable Consumer reported for two family members. A male patient of an unspecified age received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient died on an unspecified date within two weeks of receiving the vaccine. It was not reported if an autopsy was performed. No follow-up attempts are possible, information about lot/batch number cannot been obtained.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1227818 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-04-19

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | - / UNK    | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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: Clot blood (She was prone to blood clots her entire life, but managed it.)

**Preexisting Conditions:** Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210420170

Write-up: BLOOD CLOT; This spontaneous report received from a consumer via media by a company representative concerned a female of unspecified age. The

patient"s height, and weight were not reported. The patient was prone to blood clots her entire life, but managed it. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration and batch number were not reported) dose (1 total), start therapy date were not reported, for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient developed a blood clot. A day after the vaccination, the patient died from the blood clot. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, and Other Medically Important Condition).; Sender"s Comments: This anecdotal report from media involves a female patient of unspecified age who was prone to blood clots her entire life and on an unspecified date developed a blood clot and died from the blood clot a day after received the Janssen COVID-19 Vaccine Ad26.COV2. Concomitant medications, and details of the event were not reported. This case has insufficient information to make a meaningful medical assessment. The case will be assessed further when additional information is received.; Reported Cause(s) of Death: BLOOD CLOT

VAERS ID: <u>1227922</u> (<u>history</u>) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-04-19

Location: Pennsylvania

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Exposure during pregnancy, Skeletal injury, Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (broad), Accidents and injuries (narrow),

Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (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: Comments: Gravida/Para: 1/1. The patient was 4 weeks post-partum.

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210427241

Write-up: BLOOD CLOT; BROKE TAIL BONE; VACCINE EXPOSURE DURING PREGNANCY; This spontaneous pregnancy report was received from a pharmacist via a company representative, and concerned an approximately 40 year old female. The patient's height, weight, and medical history were not reported. The patient received Covid-19 vaccine Ad26.COV2.S (suspension for injection, route of administration not reported, batch number: unknown) dose and vaccination site were not reported, administered in 2021 for prophylactic vaccination. No concomitant medications were reported. In 2021, the patient experienced vaccine exposure during pregnancy. The date of the patient's last menstrual period and expected delivery date were not provided. In 2021, the patient experienced broke tail bone during labor and gave birth (live birth). On an unspecified date in 2021, the patient experienced ablood clot and died. It was noted that she was at high risk for clots because she was 4 weeks post partum (gravida 1, para 1). Action taken with Covid-19 vaccine Ad26.COV2.S was not applicable. The patient died of a blood clot and broke tail bone in 2021; the outcome of vaccine exposure during pregnancy was not reported. It was unspecified if an autopsy was performed. This report was serious (Death). This case, from the same reporter is linked to 20210430297.; Sender's Comments: V0: The case concerns a pregnant female subject around age of 40, who developed thrombosis, skeletal injury and exposure during pregnancy an unspecified time after Janssen COVID-19 vaccine was administered intramuscularly for prevention of symptomatic SARS-CoV-2 virus infection. The subject"s past medial history, last menstrual period, estimated date of delivery and concomitant medications were not provided. Per the reporter (pharmacist) the patient was at a high risk for blood clots because she was 4 weeks post-partum. The patient broke her tail bone during the labor, gave a birth, and later died of a blood clot. No additional information was provided. It is not known whether the autopsy was performed. Given alternative explanation and risk factors of pregnancy, labor and skeletal injury (trauma) the event of thrombosis is considered inconsistent with the causal association to immunization, per the WHO causality classification for adverse events following immunization. Events of skeletal injury was result of an accident and therefore not considered related. Company causality for event of thrombosis is considered not related to Janssen COVID-19 vaccine (Level 4 -Insufficient information available to confirm a possible, probable or a definitive case of venous thrombosis, per the Brighton Collaboration case definition); Reported Cause(s) of Death: BLOOD CLOTS; BROKE TAIL BONE

VAERS ID: <u>1227925</u> (history) Vaccinated: 0000-00-00 Version 2.0 Onset: 0000-00-00 Form: Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-04-19

Location: Kansas

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Platelet count, Pulmonary embolism, Thrombocytopenia

SMQs:, Haematopoietic thrombocytopenia (narrow), Systemic lupus erythematosus (broad), Embolic and thrombotic events, venous (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? Yes

Hospitalized? No

**Previous Vaccinations:** Other Medications:

Current Illness: General physical health deterioration

Preexisting Conditions: Medical History/Concurrent Conditions: Cancer (Unspecified type)

Allergies:

Diagnostic Lab Data: Test Name: Platelet count; Result Unstructured Data: Thrombocytopenia (count unspecified)

CDC Split Type: USJNJFOC20210427876

Write-up: SUSPECTED PULMONARY EMBOLISM; THROMBOCYTOPENIA; This spontaneous report received from a health care professional from a state immunization program concerned a 60 year old male. The patient"s height, and weight were not reported. The patient"s past medical history included cancer, and concurrent conditions included overall poor health. The patient received COVID-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown), date of administration was not reported, for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, approximately 24 hours post-vaccination, the patient was taken to the hospital after being found unresponsive. It was suspected that the patient had experienced a pulmonary embolism, resulting in his death. Laboratory results revealed thrombocytopenia. Reportedly, no heparin was used in his treatment. On an unspecified date, the subject died from suspected pulmonary embolism, and had not recovered from thrombocytopenia. An autopsy had not been performed at the time of the report, as it was pending family"s approval. The action taken with COVID-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, and Other Medically Important Condition).; Sender's Comments: V0: This is a spontaneous report of a 60-year-old male patient, who died of a suspected pulmonary embolism approximately 24 hours after receipt of the Janssen COVID-19 vaccine. The patient had an unspecified cancer and was described as in overall poor health. He was brought to a hospital, where it was suspected that he had died due to a pulmonary embolism. He was also found to be thrombocytopenic. The patient's cancer could provide a plausible alternative explanation for the event, although there are insufficient details to make a meaningful medical assessment at this time.; Reported Cause(s) of Death: SUSPECTED PULMONARY EMBOLISM

 VAERS ID: 1227926 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Male
 Entered:
 2021-04-19

Location: New Jersey

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK - / -

Administered by: Other Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210428310

Write-up: BLOOD CLOT; This spontaneous report received from a consumer via a company representative and concerned a male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, a week or so after the Covid-19 vaccination the patient passed away in his sleep. The patient had no underlying condition. An autopsy was performed on an unspecified date and the patient was found to have blood clot. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0: A male patient of unspecified age passed away in his sleep an unspecified time after receiving the Janssen COVID-19 vaccine for prevention of COVID-19 infection. It stated that the patient had no underlying condition. A blood clot was found by autopsy; no further details are provided. There is insufficient information to make a meaningful medical assessment. Additional information is being sought.; Reported Cause(s) of Death: BLOOD CLOT; Autopsy-determined Cause(s) of Death: BLOOD CLOT

 VAERS ID: 1227927 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-04-19

Location: North Carolina

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | - / UNK    | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death
SMQs:

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: Caffeine consumption (heavy); Feeling unwell (upon waking the morning prior to receiving vaccination.); Heart disorder; Heavy smoker

Preexisting Conditions: Medical History/Concurrent Conditions: Stroke

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210428883

Write-up: PASSED AWAY; This spontaneous report was received from a partner, and concerned a 64 year old patient of an unspecified sex. The patient's height, and

weight were not reported. The patient"s past medical history included strokes; concurrent conditions included heavy smoker, caffeine consumption, unspecified heart issues, and felling unwell. The patient received Covid-19 vaccine Ad26.COV2.S (suspension for injection, route of admin, and batch number were not reported) dose, vaccination site, and start therapy date were not reported, for prophylactic vaccination. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient passed away. It was reported that the patient received Covid-19 vaccine in the morning and passed away later that day. The patient had felt unwell upon waking up that morning prior to vaccination. The coroner ruled out the vaccine as a potential cause of death due to the individual"s past and concurrent medical conditions. It was unspecified if an autopsy was performed. Action taken with Covid-19 vaccine Ad26.COV2.S was not applicable. This report was serious (Death), Sender's Comments: V0: A 64-year-old patient of unspecified sex received the Janssen COVID vaccine in the morning and died later that day. The coroner ruled out the vaccine as a potential cause of death due to the individual"s past and concurrent medical conditions, although these conditions weren"t specifically reported. Given the coroner"s assessment and symptoms preceding vaccination, there is a plausible alternate explanation for the death.; Reported Cause(s) of Death: PASSED AWAY

VAERS ID: <u>1227962</u> (history) Vaccinated: 2021-04-09 Version 2.0 Form: Onset: 2021-04-11

Age: Davs after Sex: Male vaccination:

Submitted: 0000-00-00 Location: Unknown Entered: 2021-04-19

| Vaccination / Manufacturer                                   |    | Lot / Dose | Site / Route |
|--|----|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTE | СН | -/1        | -/-          |

Administered by: Unknown Purchased by: ?

Symptoms: Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-04-11 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: Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: CDC Split Type: USPFIZER INC2021404657

Write-up: suddenly passed away; This is a spontaneous report from a contactable healthcare professional reporting on behalf of friend"s husband. A 43-year-old male patient received the first single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on 09Apr20201, for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient suddenly passed away on 11Apr2021. It was unknown if an autopsy was performed or not. The patient passed away at home and he was otherwise healthy. The reporter stated there was not a way to know if it was related to the vaccine as of right now. Information on lot number/batch number has been requested.; Sender"s Comments: Limited information precludes a medically meaningful assessment of the case. A possible contributory role of the suspect product BNT162B2 to the development of event Sudden death cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: suddenly passed awav

Vaccinated: 0000-00-00 VAERS ID: <u>1227966</u> (history) Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Entered: 2021-04-19 Sex: Male

Location: Ohio

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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: Comments: List of non-encoded Patient Relevant History: Patient Other Relevant History 1: None

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021404945

Write-up: got the shot for covid and died a few weeks later; This is a spontaneous report from a contactable consumer. A male patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The relevant medical history and concomitant medications were reported as none. The patient got the shot for covid and died a few weeks later on an unspecified date. It was unknown if an autopsy was performed. The outcome of the event was fatal. Information on the Lot/Batch number has been requested.;

Reported Cause(s) of Death: got the shot for covid and died a few weeks later

 VAERS ID: 1227977 (history)
 Vaccinated:
 2021-03-24

 Form:
 Version 2.0
 Onset:
 2021-03-26

Age: Days after Sex: Male vaccination: 2

Location: Indiana Submitted: 0000-00-00 Entered: 2021-04-19

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EN6208 / 1 | -/-          |

Administered by: Other Purchased by: ?
Symptoms: Laboratory test, Pulmonary embolism
SMQs:, Embolic and thrombotic events, venous (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-26
Days after onset: 0
Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No ER or Doctor Vi

ER or Doctor Visit? Yes Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Colon cancer

Allergies:

Diagnostic Lab Data: Test Date: 2011; Test Name: lab work; Result Unstructured Data: Test Result:Good

CDC Split Type: USPFIZER INC2021406385

Write-up: Pulmonary embolism/ blood clot/ passed out; This is a spontaneous report from a contactable consumer (patient"s daughter). A male patient of an unspecified age received BNT162B2 (Pfizer COVID-19 vaccine), dose 1 via an unspecified route of administration, administered in arm, side unknown, on 24Mar2021 14:30 (Lot Number: EN6208) as single dose for COVID-19 immunisation. Vaccination facility type was clinic. Medical history included colon cancer in 2011. He had cancer in 2011 but resolved that year without chemotherapy or radiation. His lab work was good. There were no concomitant medications. No prior vaccinations (within 4 weeks). No family medical history relevant to AE. The patient experienced pulmonary embolism on 26Mar2021 with fatal outcome. The reporter was reporting on the Pfizer COVID vaccine that her father received. She stated he died from a blood clot after receiving the first dose. Stated she needs help because he had no health issues and he died. She just wanted this information to be out there and for people to be aware. This morning they had been reading on the news that the Johnson and Johnson vaccine is on hold. It seems to be put on the market without research. She felt like her father was a guinea pig. Her mother didn"t want to get her second dose. Stated there seems to be an issue with Pfizer too. Her father had no issues whatsoever. His death certificate stated the cause of death was a pulmonary embolism, but he had no history of blood clots. Passed away Friday 26Mar2021 at 11:33 am. The reporter stated when he went to Emergency Room they thought he was having a heart attack. All physicians were wondering what happened because he had no health issues. The event required a visit to the emergency room that day because he passed out at his job. The patient underwent lab tests and procedures which included lab work: good in 2011. The patient died on 26Mar2021. An autopsy was performed that revealed pulmonary embolism.; Reported Cause(s) of Death: Pulmonary embolism; Autopsy-determine

 VAERS ID: 1227979 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 2021-03-01

 Age:
 Submitted:
 0000-00-00

 Sex:
 Male
 Entered:
 2021-04-19

Location: Texas

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

Administered by: Unknown Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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:

CDC Split Type: USPFIZER INC2021406715

Write-up: got clots all over the body; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced got clots all over the body in Mar2021 and he passed away. Pfizer has not been reporting any effects of blood clot. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: got clots all over the body

VAERS ID: 1232815 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-04-20

Location: Ohio

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN 1802068 / 1 LA / IM

Administered by: Private Purchased by: ?

Symptoms: Abdominal pain, Blood lactic acid, Blood phosphorus increased, Blood pressure immeasurable, Coma, Death, Headache, Hypotension, Shock, Syncope,

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (narrow), Acute pancreatitis (broad), Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Retroperitoneal fibrosis (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Torsade de pointes, shock-associated conditions (broad), Hypovolaemic shock conditions (narrow), Toxic-septic shock conditions (narrow), Anaphylactic/anaphylactoid shock conditions (narrow), Hypoglycaemic and neurogenic shock conditions (narrow), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Cardiomyopathy (broad), Hypotonic-hyporesponsive episode (broad), Čhronic kidney disease (broad), Hypersensitivity (narrow), Tumour lysis syndrome (broad), Hypoglycaemia (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? Yes ER Visit? No ER or Doctor Visit? Yes

Hospitalized? Yes, ? days Extended hospital stay? No **Previous Vaccinations:** Other Medications: Current Illness:

**Preexisting Conditions:** Allergies:

Diagnostic Lab Data: BP unobtainable, pH 6.8, lactate 15 Contact Hospital for lab and clinical details

CDC Split Type:

Write-up: Abdominal pain, vomiting, headache, hypotension, syncope, coma, shock, death at 2:00 pm 03/08/2021

VAERS ID: <u>1235806</u> (history) 2021-03-24 Vaccinated: Form: Version 2.0 Onset: 2021-04-01 Age: Days after

vaccination: Sex: Male

Submitted: 0000-00-00 Location: North Carolina Entered: 2021-04-21

| Vaccination / Manufacturer                                    | Lot / Dose | Site / Route |
|---|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTEC | H -/1      | -/-          |

Administered by: Unknown Purchased by: ?

Symptoms: Blood glucose, Blood glucose decreased, Diabetic coma

SMQs:, Hyperglycaemia/new onset diabetes mellitus (narrow), Hypoglycaemia (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-02 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:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Back surgery; Coronary heart disease; Diabetes

Allergies:

Diagnostic Lab Data: Test Date: 20210401; Test Name: Blood sugar; Result Unstructured Data: Test Result:dropping/low

CDC Split Type: USPFIZER INC2021403062

Write-up: diabetic coma; blood sugar kept dropping; This is a spontaneous report from a contactable consumer (patient"s neighbor). A 60-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 24Mar2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. Medical history included diabetes and coronary artery disease, and back surgery. The patient"s concomitant medications were not reported. They think the patient went into a diabetic coma from low blood sugar dropping on 01Apr2021 and the patient passed away in his sleep. Reporter does not know if it had anything to do with the shot or anything but he thought they may want to know that. The patient started having problems with his blood sugar on Thursday 01Apr2021. The patient's blood sugar kept dropping and he went to bed that night and died. Patient was found deceased Friday morning 02Apr2021. Information about batch/lot number has been requested.; Reported Cause(s) of Death: Blood glucose decreased; diabetic coma

VAERS ID: 1235825 (history) Vaccinated: 2021-03-26 Version 2.0 0000-00-00 Form: Onset: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-04-21

Location: New Hampshire

Vaccination / Manufacturer Lot / Dose Site / Route

COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EL9269 / 1

Administered by: Senior Living Purchased by: ?

Symptoms: <u>Bradycardia, Hypotension, Investigation</u>
SMQs:, Anaphylactic reaction (broad), Neuroleptic malignant syndrome (broad), Arrhythmia related investigations, signs and symptoms (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? Yes Hospitalized? Yes, ? days Extended hospital stay? No

Previous Vaccinations: Other Medications: **Current Illness: Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: Test Name: critical labs; Result Unstructured Data: Test Result:Unknown results

CDC Split Type: USPFIZER INC2021412017

Write-up: bradycardia; hypotension; This is a spontaneous report from a contactable nurse (Registered nurse with title of Infection Preventionist). A female patient of an unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EL9269; expiration date: 01May2021) via an unspecified route of administration on 26Mar2021 at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient was with bradycardia, hypotension (seriousness criteria: hospitalization, death) and she passed away in the emergency room (ER), critical labs, she didn"t even make it one day, the reporter send her out and she passed away in the ER. The patient died on an unspecified date. It was not reported if an autopsy was performed.; Sender"s Comments: A causal relationship between BNT162B2 and the events hypotension, bradycardia cannot be excluded based on temporal association. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate .; Reported Cause(s) of Death: bradycardia; hypotension

VAERS ID: <u>1235830</u> (history) Vaccinated: 0000-00-00 Onset: 0000-00-00 Form: Version 2.0 Age: Submitted: 0000-00-00 Sex: Male Entered: 2021-04-21

Location: South Carolina

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

Purchased by: ? Administered by: Unknown

Symptoms: Death, Drug ineffective, SARS-CoV-2 test, Suspected COVID-19

SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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: Atrial fibrillation (Underlying health issues); Pre-diabetes (Underlying health issues) Allergies:

Diagnostic Lab Data: Test Name: two weeks after testing positive for the virus; Test Result: Positive

CDC Split Type: USPFIZER INC2021415071

Write-up: died about a month ago; two weeks after testing positive for the virus; two weeks after testing positive for the virus; This is a spontaneous report from a noncontactable consumer. An 80-years-old male patient received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date at SINGLE DOSE for covid-19 immunisation. Medical history included pre-diabetes and atrial fibrillation (Underlying health issues). The patient's concomitant medications were not reported. The patient previously received first dose of bnt162b2 on an unspecified date at SINGLE DOSÉ for covid-19 immunisation. The patient died about a month ago, two weeks after testing positive for the virus. The death occurred about four weeks after the second dose of the Pfizer/BNT vaccine. The patient died on an unspecified date. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Deceased

VAERS ID: <u>1235832</u> (<u>history</u>) Vaccinated: 2021-03-26 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-04-21

Location: New Hampshire

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EL9269 / 1

Administered by: Senior Living Purchased by: ? Symptoms: Confusional state, Dyspnoea, Hypoxia, Sepsis

SMQs:, Anaphylactic reaction (broad), Asthma/bronchospasm (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Dementia (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Cardiomyopathy (broad), Eosinophilic pneumonia (broad), Respiratory failure (broad), Hypoglycaemia (broad), Infective pneumonia (broad), Sepsis (narrow), Opportunistic infections (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? Yes
Hospitalized? Yes, ? days
Extended hospital stay? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:

Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021415135

Write-up: wound up in the ER with hypoxia and sepsis; wound up in the ER with hypoxia and sepsis; shortness of breath; increased confusion; This is a spontaneous report from a contactable Nurse. A female patient of an unspecified age received first dose of bnt162b2 (BNT162B2), via an unspecified route of administration on 26Mar2021 (Lot Number: EL9269; Expiration Date: 01May2021) as single dose for Covid-19 immunisation. The patient medical history was not reported. The patient sconcomitant medications were not reported. It was reported that the female patient who we sent out with shortness of breath and increased confusion, she wound up in the ER (emergency room) with hypoxia and sepsis and she passed away. The events were serious as hospitalization and death. The patient died on an unspecified date. It was not reported if an autopsy was performed.; Sender's Comments: Based on the limited available information, the Company considered there was not a reasonable possibility that the reported events were related to the suspect product BNT162B2 (COMIRNATY). The impact of this report on the benefit/risk profile of the Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: increased confusion; shortness of breath; wound up in the ER with hypoxia and sepsis; wound up in the ER with hypoxia and sepsis

 VAERS ID: 1237704 (history)
 Vaccinated:
 2021-03-10

 Form:
 Version 2.0
 Onset:
 2021-03-25

Age: Days after Sex: Female vaccination:

 Location:
 Montana
 Submitted:
 0000-00-00

 Entered:
 2021-04-21

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN 1805029 / 1 RA / IM

Administered by: Other Purchased by: ?

Symptoms: Chest X-ray, Computerised tomogram, Death, Echocardiogram, Hepatic vein thrombosis

SMQs:, Embolic and thrombotic events, venous (narrow)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-03-29

Days after onset: 4
Permanent Disability? No
Recovered? No

Office Visit? No ER Visit? No ER or Doctor Visit? No Hospitalized? Yes, 3 days Extended hospital stay? No Previous Vaccinations:

Other Medications: Ferrous Sulfate; Omeprazole

Current Illness: None

Preexisting Conditions: Lupus; Depressive Disorder; Myalgia

Allergies: NKDA

Diagnostic Lab Data: TEE 4/12/19 CXR multiple 4/11, 4/12 Echo 4/17 CT 3/26

CDC Split Type:

Write-up: Death, blood clots in liver

 VAERS ID: 1240535 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 2021-04-09

 Age:
 Submitted:
 0000-00-00

 Sex:
 Male
 Entered:
 2021-04-22

Location: Pennsylvania

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK - / -

Administered by: Other Purchased by: ?

Symptoms: Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (narrow)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-04-09

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: Obesity

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210423780

Write-up: HEART ATTACK; This spontaneous report received from a consumer (company representative) concerned a 47 year old male. The patient"s height, and weight were not reported. The patient"s concurrent conditions included obese. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported,1 total administered on 07-APR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up would be requested for this case. No concomitant medications were reported. On 09-APR-2021,the patient died from heart attack. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: 20210423780 -covid-19 vaccine ad26.cov2.s-heart attack. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: HEART ATTACK

 VAERS ID: 1240574 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2021-04-08

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-04-22

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-08 Days after onset: 0 Permanent Disability? No Recovered? No Office Visit? No

Office Visit? No ER Visit? No ER or Doctor Visit? No Hospitalized? No

Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210424597

Write-up: DEATH; This spontaneous report received from a consumer concerned a female of unspecified age and unknown race and ethnicity. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN) dose was not reported, administered on 05-APR-2021 for prophylactic vaccination. The batch number was not reported, the company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 08-APR-2021, after 3 days of vaccination the patient died due to unknown cause. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: This is a spontaneous report of a female of unspecified age who died 3 days following the administration of the Janssen COVID-19 vaccine. Cause of death, details surrounding the death, the patient"s medical history and concomitant medications were not reported. There are insufficient details to make a meaningful medical assessment at this time.; Reported Cause(s) of Death: UNKNOWN CASE OF DEATH

 VAERS ID: 1241246 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 2021-04-01

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-04-22

Location: Mississippi

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death, Hemiplegia

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Conditions associated with central nervous system

haemorrhages and cerebrovascular accidents (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-16 Days after onset: 15 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? Yes Hospitalized? Yes, 7 days Extended hospital stay? No Previous Vaccinations:

Other Medications: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210436462

Write-up: PARALYZED LEFT SIDE OF THE BODY; DEATH; This spontaneous report received from a health care professional concerned a 29 year old female. Initial information received on 16-APR-2021, processed along with information received via telephone communication on 20-APR-2021. The patient"s weight was estimated about 200 pounds (reported as overweight but healthy). The patient's height and medical history were not reported. The patient had a baby in JAN-2021 and had a epidural at the time of birth. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN) dose, start therapy date were not reported, 1 total for prophylactic vaccination. The vaccination site was not reported. No concomitant medications were reported. The reporter, which is a health care professional, reported that the patient"s (the reporter"s cousin) death cause could be JANSSEN COVID-19 vaccine. The reporter said that the patient was fine without symptoms for one week after her scheduled vaccine. As per the reporter, the patient received the JANSSEN COVID-19 vaccine approximately 2 weeks ago (the patient was scheduled and her family assumed she went and received the vaccine). The reporter said that one week after the vaccine date the patient went to get her hair done, and when the patient sat on the chair, she suddenly could not move her left side. Ambulance/emergency room was called and the patient was taken to the hospital. The patient was in the hospital about a week and then passed away. An autopsy was performed but results were pending. The reporter had no details regarding imaging studies or laboratory values (platelet counts, D-dimer or fibrinogen), and does not know anything about the hospital course. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died on 16-APR-2021, and the outcome of paralyzed left side of the body was not reported. This report was serious (Death, and Hospitalization Caused / Prolonged).; Sender"s Comments: V0: This is a spontaneous report of a 29-year-old female who developed sudden hemiplegia approximately one week after receiving the Janssen COVID-19 vaccine, was hospitalized and died one week later. The patient had a history of being overweight, and was approximately 3 months post-partum. No medical history or concomitant medications were reported. The hospital details and cause of death were not provided. There are insufficient details to make a meaningful medical assessment at this time. Additional information has been requested. The case will be assessed further when additional information is received.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1245392 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 2021-04-13

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-04-23

Location: Texas

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route | ı |
|--|------------|--------------|---|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       | ı |

Administered by: Unknown Purchased by: ? Symptoms: Death, Fatigue, Vaccination site pain

SMQs:

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-04-13 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:

Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event (No reported medical history)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: arm was really sore; felt tired; passed away / she was dead; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEATH (passed away / she was dead) in a 71-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient"s past medical history included No adverse event (No reported medical history). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced VACCINATION SITE PAIN (arm was really sore) and FATIGUE (felt tired). The patient died on 13-Apr-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, VACCINATION SITE PAIN (arm was really sore) and FATIGUE (felt tired) outcome was unknown. No treatment information was provided. No concomitant medications was provided. Reporter did not allow further contact; Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1245485 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-04-23

Location: California

Vaccination / Manufacturer | Lot / Dose | Site / Route | COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1 | -/ OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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: No adverse event

Allergies:

Diagnostic Lab Data:

CDČ Split Type: USMODERNATX, INC.MOD20210

Write-up: death after 1 dose of vaccine; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (death after 1 dose of vaccine) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient"s past medical history included No adverse event. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. This spontaneous case was reported by a consumer and describes the occurrence of DEATH (death after 1 dose of vaccine) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient"s past medical history included No adverse event. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. Not Provided The reporter stated that she was not sure of the vaccine name that the patient used.; Sender"s Comments: This is a male patient of unknown age, who received mRNA-1273 Vaccine and died on an unknown date after receiving first dose of vaccine. No medical hx or conmeds were provided. The fatal outcome may be related to the patient"s pre-existing comorbidities Very limited information has been reported at this time. Further information is expected.; Reported Cause(s) of Death: death after 1 dose of vaccine

 VAERS ID: 1249208 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 2021-04-01

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-04-23

Location: Illinois

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN 042A21A / UNK
 - /

Administered by: Other Purchased by: ?

Symptoms: Blood glucose abnormal, Blood glucose increased, Gastrointestinal haemorrhage

SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Hyperglycaemia/new onset diabetes mellitus (narrow), Gastrointestinal haemorrhage (narrow),

Ischaemic colitis (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 Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Non-insulin-dependent diabetes mellitus

Allergies:
Diagnostic Lab Data: Test Name: Blood sugar abnormal; Result Unstructured Data: 475 mg/dL, 475 mg/dL

CDC Split Type: USJNJFOC20210424418

Write-up: HIGH BLOOD SUGAR; GI BLEED; This spontaneous report received from a consumer concerned a 71 years old female. The patient"s height, and weight were not reported. The patient"s past medical history included NIDDM (Non-Insulin-Dependent Diabetes Mellitus Diabetes). The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: 042A21A, expiry: 21-JUN-2021) dose was not reported, 1 total administered on 05-APR-2021 at left arm for prophylactic vaccination. No concomitant medications were reported. In APR-2021, the patient experienced GI (gastrointestinal) bleed. On an unspecified date, the patient experienced high blood sugar. It was reported that the reporter was not sure if the GI (gastrointestinal) bleed was just coincidence because the patient passed so soon after getting the covid-19 vaccine ad26.cov2.s. The patient had to go to her Doctor to get an unknown shot on the day of or close to the day of the vaccine, probably insulin because the patient had a 475 blood sugar. Laboratory data (dates unspecified) included: Blood sugar abnormal (NR: not provided) 475 mg/dL. On an unspecified date the patient died from GI (gastrointestinal) bleed. Patient was lying there for a while. Patient had been bleeding when it was discovered on 11-APR-2021 that she had expired. Coroner"s report said it was from GI (gastrointestinal) bleed. An autopsy was not performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of GI (gastrointestinal) bleed on an unspecified date, and the outcome of high blood sugar was not reported. This report was serious (Death).; Sender"s Comments: covid-19 vaccine ad26.cov2.s-GI bleed. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s) has an unknown/unclear temporal relationship, is unlabeled, and has u

 VAERS ID: 1249228 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-04-23

Location: Florida

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK - / -

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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:** Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210426837

Write-up: DEATH; This spontaneous report received from a physician via a company representative concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, once total, administered on 2021 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, three days after vaccination, the patient died of unknown cause. It was unknown, whether autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1249255 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-04-23

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK - / -

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210428967

Write-up: DIED IN SLEEP; This spontaneous report received from a patient via a company representative concerned a female of unspecified age. The patient"s weight, height, and medical history were not reported. Patient had children. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN, expiry: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Company is unable to perform follow-up to confirm batch/lot number. No concomitant medications were reported. On an unspecified date, the patient died in her sleep from an unknown cause of death. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death). This case, from the same reporter is linked to 20210429895.; Sender"s Comments: V0: 20210428967-COVID-19 VACCINE AD26.COV2.S- Died in sleep. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1249260 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2021-04-14

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-04-23

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death
SMQs:
Life Threatening? No
Birth Defect? No

Died? Yes
Date died: 2021-04-14
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:
Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210429218

Write-up: DIED; This spontaneous report received from a consumer via a company representative concerned a female of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 14-APR-2021, the patient died due to unknown cause. An autopsy was not performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210429218 - COVID-19

VACCINE AD26.COV2.S- Died. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1249269</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-04-04 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-04-23

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Purchased by: ?

Administered by: Other

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-04 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:** 

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210429895

Write-up: DIED IN SLEEP: This spontaneous report received from a consumer via social media concerned a 42-year-old male. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry date: unknown) with unknown dose, on unspecified date for prophylactic vaccination. The batch number was not reported, back in military date in the course of dath was unknown. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This case was linked to 20210428967 (same reporter) This report was serious (Death).; Sender's Comments: V0:20210429895-COVID-19 VACCINE AD26.COV2.S- Died in sleep. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1249280</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Entered: 2021-04-23 Male Sex:

Location: Florida

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Coronary artery occlusion

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210431438

Write-up: HEART ATTACK FROM BLOOD CLOT, This spontaneous report received from a patient via a company representative concerned a Not Hispanic or Latino and Asian male of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient experienced heart attack from blood clot and the patient died. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death). Sender"s Comments: V0: This is an Asian male, unspecified age, who experienced a heart attack from a blood clot on an unspecified date after receiving the covid-19 vaccine ad26.cov2.s also on an unspecified date. No other details given. The information provided precludes a meaningful medical assessment. Additional information will be requested.; Reported Cause(s) of Death: DEATH

 VAERS ID: 1249559 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 2021-04-08

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-04-23

Location: New Jersey

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 -/ OT

Administered by: Unknown Purchased by: ?

Symptoms: Cardiac arrest, Pulmonary embolism, Respiratory distress

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (narrow), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Embolic and thrombotic events, venous (narrow), Acute central respiratory depression (broad), Cardiomyopathy (broad), Hypersensitivity (broad), Respiratory failure (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-11 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: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Lipid metabolism disorder NOS

Allergies:

Diagnostic Lab Data

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: respiratory distress; cardiac arrest; pulmonary emboliasm; This spontaneous case was reported by a consumer and describes the occurrence of RESPIRATORY DISTRESS (respiratory distress), CARDIAC ARREST (cardiac arrest) and PULMONARY EMBOLISM (pulmonary emboliasm) in a 76-year-old female patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Lipid metabolism disorder NOS. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 08-Apr-2021, the patient experienced RESPIRATORY DISTRESS (respiratory distress) (seriousness criterion death), CARDIAC ARREST (cardiac arrest) (seriousness criterion death) and PULMONARY EMBOLISM (pulmonary emboliasm) (seriousness criterion death). The patient died on 11-Apr-2021. It is unknown if an autopsy was performed. Not Provided For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. NO treatment or Concomitant medication were provided. Company Comment This is a case of sudden death in a 76-year-old female patient with a history of Lipid metabolism disorder, who died (date unknown) of respiratory distress, cardiac arrest and PULMONARY EMBOLISM after receiving first dose of vaccine. Very limited information has been provided at this time.

 VAERS ID: 1249697 (history)
 Vaccinated: 2021-04-09

 Form:
 Version 2.0
 Onset: 0000-0-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-04-24

Location: Virginia

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/2        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: <u>Intentional self-injury</u> SMQs:, Suicide/self-injury (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-18 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: No adverse event

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: passed away from self inflicted injury; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by an other health care professional (subsequently medically confirmed) and describes the occurrence of INTENTIONAL SELF-INJURY (passed away from self inflicted injury) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient"s past medical history included No adverse event. On 09-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced INTENTIONAL SELF-INJURY (passed away from self inflicted injury) (seriousness criterion death). The patient died on 18-Apr-2021. The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided. Action taken with mRNA-1273 in response to the event was not applicable. Reporter did not allow further contact; Sender"s Comments: Patient died of an unknown cause from a self-inflicted injury nine days after receiving second dose of Moderna Vaccine. Very limited information regarding this event has been provided at this time. Further information can not be requested.; Reported Cause(s) of Death: cause of death unknown

 VAERS ID: 1253991 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-04-24

Location: Unknown

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK
 - /

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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 Visit? No ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies: Diagnostic Lab Data: CDC Split Type:

Write-up: DEATH; This spontaneous report received from a consumer concerned two patients unspecified age and sex. This report received via social media.. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) dose, start therapy date were not reported, 1 total for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. It was reported that two people died recently after the vaccine. The cause of death was unknown. It was unspecified if an autopsy was performed The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: -covid-19 vaccine ad26.cov2.s-death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1254024 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-04-24

Location: Michigan

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | - / UNK    | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Completed suicide, Tinnitus

SMQs:, Suicide/self-injury (narrow), Hearing impairment (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 0000-00-00 Permanent Disability? No Recovered? 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:

CDC Split Type:

Write-up: committed suicide; ringing in his ears; This spontaneous case was reported by a consumer and describes the occurrence of COMPLETED SUICIDE (committed suicide) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced COMPLETED SUICIDE (committed suicide) (seriousness criterion death) and TINNITUS (ringing in his ears). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, TINNITUS (ringing in his ears) outcome was unknown. Concomitant medications were not reported; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1254028 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Male
 Entered:
 2021-04-24

Location: Pennsylvania

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | - / UNK    | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death, Hypotension, Thrombosis
SMQs:, Anaphylactic reaction (broad), Neuroleptic malignant syndrome (broad), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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: No adverse event

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATXINC.MOD2021083

Write-up: Patient passed away; patient had blood clots in his brain/ Legs/ Lungs/ Arms; Severe hypotension; This spontaneous case was reported by a physician (subsequently medically confirmed) and describes the occurrence of DEATH (Patient passed away), THROMBOSIS (patient had blood clots in his brain/ Legs/ Lungs/ Arms) and HYPOTENSION (Severe hypotension) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The patient"s past medical history included No adverse event. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEATH (Patient passed away) (seriousness criterion death), THROMBOSIS (patient had blood clots in his brain/ Legs/ Lungs/ Arms) (seriousness criterion death) and HYPOTENSION (Severe hypotension) (seriousness criterion death). The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Treatment information was not provided. Company comment: This case concerns the death of a patient of unknown age and gender after administration of mrna-1273 ()LOT UNKNOWN). Very limited information regarding this event/s has been provided at this time. Further information has been requested. Critical details such as the mRNA-1273 date of administration, onset of any signs and symptoms, and date of death is lacking.; Sender"s Comments: This case concerns the death of a patient of unknown age and gender after administration of mrna-1273 ()LOT UNKNOWN). Very limited information regarding this event/s has been provided at this time. Further information has been requested. Critical details such as the mRNA-1273 date of administration, onset of any signs and symptoms, and date of death is lacking.; Reported Cause(s) of Death: Unknown cause of death

**VAERS ID:** <u>1255617</u> (history) Vaccinated: 2021-03-26 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-04-25

Location: New Hampshire

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EL9269 / 1

Administered by: Senior Living Purchased by: ?

Symptoms: Cardiac failure congestive, Hypotension, Hypoxia SMQs:, Cardiac failure (narrow), Anaphylactic reaction (broad), Asthma/bronchospasm (broad), Neuroleptic malignant syndrome (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Cardiomyopathy (broad), Eosinophilic pneumonia (broad), Respiratory failure (broad), Infective pneumonia (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

**Current Illness:** 

ER or Doctor Visit? Yes Hospitalized? Yes, ? days Extended hospital stay? No

**Previous Vaccinations:** Other Medications:

**Preexisting Conditions:** Allergies:

Diagnostic Lab Data: CDC Split Type:

Write-up: she ended up passing away in the hospital, her diagnosis there was hypoxia and acute CHF; she ended up passing away in the hospital, her diagnosis there was hypoxia and acute CHF; hypotensive; This is a spontaneous report from a contactable Nurse. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on 26Mar2021 (Lot Number: EL9269; Expiration Date: 01May2021) as single dose for covid-19 immunisation. The patient"s medical history and concomitant medications were not reported. The patient sent to the ER hypoxic, hypotensive, short of breath, she ended up passing away in the hospital, her diagnosis there was hypoxia and acute CHF (Congestive heart failure). Serious: No. The patient died on an unspecified date. It was not reported if an autopsy was performed.; Sender"s Comments: Based on the information available, a causal association between BNT162B2 and the reported events cannot be excluded. However, details on the patent"s age, medical history, drug-event temporal relationship, clinical course of the event and relevant test results would allow for a meaningful medical assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: she ended up passing away in the hospital, her diagnosis there was hypoxia and acute CHF; she ended up passing away in the hospital, her diagnosis there was hypoxia and acute CHF

VAERS ID: <u>1255618</u> (<u>history</u>) Vaccinated: 2021-03-26 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-04-25

Location: New Hampshire

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EL9269 / 1 | -/-          |

Administered by: Senior Living Purchased by: ?

Symptoms: Cerebral artery occlusion, Cerebrovascular accident

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? Yes, ? days Extended hospital stay? No Previous Vaccinations: Other Medications: **Current Illness:** 

**Preexisting Conditions:** Allergies:

Diagnostic Lab Data:

CDC Split Type:

Write-up: I have another male (patient) who had an acute CVA we send him to the hospital he had acute CVA, he had a right artery occlusion, he passed away; I have another male (patient) who had an acute CVA we send him to the hospital he had acute CVA, he had a right artery occlusion, he passed away; This is a spontaneous report from a contactable Nurse (Registered nurse with title of Infection Preventionist). A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 26Mar2021 (Lot Number: EL9269; Expiration Date: 01May2021) as single dose for COVID-19 immunization. The patient s medical history and concomitant medications were not reported. The patient had an acute CVA and was sent him to the hospital he had acute Cerebrovascular accident (CVA), he had a right artery occlusion, he passed away. The patient died on an unspecified date in 2021. It was not reported if an autopsy was performed.; Sender's Comments: The information currently available is very limited. There is no sufficient evidence that the reported events may be related to administration of BNT162B2. Of note, medical history and concomitant medications were not provided to determine pre-existing risk factors or conditions that may have led to the events. Case will be re-assess once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAS, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: patient had an acute CVA and was sent him to the hospital he had acute CVA, he had a right artery occlusion; patient had an acute CVA and was sent him to the hospital he had acute CVA, he had a right artery occlusion

VAERS ID: <u>1255628</u> (<u>history</u>) Vaccinated: 2021-03-28 Version 2.0 Form: Onset: 2021-04-14 Age: Days after vaccination: Sex: Female Submitted: 0000-00-00 Location: Missouri Entered: 2021-04-25

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

Administered by: Unknown Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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:

CDC Split Type: USPFIZER INC2021416881

Write-up: died yesterday due to blood clots; This is a spontaneous report from a contactable consumer. A 55-year-old female patient (mother) received the first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 28Mar2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and the patient"s concomitant medications were not reported. The patient experienced blood clots and died due to the event. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: died yesterday due to blood clots

VAERS ID: <u>1255703</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 2021-04-25 Female Entered: Sex:

Location: Unknown

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

Administered by: Unknown Purchased by: ? Symptoms: Death, Portal vein thrombosis, Thrombocytopenia

SMQs:, Haematopoietic thrombocytopenia (narrow), Systemic lupus erythematosus (broad), Embolic and thrombotic events, venous (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:

CDC Split Type: USPFIZER INC2021425367

Write-up: Patient died; portal vein thrombosis; thrombocytopenia; This is a spontaneous report from a contactable physician. A 50-years-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on an unspecified date as SINGLE DOSE for covid-19 immunisation. The patient medical history was not reported. The patient"s concomitant medications were not reported. The patient experienced portal vein thrombosis and thrombocytopenia 2 weeks after first Pfizer vaccine. Patient died. The patient died on an unspecified date. It was not reported if an autopsy was performed. The outcome of the events portal vein thrombosis and thrombocytopenia was unknown. The outcome of the event unknown cause of death was fatal. Information on the lot/ batch number has been requested.; Sender"s Comments: The information available in this report is limited and does not allow a medically meaningful assessment of the case. Based on temporal association, a causal association between the reported events and BNT162B2 cannot be fully excluded. Case will be reassessed when additional information is available including medical history and concomitant drug information. The impact of this report on the benefit/risk profile of the Pfizer

product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAS, Ethics Committees, and investigators, as appropriate.; Reported Cause(s) of Death: Patient died

VAERS ID: <u>1255705</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-04-25

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021426236

Write-up: died after taking the vaccine; This is a spontaneous report from a contactable consumer reporting on behalf of the mother. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date, at single dose, for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient died after taking the vaccine, on an unspecified date. It was unknown if an autopsy was performed. Cause of death was unknown. The reporter believed that it was from the vaccine and ICU nurse said, doctor questioned about what the patient got sick and reporter just wanted to report it. Information about lot/batch number has been requested.; Reported Cause(s) of Death: died after taking the vaccine

VAERS ID: <u>1255731</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 2021-04-25 Sex: Male Entered:

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: COVID-19, Drug ineffective, Organ failure, Thrombosis

SMQs:, Lack of efficacy/effect (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, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (broad), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021432758

Write-up: Hot a fever then full blown covid; Hot a A contactable consumer reported that a male patient of an unspecified age received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Previously on an unknown date, the patient received the first dose of BNT162B2 vaccine. On an unspecified date, the patient experienced hot a fever then full blown COVID, blood clot and organ failure leading to patient death on an unknown date. It was not reported if an autopsy was performed. No follow-up attempts are possible. Information about lot/batch number cannot be obtained. No further information is expected; Reported Cause(s) of Death: Drug ineffective; Covid-19; Blood clot; Organ failure

Vaccinated: 2021-03-30 **VAERS ID: 1255738** (history) Version 2.0 Form: Onset: 0000-00-00 Age: Submitted: 0000-00-00 Sex: Male Entered: 2021-04-25

Location: Unknown

| Vaccination / Manufacturer  | Lot / Dose    | Site / Route |
|---|---------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH    | - / UNK       | -/-          |
| UNK: VACCINE NOT SPECIFIED (NO BRAND NAME) / UNKNOWN MANUFACTURER | 2101912 / UNK | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death, Dyspnoea, Illness, Myalgia, Nausea, Pain, Vomiting

SMQs:, Rhabdomyolysis/myopathy (broad), Anaphylactic reaction (broad), Acute pancreatitis (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Cardiomyopathy (broad), Eosinophilic pneumonia (broad), Tendinopathies and ligament disorders (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? Yes, ? days Extended hospital stay? No

Previous Vaccinations:
Other Medications: ADEMPAS; AMLODIPINE BESILATE; XARELTO

Current Illness: Pulmonary arterial hypertension

**Preexisting Conditions:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021434134

Write-up: Nausea; Vomiting; Shortness of breath; Muscle aches; Extremely ill; Body aches; expired; This is a report from a contactable consumer based on the information received by Pfizer. (Manufacturer Report Number: UNT-2021-006444). A 76-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for Covid-19 immunization; and treprostinil sodium (TYVASO, strength: 0.6, mg/ml), via resp inhalation (reported as via inhalation route) from 30Mar2021 (Batch/Lot Number: 2101912: Expiration Date: 31Jan2022) to an unspecified date, at 18-54 ug, four times a day (QID) for primary pulmonary arterial hypertension. Medical history included ongoing pulmonary arterial hypertension. Concomitant medications included riociguat (ADEMPAS), amlodipine besilate, rivaroxaban (XARELTO); all taken for an unspecified indication, start and stop date were not reported. It was reported that the patient began therapy with IH Tyvaso (treprostinil sodium, concentration of 0.6 mg/ml) delivered by Tyvaso Inhalation Device (TD-300/A), on 30Mar2021 for primary pulmonary arterial hypertension. The current dose was reported as 18-54 ug (3-9 breaths), four times a day (QID) via inhalation (IH) route. On an unspecified date, the patient experienced nausea, vomiting, shortness of breath, muscle aches, extremely ill, and body aches. The patient was hospitalized in response to the events on an unspecified date. The outcome of events was unknown. On an unspecified date in 2021, the patient expired, and cause of death was not reported. The action taken in response to the events for treprostinil sodium was unknown. The patient died on an unspecified date in 2021. It was unknown if an autopsy was performed. The reporter's assessment of the causal relationship between the events with the suspect product was not provided at the time of this report. Since no determination has been received, the case is managed based on the company causality assessment. Case Comment/Senders Comment: The company has assessed the serious adverse event of death as not related to IH treprostinil and TD-300/A device. The event was likely due to progressive complications and life limiting nature of underlying PAH in this elderly patient. Information about lot/batch number has been requested.; Sender"s Comments: The information currently available is limited and does not allow a meaningful causality assessment for reported event of death (unknown cause); however, based solely on implied vaccine-event chronological association a causal relationship between this event and BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) cannot be completely excluded. The other reported events; Reported Cause(s) of Death: expired

VAERS ID: <u>1255744</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Entered: 2021-04-25 Unknown Sex:

Location: Unknown

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PEIZER-BIONTECH)) / PEIZER/BIONTECH | -/2        | - / -        |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021438418

Write-up: Deceased; This is a spontaneous report from a Pfizer. A non-contactable consumer reported that a patient of unspecified age and gender received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for COVID-19 immunization. The patient"s medical history and concomitant medications were not reported. The patient previously received bnt162b2 (BNT162b2), dose 1 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for COVID-19 immunization. Consumer reported that, "Amongst my coworkers about 50% were put down for two to three days and one person became deceased a few hours after the second shot." The patient died on an unspecified date. It was not reported if an autopsy was performed. No follow up attempts are possible; Information on the lot/batch number cannot be obtained.; Reported Cause(s) of Death: Deceased

Vaccinated: 0000-00-00 **VAERS ID:** <u>1255749</u> (history) Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: 2021-04-25 Sex: Unknown Entered:

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: COVID-19, Drug ineffective
SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021445170

Write-up: died after the second one when they had covid; died after the second one when they had covid; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose via an unspecified route of administration on an unspecified date (batch/lot number was not reported) as a single dose for COVID-19 immunisation. The patient "a medical history and concomitant medications were not reported. The patient died after the second one when they had Covid because there were too many antibodies on an unspecified date. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: died after the second one when they had covid; died after the second one when they had covid

VAERS ID: <u>1261835</u> (history) Vaccinated: 0000-00-00 Version 2.0 0000-00-00 Form: Onset: Submitted: 0000-00-00 Age: Unknown Entered: 2021-04-27 Sex:

Location: Ohio

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

Administered by: Unknown Purchased by: ?

Symptoms: Death, Injury

SMQs:, Accidents and injuries (narrow), Hostility/aggression (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

**Current Illness:** 

ER or Doctor Visit? No Hospitalized? No

**Previous Vaccinations:** Other Medications:

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021448793

Write-up: who is responsible and/or liable when a child is injured or dies during a COVID vaccine trial; who is responsible and/or liable when a child is injured or dies during a COVID vaccine trial; This is a spontaneous report from a contactable consumer or other non hcp. A child patient of an unspecified gender received bnt162b2 (BNT162B2), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for covid-19 immunisation. The patient medical history was not reported. The patient "s concomitant medications were not reported. It was reported that the consumer had searched the website and cannot find anywhere that states who is responsible and/or liable when a child is injured or dies during a COVID vaccine trial. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: who is responsible and/or liable when a child is injured or dies during a COVID vaccine trial

 VAERS ID: 1261836 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2021-04-01

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-04-27

Location: Michigan

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-04-01 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: Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021449093

Write-up: Mom Passed away last Tuesday; This is a spontaneous report from a Pfizer from a contactable consumer reported (patient"s child). A female patient of an unknown age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Lot number was not reported) as single dose for covid-19 immunisation. Medical history and concomitant medications were not reported. Patient passed away on an unspecified date in Apr2021 (reported as last tuesday). It was reported that patient"s child and entire family were scheduled to get second dose of Covid Vaccine on 29Apr2021. Clarified that they tested postive after first (1 st) dose. Patient (Mom) passed away last Tuesday. She was wondering about getting the second dose. The patient died on an unspecified date in Apr2021. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Mom Passed away last Tuesday

 VAERS ID: 1265871 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2021-04-01

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-04-28

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-01 Days after onset: 0 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No ER or Doctor Visit? No Hospitalized? No

Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210429719

Write-up: HEART ATTACK; This spontaneous report received from a consumer via a company representative concerned two patients. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on MAR-2021 (a month prior to this report) for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On APR-2021, two patients" suffered a heart attack addied. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, and Other Medically Important Condition). This case, from the same reporter is linked. Sender"s Comments: V0: COVID-19 VACCINE AD26.COV2.S - Heart Attack. This event is

considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: HEART ATTACK

VAERS ID: <u>1266077</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-04-28

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: COVID-19, Drug ineffective

SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021458298

Write-up: Had both vaccines and died from COVID-19 afterwards; Had both vaccines and died from COVID-19 afterwards; This is a spontaneous report from a contactable nurse. A 42-year-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), dose 1 and dose 2; both via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization. The patient"s medical history and concomitant medications were not reported. The patient had both vaccines and died from COVID-19 afterwards on an unspecified date. The patient did not have any known underlying health conditions or issues. The patient died on an unspecified date. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender"s Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. This impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Had both vaccines and died from COVID-19 afterwards; Had both vaccines and died from COVID-19 afterwards

VAERS ID: <u>1266078</u> (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Age: Submitted: 0000-00-00 Sex: Female Entered: 2021-04-28

Location: Arkansas

|  |     | Site / Route |
|--|-----|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | -/2 | -/-          |

Administered by: Pharmacy Purchased by: ? Symptoms: Dyspnoea, Pulmonary embo

SMQs:, Anaphylactic reaction (broad), Embolic and thrombotic events, venous (narrow), Acute central respiratory depression (broad), Pulmonary hypertension

(broad), Cardiomyopathy (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:

CDC Split Type: USPFIZER INC2021459420

Write-up: pulmonary embolism; short of breath; This is a spontaneous report from a non-contactable consumer via Pfizer sales representative. A 63-years-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient died of pulmonary embolism 2 days after 2nd vaccine dose. She had been short of breath the day after the shot, called the pharmacy where she"d received it, and they told her to go to ER. The reporter thought that she did not go to the ER, and then later died at home. It was unknown if an autopsy was performed. Outcome of the event short of breath at the time of death was unknown. No follow-up attempts are possible; Information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: pulmonary embolism

VAERS ID: 1269770 (history) Vaccinated: 2021-03-01 Form: Version 2.0 Onset: 2021-04-13

Age: Days after 43 vaccination: Sex: Male

Submitted: 0000-00-00 Location: Unknown Entered: 2021-04-29

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

Administered by: Unknown Purchased by: ?

Symptoms: Biopsy, Death, Dizziness, Fatigue, Seizure, X-ray, SMQs:, Systemic lupus erythematosus (broad), Anticholinergic syndrome (broad), Convulsions (narrow), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Vestibular disorders (broad), Generalised convulsive seizures following immunisation (narrow), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-13 Days after onset: 0 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: **Current Illness:** 

Preexisting Conditions: Comments: List of non-encoded Patient Relevant History: Patient Other Relevant History 1: None, Comment: no past medical issues

Allergies:

Diagnostic Lab Data: Test Name: biopsies; Test Result: Negative; Test Name: X-Rays; Test Result: Negative

CDC Split Type: USPFIZER INC2021456988

Write-up: seizures; dizziness; fatigue; passed away; This is a spontaneous report from a contactable Consumer. This Consumer reported for a 33-year-old male patient (friend) who deceased who received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number unknown), via an unspecified route of administration on an unknown date in Mar2021 at a single dose for COVID-19 immunization. The reporter wanted to know if there were any reports or information on patients having severe seizures or blood clotting, he was trying to find out for some information on similar adverse events that occurred with the Johnson & Johnson COVID vaccine, but from receiving the Pfizer-BioNTech COVID-19 vaccine the person that had the severe reaction went to the doctor and the doctor said it was highly unlikely from the vaccine. The reporter tried to look online for potential side effects, to help the family provide some type of (information about this). The reported stated the patient was very healthy, young 33 years old, never had a history of seizures, he had no past medical issues. He received second dose middle of march, he passed on 13Apr2021. On the third week after receiving second dose, he started experiencing dizziness and fatigue that later progress into seizures, he was admitted into the hospital, and was no longer under control. Doctors said was highly unlikely it was from the vaccine however every test came back negative; X-Rays, biopsies, everything negative. The patient deceased and outcome of the events was unknwon. Information on the Lot/Batch number has been requested.; Reported Cause(s) of Death: passed away

VAERS ID: <u>1269775</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-04-29

Location: Unknown

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PEIZER-BIONTECH)) / PEIZER/BIONTECH | -/UNK      | -/-          |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: 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:

CDC Split Type: USPFIZER INC2021465549

Write-up: dies hours after getting Covid-19 vaccine; This is a spontaneous report from a non-contactable consumer (Pfizer-sponsored program). A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; Lot Number: Unknown), via an unspecified route of administration on an unspecified date as SINGLE DOSE for covid-19 immunization. The patient medical history and concomitant medications were not reported. The patient experienced dies hours after getting covid-19 vaccine on an unspecified date. It was not reported if an autopsy was performed. The outcome of the event was fatal. No follow-up attempts are Possible; information about batch/ lot number cannot be obtained.; Reported Cause(s) of Death: dies hours after getting Covid-19 vaccine

 VAERS ID: 1269944 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-04-29

Location: Arizona

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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? Hospitalized? No

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210444879

Write-up: PASSED AWAY/ DEATH; This spontaneous report received from a consumer via company representative concerned a 70 year old female. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry date: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot number. No concomitant medications were reported. On an unspecified date, the patient passed away after receiving the vaccine. The patient died from an unknown cause of death. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0:-covid-19 vaccine ad26.cov2.s-death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1269961 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-04-29

Location: Pennsylvania

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 0000-00-00
Permanent Disability? No
Recovered? No

Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No

Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210450529

Write-up: DÉATH; This spontaneous report received from a pharmacist concerned a male of an unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, start therapy date were not reported,1 total, administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient who received the JANSSEN COVID-19 vaccine and passed away a few weeks later. It was not sure whether his other medical issues contributed to his death. The patient died from unknown cause of death. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: - COVID-19 VACCINE AD26.COV2.S - Death, This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1270907 (history)
 Vaccinated:
 2021-04-20

 Form:
 Version 2.0
 Onset:
 2021-04-26

Age: Days after Sex: Male vaccination: 6

Location: Michigan Submitted: 0000-00-00 Entered: 2021-04-29

| Vaccination / Manufacturer                                     |            | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EWO162 / 2 | -/SYR        |

Administered by: Unknown Purchased by: ?

Symptoms: Hyperhidrosis, Seizure

SMQs:, Neuroleptic malignant syndrome (broad), Systemic lupus erythematosus (broad), Convulsions (narrow), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Generalised convulsive seizures following immunisation (narrow), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-26 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: None Current Illness: Pre-diabetic high blood pressure

Preexisting Conditions: None

Allergies: None Diagnostic Lab Data: CDC Split Type:

Write-up: Sweatting and seizing

 VAERS ID: 1276385 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 2021-04-01

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-05-01

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / 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: 2021-04-01 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:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210430884

Write-up: MASSIVE STROKE; This spontaneous report received from a consumer concerned a female of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose was not reported, 1 total, administered in APR-2021 (about eight days prior to this report) for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. It was reported that, in APR-2021, the patient had a massive stroke and died. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: - Covid-19 Vaccine Ad26.Cov2.S - Massive Stroke. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: MASSIVE STROKE

 VAERS ID: 1276412 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-05-01

Location: Alabama

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death, Hospitalisation

SMQs:

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, 6 days

Extended hospital stay? No Previous Vaccinations: Other Medications:

Preexisting Conditions: Comments: Unknown

Allergies:

**Current Illness:** 

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210443181

Write-up: HOSPITALIZATION; DEATH; This spontaneous report received from a patient via a company representative concerned a female of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported, 01 total, for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. After receiving the vaccine, on an unspecified date, the patient was hospitalized. The patient died after 6 days of hospitalization. The reason of death was unknown. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome was fatal. This report was serious (Death, and Hospitalization Caused / Prolonged).; Sender"s Comments: V0:-JANSSEN COVID-19 VACCINE Ad26.COV2.S- Death, Hospitalization. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1276416 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2021-03-31

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-05-01

Location: Unknown

Vaccination / Manufacturer | Lot / Dose | Site / Route | COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | -/ UNK | -/ -

Administered by: Other Purchased by: ?

Symptoms: COVID-19 pneumonia, Cerebrovascular accident, Computerised tomogram, Fibrin D dimer, Fibrin D dimer increased, Gastric haemorrhage, Platelet count, SARS-CoV-2 test positive, Thrombocytopenia

SMQs:, Haematopoietic thrombocytopenia (narrow), Haemorrhage terms (excl laboratory terms) (narrow), Haemorrhage laboratory terms (broad), Systemic lupus erythematosus (broad), 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), Gastrointestinal haemorrhage (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Infective pneumonia (narrow), Opportunistic infections (broad), COVID-19 (narrow)

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? Yes, 12 days
Extended hospital stay? No

Previous Vaccinations:

Other Medications: EFFEXOR; ALBUTEROL [SALBUTAMOL]; AMLODIPINE

Current Illness: Asthma; Bipolar disorder; Depression; Hypertension Preexisting Conditions: Comments: No known allergies (NKDA)

Allergies:

Diagnostic Lab Data: Test Date: 202103; Test Name: Fibrin D dimer; Result Unstructured Data: high; Test Name: COVID-19 virus test positive; Result Unstructured Data: positive; Test Name: Platelet count; Result Unstructured Data: 86; Test Name: CAT scan; Result Unstructured Data: focal stroke; Test Name: CT scan; Result Unstructured Data: see comments; Comments: worsening large multi-focal left hemispheric stroke in multiple distributions.

CDC Split Type: USJNJFOC20210444500

Write-up: COVID-19 PNEUMONIA; STOMACH BLEEDING; THROMBOCYTOPENIA; MASSIVE STROKE; FIBRIN D DIMER HIGH; This spontaneous report received from a consumer (daughter of patient) via a Regulatory Authority [VAERS FDA 1218360] and concerned a 79 year old female. The patient's height, and weight were not reported. The patient's concurrent conditions included bi-polar, mild asthma, hypertension, and depression. The patient had no allergies and no known drug allergies. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: 1805020) dose was not reported, 1 in total administered on 30-MAR-2021 to left arm for prophylactic vaccination. Concomitant medications included amlodipine, salbutamol, and venlafaxine hydrochloride. The patient felt poorly after vaccination. The patient presented to emergency room with gastrointestinal upset, diarrhea, nausea, vomiting, fever and cough on unspecified date. The patient was sent home. On 31-MAR-2021, the patient was COVID-19 positive and was admitted to the hospital with Covid-19 pneumonia. The patient was on oxygen via nasal cannula. On 31-MAR-2021, the patient had high fibrin D dimer and patient had a stomach bleeding. The patient was worsening and was admitted to intensive care unit. On unspecified date, the patient developed arm weakness which progressed over days. On unspecified date in 2021, the patient had massive stroke and passed in the morning. The stroke did not show the signs of hemorrhage. The distribution of stroke was multifocal and could suggest thrombus. The patient developed thrombocytopenia in the last 24 hours of life. The initial computerized tomogram (CT) noted one area of focal stroke. The second CT showed worsening large multi-focal left hemispheric stroke in multiple distributions. This was an acute development over the previous CT. On 26-APR-2021, physician reported the radiology report was not clear whether the Cerebroventricular accident (CVA), the patient had experienced was a thrombotic event as the patient had areas on the CT scan that could be old CVAs and in addition the patient had hypertension. The patient developed thrombocytopenia on day 12 while she was treated with heparin. D-dimer was elevated on admission and throughout the hospitalization and the anti- PF4 antibodies were not able to be performed from the sample available. As per the physician, the radiology report was not clear whether the CVA the subject had experienced was a thrombotic event as the subject had areas on the CT scan that could be old CVAs and in addition the subject had a hypertension. The subject develop thrombocytopenia on day 12 while she was treated with heparin. Additional laboratory test included platelet count was 157 and dropped to 86 on unspecified date. The patient was treated with heparin. Laboratory data (dates unspecified) included: Fibrin D dimer (NR: not provided) high. The patient died on unspecified date. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of covid-19 pneumonia, massive stroke and thrombocytopenia on an unspecified date, had not recovered stomach bleeding, and fibrin d dimer high. This report was serious (Death, Hospitalization Caused / Prolonged, Other Medically Important Condition, and Life Threatening). Additional information was received from physician on 26-APR-2021 via telephone log from a company employee. The following information was updated and incorporated into the case narrative: reporters added (physician and contact), due diligence updated and physicians statement.; Sender"s Comments: V1: The follow up information in this version is regarding addition of reporters (physician and contact) physicians statement and due diligence. This updated information does not alter the causality of previously reported events. This 79-year-old hypertensive female died from massive stroke after being hospitalized from COVID-19 pneumonia 1 day after receiving Janssen COVID-19 vaccine for the prevention of symptomatic SARS-CoV-2 virus infection. On admission to hospital the patient had positive COVID-19 test. She also had a high fibrin D-dimer throughout the hospitalization and developed a stomach bleeding. Other symptoms included arm weakness that progressed over a couple of days. Initial CT scan noted one area of focal stroke; the second CT scan showed worsening large multi-focal left hemispheric stroke in multiple distributions. Platelet count was initially 157 and dropped to 86 on an unspecified date. The patient was treated with heparin. The event of stroke is confounded by the underlying hypertension and COVID-19 disease; and the event of thrombocytopenia is confounded in COVID-19 infection. The information available precludes a complete and meaningful assessment. However, considering the temporal plausibility and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine contribution cannot be excluded. Additional information has been requested.; Reported Cause(s) of Death:

## MASSIVE STROKE; COVID-19 PNEUMONIA; THROMBOCYTOPENIA

 VAERS ID: 1276430 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 2021-04-01

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-05-01

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK - / -

Administered by: Other Purchased by: ?

Symptoms: Platelet count, Thrombocytopenia, Thrombosis

SMQs:, Haematopoietic thrombocytopenia (narrow), Systemic lupus erythematosus (broad), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-01 Days after onset: 0 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: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data: Test Date: 202104; Test Name: Platelet count; Result Unstructured Data: Low platelets

CDC Split Type: USJNJFOC20210446964

Write-up: RARE BLOOD CLOT; LOW PLATELETS; This spontaneous report received from a consumer concerned about 50 years old female. The reporter obtained the information from news/media. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total administered on APR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unknown date in APR-2021 after vaccination, the patient experienced severe headache, abdominal pain, leg pain and shortness of breath. The patient developed a rare blood clot and low platelets on an unspecified date in APR-2021, within two weeks of receiving JANSSEN COVID-19 vaccine. The patient was hospitalized on an unspecified date in APR-2021. On APR-2021, the patient died from blood clot. The reporter was not sure whether the events was related to the vaccination. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of rare blood clot on APR-2021, and had not recovered from low platelets. This report was serious (Death, and Hospitalization Caused / Prolonged).; Sender"s Comments: V0: This female patient in her 50s was reported to have developed a rare blood clot and low platelets within two weeks of receiving JANSSEN COVID-19 vaccine. On an unspecified date, symptoms reported were severe headache, abdominal pain, leg pain and shortness of breath. The patient was hospitalized on an unspecified date and subsequently died from blood clot. It was not known if autopsy was performed. No other details reported. The information available precludes a complete and meaningful assessment. However, considering the temporal relationship and recently evolving theories in the literature about COVID infections and vaccinations, potential vaccine

 VAERS ID: 1276508 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-01

Location: Pennsylvania

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Adverse reaction, Death

SMQs:

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:

Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210452419

Write-up: DEATH; UNSPECIFIED COMPLICATIONS; This spontaneous report received from a consumer concerned multiple patients. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported, once total, for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. The six patients died on unspecified date due to unknown cause. It was also stated that these patients had some unspecified complications. It was unknown, whether autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patients died of death on an unspecified date, and the outcome of complications was not reported. This report was serious (Death).; Sender's Comments: V0: 20210452419-covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with

the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1276513 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Submitted: 0000-00-00

 Sex: Male Entered: 2021-05-01

Location: New York

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: <u>Death</u>, <u>Malaise</u> SMQs: 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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210452604

Write-up: DEATH; FELT SICK; This spontaneous report received from a consumer (social media) via a company representative concerned a male of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, Expiry date: Unknown) frequency 1 total, dose and start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, after getting the vaccine, the patient felt sick. On the next dat, the patient was deceased. The cause of death was not reported. It was unknown whether autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: -covid-19 vaccine ad26.cov2.s -Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1276522 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-05-01

Location: Texas

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Adverse reaction, Death

SMQs:

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:

Preexisting Conditions: Comments: Unknown Allergies:

Diagnostic Lab Data:

**Current Illness:** 

CDC Split Type: USJNJFOC20210453204

Write-up: DEATH, COMPLICATIONS FROM THE VACCINE; This spontaneous report received from a consumer concerned an adult male. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported, once total for prophylactic vaccination. The batch number was not reported. In this scenario follow-up is not required to obtain batch/lot numbers. No concomitant medications were reported. On an unspecified date, two months after vaccination, the patient died of unknown cause. The patient death occurred in hospital. It was also stated that patient had some unspecified complications. IT was also reported that, patient was healthy man in his early sixties. It was unknown, whether autopsy was performed or not. On an unspecified date, the subject experienced death, and complications from the vaccine. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of death on an unspecified date, and the outcome of complications from the vaccine was not reported. This report was serious (Death).; Sender"s Comments: V0:-covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s); Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1276535 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-05-01

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Symptoms: Death Purchased by: ?

SMQs:

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: Unknown cause of death

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210453979

Write-up: DEATH; This spontaneous report received from a consumer via social media concerned a female of unspecified age. The patient"s height, and weight were not reported. The patient"s past medical history included unknown cause of death. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN) 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. Consumer posted on social media that the J and J vaccine killed her mother and they are waiting on her autopsy. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0- 20210453979 - Covid-19 vaccine ad26.cov2.s-death. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.

 VAERS ID: 1276579 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2021-04-26

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-05-01

Location: Florida

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death, Malaise, Unresponsive to stimuli

SMQs:, Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Guillain-Barre syndrome (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Hypotonic-hyporesponsive episode (broad), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-27 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:

Preexisting Conditions: Medical History/Concurrent Conditions: Anticoagulant therapy

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210456243

Write-up: DEATH; NON-RESPONSIVE; NOT FEELING WELL; This spontaneous report received from a consumer concerned a male of unspecified age. The patient"s height, and weight were not reported. The patient"s past medical history included on blood thinners. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, 1 total, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. The consumer had called and stated that their father had passed away and had received JANSSEN covid 19 vaccine 10 to 12 days before. On 26-Apr-2021 the patient was non responsive, lethargic, seemed out of it and was not feeling well. The patient was on blood thinners. On 27-Apr-2021 the consumer's father had passed away, the consumer was still waiting for the cause of death. An autopsy was not performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died on 27-APR-2021, and the outcome of non-responsive, not feeling well was not reported. This report was serious (Death, Medically significant).; Sender"s Comments: 20210456243-covid-19 vaccine ad26.cov2.s -Death, Non responsive. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: CAUSE OF DEATH UNKNOWN

 VAERS ID: 1276582 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-01

Location: New Jersey

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs:

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: Comments: unknown cause of death.

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210456256

Write-up: DEATH; This spontaneous report received from a consumer concerned a patient of unspecified age and sex. The patient"s height, and weight were not reported. The patient"s pre-existing medical conditions included unknown cause of death. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for 1 total administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient received the Janssen COVID-19 vaccine and then died 15 days later. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death)..; Sender"s Comments: V0-20210456256- COVID-19 VACCINE AD26.COV2.s.adverse effect. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1276796 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-05-01

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (broad)

Life Threatening? No Birth Defect? No Died? You

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:

**CDC** Split Type:

Write-up: blood clot; This spontaneous case was reported by a consumer and describes the occurrence of THROMBOSIS (blood clot) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage form. On an unknown date, the patient experienced THROMBOSIS (blood clot) (seriousness criterion death). The reported cause of death was Clot blood. It is unknown if an autopsy was performed. The reporter stated that his wife had recently passed away from a blood clot after receiving a second dose of the Moderna COVID-19 vaccine. Treatment information was not provided. Very limited information regarding this event has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this

 VAERS ID: 1279428 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2021-04-01

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-05-02

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death, Rash, Syncope

**SMQs:**, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad), Hypotonic-hyporesponsive episode (broad), Hypersensitivity (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Hypoglycaemia (broad)

Life Threatening? No

Birth Defect? No Died? Yes

Date died: 2021-04-01
Days after onset: 0
Permanent Disability? No.

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:

Other Medications: Current Illness: Preexisting Conditions:

Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021465752

Write-up: fainted; rash; died 2 weeks ago after receiving the covid vaccine/ passed away; This is a spontaneous report received from a non-contactable consumer reporting on behalf of the patient via a Pfizer-sponsored program. A female patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), first and second dose, both via unspecified route of administration on unspecified dates (Batch/Lot number was not reported) as a single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The reporter mentioned that she had a friend that died 2 weeks ago after receiving the COVID vaccine. They are going to search for the cause of death (autopsy) because after the vaccine she had a rash, fainted, and went to the hospital, and she recovered (unspecified dates). But after a month or so, she passed away. The reporter mentioned that the patient was born very unhealthy person. Outcome of rash and fainted was recovered on unspecified dates. The patient died in Apr2021. It was unknown if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: died 2 weeks ago after receiving the covid vaccine/ passed away

 VAERS ID: 1279433 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-05-02

Location: Pennsylvania

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

Administered by: Unknown Purchased by: ? Symptoms: Heart rate, Heart rate increased

SMQs:, Neuroleptic malignant syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Dehydration (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 VISIT? NO
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:

Allergies:

Diagnostic Lab Data: Test Name: heartbeat; Result Unstructured Data: Test Result:racing CDC Split Type: USPFIZER INC2021467483

Write-up: racing heartbeat; This is a spontaneous report from a contactable consumer via Medical information team. A female patient of an unspecified age (reported as age: 55, unit: unknown) received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as SINGLE DOSE for COVID-19 immunization. The patient"s medical history and concomitant medications were not reported. The patient died a few days later after getting vaccinated from a racing heartbeat. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information about batch/lot number has been requested.; Reported Cause(s) of Death: racing heartbeat

 VAERS ID: 1279434 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-05-02

Location: Utah

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PEIZER-BIONTECH)) / PEIZER/BIONTECH | -/2        | - / -        |

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs: 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:

CDC Split Type: USPFIZER INC2021467484

Write-up: Died after the 2nd dose; This is a spontaneous report from a contactable consumer from a Pfizer-sponsored program. A 39-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunization. Medical history and concomitant medications were not reported. The patient previously received the first dose of BNT162B2 on an unspecified date for COVID-19 immunization. The patient died after the 2nd dose on an unspecified date. The cause of death was not reported. It was not reported if an autopsy was performed. Information on the batch/lot number has been requested.; Reported Cause(s) of Death: died after the 2nd dose

 VAERS ID: 1284660 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-04

Location: Florida

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK - / -

Administered by: Other Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210456400

Write-up: CLOTS; This spontaneous report received from a physician concerned a patient of unspecified age and sex. The patient"s weight, height and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) frequency one total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient died due to clot. It was unknown if autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died to clots on an unspecified date. This report was serious (Death). This case, from the same reporter is linked to 20210457363.; Sender"s Comments: V0: 20210456400-Covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: CLOTS

 VAERS ID: 1284731 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-05-04

Location: New York

| Vaccination / Manufacturer                     | Lot / | Dose | Site / | Route |
|--|-------|------|--------|-------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA |       | / 1  | - /    | OT    |

Administered by: Unknown Purchased by: ?

Symptoms: General physical health deterioration, Product dose omission issue

SMQs:, Medication errors (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: General physical health deterioration (It is reported that patient had history of many medical conditions, unspecified.); Rehabilitation therapy (Patient was in rehabilitation center)

Allergies:

Diagnostic Lab Data:

CDČ Split Type: USMODERNATX, INC.MOD20210

Write-up: Died due to his many medical conditions; could not administer second vaccine; This spontaneous case was reported by a pharmacist (subsequently medically confirmed) and describes the occurrence of GENERAL PHYSICAL HEALTH DETERIORATION (Died due to his many medical conditions) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient"s past medical history included Rehabilitation therapy (Patient was in rehabilitation center) and General physical health deterioration (It is reported that patient had history of many medical conditions, unspecified.). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine)

(Intramuscular) 1 dosage form. On an unknown date, the patient experienced GENERAL PHYSICAL HEALTH DETERIORATION (Died due to his many medical conditions) (seriousness criterion death) and PRODUCT DOSE OMISSION ISSUE (could not administer second vaccine). The patient died on an unknown date. The reported cause of death was medical conditions. It is unknown if an autopsy was performed. At the time of death, PRODUCT DOSE OMISSION ISSUE (could not administer second vaccine) had resolved. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Concomitant product use was not provided by the reporter. No treatment information was provided.; Sender"s Comments: This is a male patient of unknown age who received mRNA-1273 vaccine (batch no. unknown) who died on an unknown date after receiving first dose of vaccine. Patient had history of many medical conditions. No conmeds were given. Reporter could not administer second vaccine. Very limited information has been reported at this time. No further information is expected.; Reported Cause(s) of Death: medical conditions

VAERS ID: <u>1284865</u> (history) Vaccinated: 0000-00-00 Onset: 0000-00-00 Form: Version 2.0 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-05-04

Location: Tennessee

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

Administered by: Unknown Purchased by: ?

Symptoms: Haemorrhagic stroke

SMQs:, Haemorrhage terms (excl laboratory terms) (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: 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: PLAVIX

**Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: CVA

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021477606

Write-up: hemorrhage stroke; This is a spontaneous report from a Pfizer-sponsored program, received from a contactable nurse. A 55-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number and expiration date not provided), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient's medical history included CVA. The patient's concomitant medication included oral clopidogrel bisulfate (PLAVIX) for CVA at 25 mg, 1x/day (25 mg once everyday). It was reported that a patient who had the Covid vaccine, 3 days later the patient had hemorrhage and she passed away. It was clarified that patient had a hemorrhage stroke and passed away. The reporter did not know the date the patient passed away, but this was called on the office on 16Apr2021. The patient rad a rienionhage stroke and passed away. The reported in into know the date the patient passed away, but this was called on the office on 16Apr2021. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: Based on the temporal relationship, a causal association between the reported hemorrhagic stroke and the suspect drug, BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), cannot be completely excluded. Of note, patient has a medical history of CVA. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: hemorrhage stroke

VAERS ID: 1284940 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Entered: 2021-05-04 Sex: Female

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: girl died after getting second dose of Moderna vaccine it was thought to be fault of Tylenol.; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (girl died after getting second dose of Moderna vaccine it was thought to be fault of Tylenol.) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant and treatment information was provided. Company comment This is an age unknown, female patient who

received mRNA-1273 vaccine (batch no. unk) who died, after receiving second dose of vaccine. No medical history and conmeds were provided. Existing comorbidities probably could have been the causative factor in her death. Very limited information has been reported at this time. Further information is expected.; Sender"s Comments: This is an age unknown, female patient who received mRNA-1273 vaccine (batch no. unk) who died, after receiving second dose of vaccine. No medical history and conmeds were provided. Existing comorbidities probably could have been the causative factor in her death. Very limited information has been reported at this time. Further information is expected.; Reported Cause(s) of Death: Reporter mentioned that a girl died after getting second dose of Moderna vaccine.that it was thought to be fault of Tylenol.

VAERS ID: <u>1287928</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Female 2021-05-05 Sex: Entered:

Location: Unknown

Lot / Dose Vaccination / Manufacturer Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other

Purchased by: ? Symptoms: Death

SMQs:

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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210461305

Write-up: DEATH; This spontaneous report received from Pfizer via social media from a consumer concerned a female of unspecified age. The patient's height, and weight were not reported. The patient's past medical history included unknown cause of death. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total, administered on 22-MAR-2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient died. It was unknown if the autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, and Other Medically Important Condition).; Sender's Comments: V0- 20210461305- Covid-19 vaccine ad26.cov2.s-death. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1288452</u> (history) Vaccinated: 0000-00-00 Version 2.0 2021-04-01 Form: Onset: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-05-05

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs: Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-04-01 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: **Preexisting Conditions:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021483146

Write-up: found dead/ sudden death, This is a spontaneous report from a contactable physician. A 56-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot/batch number and expiration date not reported) via an unspecified route of administration on an unspecified date at a single dose for COVID-19 immunisation. The patient"s medical history and concomitant medications were not reported. The patient was found dead with her dog by her side on Thursday night just days after she took the second dose of the Pfizer COVID-19 vaccine. The reporter noted, "Covid-19 has turned all of our lives upside down in a way that we never imagined, and now it's safe to say that we won"t even be able to say goodbye to our daughter." The (Name) mother also blamed the vaccine for the sudden death of her "healthy" daughter. While a post-mortem was expected to be held to learn more about her death, some of the family members believed she simply suffered a heart attack, while her mother was connecting her sudden death to the vaccine. The patient died in Apr2021. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Sender"s Comments: The limited information in this report precludes a full assessment of the case; therefore a possible contributory role of the Pfizer suspect product BNT162B2 to the reported Death cannot be completely excluded. Information on relevant medical history, concomitant medications, and post-mortem result would be needed for a thorough medical evaluation of the patient"s sudden death. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and

analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate., Reported Cause(s) of Death: found dead/ sudden death

VAERS ID: <u>1288660</u> (history) Vaccinated: 0000-00-00 Version 2.0 Onset: 2021-04-15 Form: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-05-05

Location: Tennessee

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Purchased by: ?

Administered by: Other

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No

Died? Yes Date died: 2021-04-15 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:** 

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210504105

Write-up: PASSED AWAY; This spontaneous report received from social media from a consumer via a company representative concerned a female of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration not reported, batch number: Unknown) frequency one total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On 15-APR-2021, the patient passed away due to unknown cause. It was unknown if the autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of unknown cause on 15-APR-2021. This report was serious (Death).; Sender's Comments: -Covid-19 vaccine ad26.cov2.s -PASSED AWAY. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: PASSED AWAY

VAERS ID: <u>1290766 (history)</u> Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-04-26 Submitted: 0000-00-00 Age: Entered: 2021-05-05 Sex: Male

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Purchased by: ? Administered by: Unknown

Symptoms: Abdominal pain, Death, Dyspnoea, Fatigue, Hyperhidrosis, Loss of consciousness, Vaccination complication
SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (broad), Acute pancreatitis (broad), Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Retroperitoneal fibrosis (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Cardiomyopathy (broad), Hypotonichyporesponsive episode (broad), Generalised convulsive seizures following immunisation (broad), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-26 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** Preexisting Conditions: Medical History/Concurrent Conditions: No adverse event

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Passed out; Abdominal pain; Trouble breathing; Sweats; Didn"t feel well; Fatigue; death; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (death) and LOSS OF CONSCIOUSNESS (Passed out) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient"s past medical history included No adverse event. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced LOSS OF CONSCIOUSNESS (Passed out) (seriousness criterion medically significant), ABDOMINAL PAIN (Abdominal pain), DYSPNOEA (Trouble breathing), HYPERHIDROSIS (Sweats), VACCINATION COMPLICATION (Didn"t feel well) and FATIGUE (Fatigue). The patient died on 26-Apr-2021. The reported cause of death was Passed out. It is unknown if an autopsy was performed. At the time of death, LOSS OF CONSCIOUSNESS (Passed out), ABDOMINAL PAIN (Abdominal pain), DYSPNOEA (Trouble breathing), HYPERHIDROSIS (Sweats), VACCINATION COMPLICATION (Didn't feel well) and FATIGUE (Fatigue) outcome was unknown. No treatment information provided by the reporter and no history of concomitant medication was reported Regarding the events of loss of consciousness, malaise, abdominal pain, dyspnea, hyperhidrosis and fatigue, based on the current available information and temporal association between the

use of the product and the start date of the events, a causal relationship cannot be excluded. However regarding the event of death, Very limited information regarding this event has been provided at this time. Further information has been requested; Sender's Comments: Regarding the events of loss of consciousness, malaise, abdominal pain, dyspnea, hyperhidrosis and fatigue, based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. However regarding the event of death, Very limited information regarding this event has been provided at this time. Further information has been requested; Reported Cause(s) of Death: passed out

 VAERS ID: 1291614 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Unknown
 Entered:
 2021-05-06

Location: California

 Vaccination / Manufacturer
 Lot / Dose Site / Route

 COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA
 -/1
 -/0T

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

Allergies: Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: had a friend who dropped dead after getting the vaccine; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (had a friend who dropped dead after getting the vaccine) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. Action taken with mRNA-1273 in response to the event was not applicable. This is a patient of unknown age and gender who received mRNA-1273 vaccine (batch no. unk) who died on an unknown date after receiving the first dose of vaccine No medical hx or concomitant products Very limited information has been reported at this time. Further information is being followed up; Sender"s Comments: This is a patient of unknown age and gender who received mRNA-1273 vaccine (batch no. unk) who died on an unknown date after receiving the first dose of vaccine No medical hx or concomitant products Very limited information has been reported at this time. Further information is being followed up; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1294841 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-07

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/2        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: Life Threatening? No

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:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: Death; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Death) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant product use was not provided by the reporter. The reporter informed there were 2 deaths of those who had received their second dose of Moderna vaccine, same day, same location who died 2 hours after vaccine administration. Treatment information was not provided. This is a patient who received mRNA-1273 (COVID 19 Vaccine Moderna) (batch no. unk) and died after he received the second dose of vaccine. No Medical History information was reported. Concomitant product use was not provided by the reporter Very limited information has been reported at this time. Further information is expected.; Reported Cause(s) of Death: Unknown cause of

death

VAERS ID: 1298832 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-05-08

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Purchased by: ?

Administered by: Other

Symptoms: Death

SMQs:

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: Comments: Unknown

Allergies: Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210507041

Write-up: DEATH; This spontaneous report received from a company representative concerned a patient of unspecified age and sex. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry date: Unknown) dose, 1 total administered, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient died after getting Janssen vaccine. The patient died from an unknown cause of death. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210507041-covid-19 vaccine ad26.cov2.s-Death. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information

**VAERS ID: 1299367** (history) Vaccinated: 0000-00-00 Version 2.0 Form: Onset: 0000-00-00

Submitted: 0000-00-00 Age: Male Entered: 2021-05-08 Sex:

Location: Unknown

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

on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

Administered by: Unknown Purchased by: ?

Symptoms: Death, Malaise

SMOs:

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:

CDC Split Type: USPFIZER INC2021497007

Write-up: received his second dose of the vaccine and then died; got very ill; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient had unspecified underlying health issues. The patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 1 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for COVID-19 immunization and experienced COVID-19. The reporter's mom's cousin who was in his late 70s/ early 80s, had some underlying health issues. He received his second dose of the vaccine, got very ill, and died. Reporter was unsure if he received Pfizer vaccine or different brand. The outcome of got very ill was unknown. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: received his second dose of the vaccine and then died

VAERS ID: <u>1299369</u> (<u>history</u>) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Age: Submitted: 0000-00-00 Entered: 2021-05-08 Sex: Male

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route

COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH

Administered by: Unknown Purchased by: ?

Symptoms: COVID-19, Drug ineffective

SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (narrow)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-05-02 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:

CDC Split Type: USPFIZER INC2021498045

Write-up: got infected with covid and died yesterday; Looks like the vaccine may not be as effective with the new variants.; This is a spontaneous report from a noncontactable consumer. A male patient (infectious disease doctor) received two doses of BNT162B2 (Solution for injection, lot number: unknown, Expiration date: Unknown) on unknown dates . The patient travelled and got infected with covid and died yesterday (02May2021). The reporter stated that it looked like the vaccine might not be as effective with the new variants. After two Pfizer vaccines shots, this doctor travelled to see his parents and succumbed to the new variant. Outcome of the event was fatal. No follow up attempts are possible; Information about Lot and batch number could not be obtained. No further information is expected.; Reported Cause(s) of Death: got infected with covid and died yesterday.

VAERS ID: <u>1301967</u> (history) Vaccinated: 0000-00-00 Version 2.0 Onset: 0000-00-00 Form: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-05-10

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Intracardiac thrombus

SMQs:, 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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210506615

Write-up: BLOOD CLOT IN HEART; This spontaneous report received from a consumer concerned a female of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total, administered on 2021 for prophylactic vaccination. The batch number was not reported and it has been requested. No concomitant medications were reported. On 2021, the patient died due to blood clot in heart. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0 20210506615-COVID-19 VACCINE AD26.COV2.S- blood clot in heart. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: BLOOD CLOT IN HEART

VAERS ID: <u>1305027</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: 2021-05-11 Sex: Unknown Entered:

Location: Texas

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs: 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:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: died after receiving the Moderna Covid-19 vaccine; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of DEATH (died after receiving the Moderna Covid-19 vaccine) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. Not Provided Concomitant medications were not reported. No treatment information was provided. Action taken with mRNA-1273 in response to the drug was not applicable. Company comment: This is a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. died on an unknown date after the first dose of vaccine. No Medical History or Concomitant medications were reported. Very limited information has been reported at this time. Further information is not expected. This case was linked to US-MODERNATX, INC.-MOD-2021-020196, MOD21-10588, MOD21-086364, MOD21-086368 (Linked Report).; Sender's Comments: This is a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. died on an unknown date after the first dose of vaccine. No Medical History or Concomitant medications were reported. Very limited information has been reported at this time. Further information is not expected. US-MODERNATX, INC.-MOD-2021-012533: US-MODERNATX, INC.-MO

 VAERS ID: 1309191 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-05-12

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK - / -

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs:

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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210506934

Write-up: PASSED AWAY; This spontaneous report received from a consumer via social media concerned a female patient of unspecified age. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration was not reported, batch number and expiry were unknown) dose, start therapy date were not reported, 1 total, administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date (a couple of days after vaccination), the patient passed away. The cause of death was unknown. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death). This case, from the same reporter is linked to 20210508328.; Sender's Comments: V0: 20210506934 -COVID-19 VACCINE AD26.COV2.S - Passed Away. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1309628 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-12

Location: Virginia

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021498707

Write-up: died 3 weeks later after getting the vaccine.; This is a spontaneous report from a Pfizer-sponsored program. A contactable nurse reported that a patient (unknown age and gender) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number unknown) at single dose for COVID-19 immunisation on unknown date. Relevant history and concomitant drugs were unknown. The patient died 3 weeks later after getting the vaccine. It was unknown if autopsy was performed or not.; Sender"s Comments: The causal relationship between BNT162B2 and the fatal event cannot be excluded as the information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: died 3 weeks later after getting the vaccine.

VAERS ID: <u>1309632</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-05-12

Location: Unknown

| Vaccination / Manufacturer                               |         | Lot / Dose | Site / Route |
|--|---------|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BI | IONTECH | -/2        | -/-          |

Administered by: Unknown Purchased by: ?

Symptoms: COVID-19, Drug ineffective

SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021501749

Write-up: patient got infected with covid; patient got infected with covid; This is spontaneous report from a non-contactable consumer. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified dates (Batch/Lot number was not reported) at 1st dose, single and 2nd dose, single for covid-19 immunization. The patient's medical history was not reported. There were no concomitant medications. While visiting abroad, patient got infected with covid and died on an unspecified date. Apparently, the patient received two Pfizer vaccines shots prior to his travel. It was unknown if an autopsy was performed. No follow-up attempts are possible, information about batch number cannot be obtained. No further information is expected.; Reported Cause(s) of Death: patient got infected with covid

**VAERS ID:** <u>1311327</u> (history) Vaccinated: 2021-05-01 Form: Version 2.0 2021-05-03 Onset:

Days after Age: vaccination: Sex: Female

Submitted: 0000-00-00 Location: Unknown 2021-05-12 Entered:

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EW0173 / 1

Administered by: Private 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: 2021-05-20 Days after onset: 17 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? Yes Hospitalized? Yes, ? days

Extended hospital stay? No

Previous Vaccinations:

Other Medications:

**Current Illness:** 

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: CDC Split Type:

Write-up: 163.9 - Acute CVA (cerebrovascular accident)

VAERS ID: 1312771 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-05-13

Location: Virginia

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death, Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210510294

Write-up: FEMALE ISSUES; BLOOD CLOTS; This spontaneous report received from a consumer concerned multiple patients. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. No concomitant medications were reported. The batch number was not reported and has been requested. On an unspecified date, the consumer called and reported that he had read in newspaper that women had gotten blood clots and 3 passed away with female issues. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of female issues on an unspecified date, and the outcome of blood clots was not reported. This report was serious (Death, and Other Medically Important Condition).; Sender's Comments: V0. 20210510294 -COVID-19 VACCINE AD26.COV2.S- Female issues, Blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1312812</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-03-17 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-05-13

Location: Virginia

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Cerebral haemorrhage, Endotracheal intubation, Headache

SMQs:, Angioedema (broad), Haemorrhage terms (excl laboratory terms) (narrow), Haemorrhagic central nervous system vascular conditions (narrow), Respiratory failure (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-18 Days after onset: 1 Permanent Disability? No Recovered? No Office Visit? No

ER Visit? No ER or Doctor Visit? No Hospitalized? Yes, 1 days Extended hospital stay? No Previous Vaccinations: Other Medications:

**Current Illness:** Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210517658

Write-up: BLEEDING IN BRAIN; INTUBATED; SEVERE HEADACHE; This spontaneous report received from a consumer via company representative concerned a 45 year old female with unknown race and ethnicity. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: not reported) dose 1 total, administered on 2021 for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 17-MAR-2021, the patient experienced severe headache and went to the hospital and diagnosed with bleeding in brain. During hospitalization patient was intubated .On 18-Mar-2021, patient died due to bleeding in brain. Patient was hospitalized for 1 day. It was unknown whether autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the intubated and severe headache was not reported. This report was serious (Death, and Hospitalization Caused / Prolonged).; Sender's Comments: V0:20210517658- covid-19 vaccine ad26.cov2.s-Bleeding in brain, intubated. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: BLEEDING IN BRAIN

 VAERS ID: 1315725 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-13

Location: Unknown

|     | Vaccination / Manufacturer                                 | Lot / Dose    | Site / Route |
|-----|--|---------------|--------------|
| COV | <mark>'ID19</mark> : COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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 Vis

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210517449

Write-up: PASSED AWAY BECAUSE OF CLOT; This spontaneous report received from a consumer concerned a patient of Unspecified Race, ethnic origin, age and sex. The patient"s weight, height and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry: unknown) dose, start therapy date were not reported for prophylactic vaccination. No concomitant medications were reported. The batch number was not reported and has been requested. On an unspecified date, the patient passed away because of clot. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210517449- covid-19 vaccine ad26.cov2.s-thrombosis. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: CLOT

 VAERS ID: 1316349 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-05-14

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 0000-00-00 Permanent Disability? No Recovered? No

Recovered? No Office Visit? No ER Visit? No ER or Doctor Vi

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210514012

Write-up: This spontaneous report received from a consumer via a company representative concerned a female of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry: Unknown) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient died from blood clot. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0. 20210514012-COVID-19 VACCINE AD26.COV2.S-Blood clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: BLOOD CLOT

 VAERS ID:
 1316353 (history)
 Vaccinated:
 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

Age: Submitted: 0000-00-00
Sex: Female Entered: 2021-05-14

Location: Michigan

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

https://medalerts.org/vaersdb/findfield.php

Administered by: Other Symptoms: Death SMQs:

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: Comments: Unknown

Purchased by: ?

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210516437

Write-up: DIED AFTER COMPLICATION FROM THE JOHNSON AND JOHNSON COVID-19 VACCINE; This spontaneous report received from a patient via a company representative concerned a female of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, administered on 2021 for prophylactic vaccination. No concomitant medications were reported. On 2021, the patient died after complication from the Johnson & Johnson COVID-19 vaccine. The cause of death was unknown. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0;20210516437-covid-19 vaccine ad26.cov2.-Died after complication from the Johnson & Johnson COVID-19 vaccine. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: DIED

 VAERS ID: 1319776 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-05-15

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK - / -

Administered by: Other Purchased by: ?

Symptoms: Cerebrovascular accident, Death, Extra dose administered

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), Medication errors (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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210506977

Write-up: DEATH; STROKE; EXTRA DOSE ADMINISTERED; This spontaneous report received from a consumer via social media concerned a male of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient administered extra dose and had a bad stroke within 12 hours of the 2nd dose. Later, the patient died. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of death on an unspecified date, and the outcome of extra dose administered was not reported. This report was serious (Death, and Other Medically Important Condition).; Sender"s Comments: V0: 20210506977- Covid-19 vaccine ad26.cov2.s- Death, Stroke. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: STROKE

 VAERS ID: 1320104 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-15

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021486645

Write-up: dropped dead; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported that a patient of unspecified gender in 20s received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as a single dose for covid-19 immunization. The patient medical history was not reported. The patient"s concomitant medications were not reported. The reporter reported that someone in town in their 20s that had the Pfizer vaccine in the morning and dropped dead in the afternoon for no reason. Between all 3, there have been quite a bit of deaths in the last few months. The patient died on an unspecified date. It was not reported if an autopsy was performed.

Information on the lot/batch number has been requested.; Reported Cause(s) of Death: dropped dead

VAERS ID: <u>1320235</u> (history) Vaccinated: 0000-00-00 0000-00-00 Onset: Form: Version 2.0 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-05-15

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Anaphylactic reaction

SMQs:, Anaphylactic reaction (narrow), Anaphylactic/anaphylactoid shock conditions (narrow), Hypersensitivity (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: Allergy

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021498273

Write-up: died from Pfizer vaccine of anaphylactic reaction; This is a spontaneous report from a non-contactable consumer. A 60-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as unknown, single for Covid-19 immunisation. Medical history included hypersensitivity (there was something he was allergic to it"s what is used in contrast imaging). Concomitant medications were not reported. The patient had an anaphylactic reaction to the vaccination and through the anaphylactic reaction he passed away. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: Anaphylactic reaction

VAERS ID: <u>1320290</u> (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Age: Submitted: 0000-00-00 Male Entered: 2021-05-15 Sex:

Location: Michigan

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

Administered by: Unknown Purchased by: ?

Symptoms: Dyspnoea, Pulmonary oede

SMQs:, Cardiac failure (narrow), Anaphylactic reaction (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Haemodynamic oedema, effusions and fluid overload (narrow), Cardiomyopathy (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: COPD

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021504517

Write-up: Lungs filled up with fluid; could not breath after the second dose; This a spontaneous report from a contactable consumer via a Pfizer sales representative.

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An 89-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as 2nd dose, single for COVID-19 immunization. Medical history included chronic obstructive pulmonary disease (COPD). The patient's concomitant medications were not reported. On an unspecified date, the patient died due to lungs filled with fluid and could not breath after the second dose. It was not reported if an autopsy was performed. Information on the batch/lot number has been requested.; Reported Cause(s) of Death: Lung filled up with fluid; could not breath after the second dose

VAERS ID: <u>1320305</u> (<u>history</u>) Vaccinated: 2021-03-04 Form: Version 2.0 Onset: 2021-03-22 Age: Days after

vaccination: Sex: Female Submitted: 0000-00-00 Location: Unknown Entered: 2021-05-15

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

Administered by: Unknown Purchased by: ?

Symptoms: COVID-19, Drug ineffective, SARS-CoV-2 test SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (narrow)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 0000-00-00 Permanent Disability? No

Recovered? No Office Visit? Yes ER Visit? No

ER or Doctor Visit? No

Hospitalized? No **Previous Vaccinations:** 

Other Medications:

**Current Illness:** 

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: Test Date: 20210323; Test Name: covid test; Test Result: Positive

CDC Split Type: USPFIZER INC2021505647

Write-up: COVID-19 confirmed by positive COVID-19 test; COVID-19 confirmed by positive COVID-19 test; This is a spontaneous report from a non-contactable consumer. A 71-year-old female patient (reporter"s mother) received 1st dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose via an other contactable consumer. unknown route on 04Mar2021 for Covid-19 immunization. Medical history and concomitant drug were not provided. It was unknown if the patient received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Patient contracted COVID a few days before her second dose (event onset date 22Mar2021). She felt symptoms about 3 days before she was scheduled to receive her second dose. Covid test on 23Mar2021 was positive. She was officially diagnosed with COVID on 25Mar2021, the day of her scheduled second dose, which she did not get. She died several days later. The adverse event result in doctor or other healthcare professional office/clinic visit. Treatment received for the event. The patient died on an unknown date with death cause of COVID. It was unknown if autopsy performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: COVID-19 confirmed by positive COVID-19 test; COVID-19 confirmed by positive COVID-19 test

VAERS ID: <u>1320312</u> (history) Vaccinated: 2021-02-01 2021-04-09 Form: Version 2.0 Onset:

Days after Age: 67 vaccination: Sex: Male

Submitted: 0000-00-00 Location: Connecticut Entered: 2021-05-15

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

Administered by: Unknown Purchased by: ?

Symptoms: Death, Inappropriate schedule of product administration

SMQs:, Medication errors (narrow)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-04-09 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:

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021506325

Write-up: first dose on 21Jan2021 and second dose on 01Feb2021; passed away; This is a spontaneous report from a Pfizer-sponsored program from a contactable consumer (patient's wife). A male patient of an unspecified age received the 2nd dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech), via an unspecified route of administration, on 01Feb2021, as single dose, for COVID-19 immunisation. The patient"s medical history and concomitant medications were not reported. Previously the patient received the 1st dose of bnt162b2 (BNT162B2, Manufacturer Pfizer-BioNTech) for COVID-19 immunisation and experienced a terrible reaction. The patient passed away (death) on 09Apr2021. It was unknown if an autopsy was performed. The information on the lot/batch number has been requested.; Reported Cause(s) of Death: passed away

 VAERS ID: 1320319 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-15

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: <u>Death</u>, <u>Product use issue</u> SMQs:, Medication errors (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:

CDC Split Type: USPFIZER INC2021507396

Write-up: Girl's family who got vaccinated died along with their dog due to have been being exposed to the members who got vaccinated; 11 year old, pre-period, girls family who got vaccinated; This is a spontaneous report from a contactable consumer. A 11-years-old patient of an unspecified gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The reporter reported that 11 year old, pre-period, girls family who got vaccinated died along with their dog due to have been being exposed to the members who got vaccinated. The patient died on an unspecified date. It was not reported if an autopsy was performed. The lot/batch number has been requested; Reported Cause(s) of Death: Girl's family who got vaccinated died along with their dog due to have been being exposed to the members who got vaccinated

 VAERS ID: 1322554 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-05-17

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Purchased by: ?

Administered by: Other

Symptoms: Death SMQs:

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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210516695

Write-up: DEATH; This spontaneous report received from a company representative via social media concerned a female patient of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, Expiry: Unknown) dose not reported, 1 total, on an unspecified date, for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. In 2021, after 2 weeks of vaccination, the patient was deceased (unknown cause). It was unknown if the autopsy was performed or not. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The putcome of the event was fatal. This report was serious (Death). This case, from the same reporter is linked to 20210517056.; Sender"s Comments: V0; 20210516695-COVID-19 VACCINE AD26.COV2.S-Death. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1322556 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-17

Location: California

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ? Symptoms: Cerebrovascular accident, Death

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: 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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210516928

Write-up: DEATH; STROKE; This spontaneous report received from a consumer concerned eight patients with unknown race and ethnicity. The patients" weight, height, and medical history were not reported. The patients received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patients had stroke and died after getting the Janssen Covid-19 vaccine, the patients died from unknown cause of death and it was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0.20210516928-covid-19 vaccine ad26.cov2.s-Death, Stroke. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1322563</u> (<u>history</u>) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Male Entered: 2021-05-17 Sex:

Location: California

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ? Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210522533

Write-up: BLOOD CLOTS; This spontaneous report received from a consumer who reported hearing a news report concerned a male of unspecified age. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number not reported, expiry not reported frequency one total, dose, therapy start date were not reported administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient had blood clots. On an unspecified date in 2021, the patient was died due to blood clots. it was not reported whether autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died due to blood clot on an unspecified date in 2021. This report was serious (Death). This case, from the same reporter is linked to 20210523500.; Sender's Comments: V0. 20210522533-COVID-19 VACCINE AD26.COV2.S-Blood clots. This event(s) is considered unassessable. The event(s) has a compatible suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: BLOOD CLOTS

VAERS ID: <u>1326271</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Male Entered: 2021-05-18 Sex:

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Cardiac arrest

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (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), Respiratory failure (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: COPD

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021538103

Write-up: Cardiac arrest; This is a spontaneous report from a contactable consumer reporting for her uncle. A male patient of unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date in 2021, at single dose, for COVID-19 immunization. Medical history included COPD. Concomitant medications were not reported. A week after the patient got his COVID shot, he was dead, he had a cardiac arrest on an unspecified date in 2021, with fatal outcome. This just happened last month. It was unknown if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Cardiac arrest

 VAERS ID: 1329576 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2021-04-01

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-05-19

Location: Washington

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19:
 COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH
 - /

Administered by: Unknown Purchased by: ?
Symptoms: COVID-19, Drug ineffective, SARS-CoV-2 test

SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (narrow)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-04-01

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: Preexisting Conditions:

Allergies:

Diagnostic Lab Data: Test Name: covid tested; Result Unstructured Data: Test Result:Unknown results

CDC Split Type: USPFIZER INC2021535519

Write-up: Received COVID-19 vaccination late Dec2020 or early Jan2021/contracted COVID-19 infection in a foreign country; Received COVID-19 vaccination late Dec2020 or early Jan2021/contracted COVID-19 infection in a foreign country; This is a spontaneous report from a contactable physician. A 58-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, lot/batch number and expiration date not available to reporter), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. It was unknown if other vaccine received in four weeks or if covid prior vaccination. It was reported that physician received COVID-19 vaccination late Dec2020 or early Jan2021. Traveled to another country (where he was originally from) sometime in early 2021, contracted COVID-19 infection in Apr2021, and unfortunately died sometime in Apr2021 while still in a foreign country. He had no known comorbidities. The patient underwent lab test which included covid tested post vaccination with unknown results on an unspecified date. It was unknown if any treatment received. The outcome of the events was fatal. The patient died in Apr2021. It was unknown if an autopsy was performed. The events Drug ineffective and COVID-19 occurred in a country different from that of the reporter. This may be a duplicate report if another reporter from the country where the events occurred has submitted the same information to his/her local agency. Information on the lot/batch number has been requested.; Sender"s Comments: Based on the current available information and the plausible drug-event temporal association, a possible contributory role of the suspect product BNT162B2 to the development of events Drug ineffective and COVID-19 cannot be totally excluded. The case will be reassessed if additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to agency, as appropriate.; Reported Cause(s) of Death: Received COVID-19 vaccination late Dec2020 or early Jan2021/contracted COVID-19 infection in a foreign country; Received COVID-19 vaccination late Dec2020 or early Jan2021/contracted COVID-19 infection in a foreign country.

 VAERS ID: 1329587 (history)
 Vaccinated:
 2021-05-05

 Form:
 Version 2.0
 Onset:
 2021-05-06

Age: Days after Sex: Male vaccination:

**Location:** Unknown **Submitted:** 0000-00-00 **Entered:** 2021-05-19

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-05-06
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: Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021542356

Write-up: death; This is a spontaneous report from a consumer. A 39 years old male patient (brother in law, sister"s husband) received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 05May2021 (Batch/Lot number was not reported) as 2nd dose, Single for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced death on 06May2021. He received his second pfizer vaccination shot less than 24 hours before his death. Official cause of death hasn"t been determined. He simply never woke up the next day and reporter"s sister found him cold and blue in their bedroom. The patient died on 06May2021. An autopsy was performed and results were not provided. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1329662</u> (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-05-19

Location: Florida

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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: Comments: Unknown

Allergies: Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210530454

Write-up: BLOOD CLOTS; This spontaneous report received from a consumer concerned 3 women with unknown race and ethnicity. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number and expiry was unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, 3 women died from blood clots after getting (Janssen) covid 19 vaccine. It was unknown whether autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210530454-COVID-19 VACCINE AD26.COV2.S-Blood clots . This event is considered unassessable. The event has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death **BLOOD CLOT** 

VAERS ID: 1332466 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-05-20

Location: California

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Pulmonary embolism

SMQs:, Embolic and thrombotic events, 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:

Preexisting Conditions: Medical History/Concurrent Conditions: Routine health maintenance (Very healthy, athletic and a marathon runner.); Comments: marathon runner, no known medical history; very healthy Mother dies last year of aneurysm. Patient"s dad is in his 80"s is very healthy.

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210533144

Write-up: PULMONARY EMBOLISM; This spontaneous report received from a consumer via a company representative concerned a 63 year old male, race and ethnicity unspecified. The patient"s height, and weight were not reported. The patient"s medical history was not reported. The patient was very healthy, athletic and a marathon runner. The patient"s mother died last year of an aneurysm. The patient"s dad is in his 80"s is very healthy. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the subject developed pulmonary embolism causing death six days after receiving the vaccination. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died on an unspecified date. This report was serious (Death).; Sender"s Comments: V0: 20210533144-covid-19 vaccine ad26.cov2.s- This case concerns to a 63 year old male. Pulmonary embolism. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: PULMONARY EMBOLISM

 VAERS ID: 1332507 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2021-04-26

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-05-20

Location: Texas

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 -/OT

Administered by: Unknown Purchased by: ?

Symptoms: Adverse event, Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-05-06 Days after onset: 10 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? Yes
Hospitalized? Yes, ? days
Extended hospital stay? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: Change in patient"s condition; Passed away; This spontaneous case was reported by a health care professional (subsequently medically confirmed) and describes the occurrence of DEATH (Passed away) and ADVERSE EVENT (Change in patient's condition) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 26-Apr-2021, the patient experienced ADVERSE EVENT (Change in patient's condition) (seriousness criterion hospitalization). The patient died on 06-May-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, ADVERSE EVENT (Change in patient's condition) outcome was unknown. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. No treatment information was provided. Very limited information regarding these events has been provided at this time. Further information has been requested; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1332839 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-05-20

Location: Illinois

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

Administered by: Unknown Purchased by: ?

Symptoms: Death, Drug ineffective, SARS-CoV-2 test, SARS-CoV-2 test positive

SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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: Chronic lymphocytic leukemia (Since 2018 or 2019)

Allergies:

Diagnostic Lab Data: Test Name: covid test; Test Result: Positive

CDC Split Type: USPFIZER INC2021541162

Write-up: died; tested positive for covid; tested positive for covid; This is a spontaneous report from a non-contactable consumer. This male patient of unspecified age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunisation. Medical history included chronic lymphocytic leukemia untreated since 2018 or 2019. Concomitant medications were not provided. It was

reported that on unspecified date, patient got BNT162B2 and later tested positive for covid and died. It was not reported if an autopsy was performed. Lab data included covid test was positive on unspecified date. The outcome of the event died was fatal, while of the other events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: died

 VAERS ID: 1332850 (history)
 Vaccinated: 2021-02-01

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-05-20

Location: Unknown

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

Administered by: Unknown Purchased by: ?
Symptoms: Pulmonary embolism, SARS-CoV-1 test
SMQs:, Embolic and thrombotic events, 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: COVID-19 (resolved one month before receiving vaccine)

Allergies:

Diagnostic Lab Data: Test Name: Covid\_19 Test; Test Result: Positive; Comments: before vaccine; Test Date: 202101; Test Name: Covid\_19 Test; Test Result:

Negative ; Comments: one month before receiving vaccine

CDC Split Type: USPFIZER INC2021547314

Write-up: Pulmonary embolism; This is a spontaneous report received from a Pfizer sponsored program, received by a contactable consumer (patient"s relative). A 91-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number not provided), via an unknown route, in Feb2021 at single dose for COVID-19 immunization, administered at facility. Relevant medical history included COVID positive from an unknown date and resolved in Jan2021 (COVID test negative one moth before receiving vaccine). No relevant concomitant medications were provided. Patient"s relative stated that she died 10 days after receiving the COVID vaccine. The cause of death was not known but caller stated it could be due to pulmonary embolism. The facility did not wait for 3 months before giving the vaccine. Caller stated it should be prominent that patient should wait for 3 months after being tested positive for COVID and receiving the vaccine. It was unknown if an autopsy was performed. Information about Lot/Batch number has been requested.; Reported Cause(s) of Death: pulmonary embolism

 VAERS ID: 1332962 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-05-20

Location: Montana

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death, Platelet count, Platelet count decreased

SMQs:, Haematopoietic thrombocytopenia (narrow), Systemic lupus erythematosus (broad), 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:

Previous Vaccinations:
Other Medications:
Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Routine health maintenance; Comments: Does the patient have any allergies? : Not asked Was there drug abuse or illicit drug usage? :Unknown Does the patient consume alcohol? :Unknown Does the patient smoke? : Unknown

Allergies:

Diagnostic Lab Data: Test Name: Platelet count; Result Unstructured Data: low (no values provided)

CDC Split Type: USJNJFOC20210526587

Write-up: DEATH; LOW PLATELET; This spontaneous report received from a consumer who reported she had seen a post approximately one month ago concerning a male of unspecified age. The patient"s height, and weight were not reported. The patient"s concurrent conditions included good health. The patient's medical history was not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, intramuscular, batch number: Unknown) dose and start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the subject experienced low platelet and died on an unspecified date. Also conflictingly reported the cause of death was unknown (adverse events captured as Low Platelet and Death). It was not reported if an autopsy was performed. As per the reporter, the patient was an emergency (ER) physician who died after receiving the vaccine due to low platelets. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died on an unspecified date. This report was serious (Death).; Sender"s Comments: V0: 20210526587-covid-19 vaccine ad26.cov2.s -Death, Low platelets. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: LOW PLATELET

VAERS ID: <u>1334827</u> (history) Vaccinated: 2021-04-01 Form: Version 2.0 Onset: 2021-04-01

Age: Days after vaccination: Sex: Male

Submitted: 0000-00-00 Location: Florida Entered: 2021-05-20

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Asthenia, Dyspnoea, Feeling abnormal, Pyrexia, Vaccination complication
SMQs:, Anaphylactic reaction (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Dementia (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Guillain-Barre syndrome (broad), Cardiomyopathy (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-05-06 Days after onset: 35 Permanent Disability? No Recovered? No

Office Visit? No ER Visit? No ER or Doctor Visit? No

Hospitalized? No **Previous Vaccinations:** 

Other Medications: VITAMIN D [COLECALCIFEROL]; MELATONIN

Preexisting Conditions: Comments: Reporter stated that the patient had a history of "health problems." No specifics were provided.

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: "severe reactions"; very weak; Felt Bad; shortness of breath; Fever; This spontaneous case was reported by a patient family member or friend and describes the occurrence of VACCINATION COMPLICATION ("severe reactions") and ASTHENIA (very weak) in a 71-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Reporter stated that the patient had a history of "health problems." No specifics were provided. Concomitant products included COLECALCIFEROL (VITAMIN D [COLECALCIFEROL]) and MELATONIN for an unknown indication. In April 2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. In April 2021, the patient experienced VACCINATION COMPLICATION ("severe reactions") (seriousness criterion death), ASTHÉNIA (very weak) (seriousness criterion death), FEELING ABNORMAL (Felt Bad), DYSPNOEA (shortness of breath) and PYREXIA (Fever). On 06-Máy-2021, FEELING ABNORMAL (Felt Bad), DYSPNOEA (shortness of breath) and PYREXIA (Fever) outcome was unknown. The patient died on 06-May-2021. The cause of death was not reported. An autopsy was not performed. Patient had no symptoms or side effects after the 1st dose. Patient was never hospitalized for the reported events. A 71-year-old male patient who received mRNA-1273 experienced Pyrexia, Feeling Abnormal, Dyspnea, Asthenia and Vaccination Complication and died on an unknown days after the second dose of vaccine. Patient had a history of unspecified health problems which may confound the event. Unlikely that the events are related to the vaccine. Very limited information has been reported at this time. Further information is not expected.; Sender's Comments: Á 71-year-old male patient who received mRNA-1273 experienced Pyrexia, Feeling Abnormal, Dyspnea, Asthenia and Vaccination Complication and died on an unknown days after the second dose of vaccine. Patient had a history of unspecified health problems which may confound the event. Unlikely that the events are related to the vaccine. Very limited information has been reported at this time. Further information is not expected.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1340228</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-05-22

Location: Washington

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death SMQs: 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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210536600

Write-up: DEATH; This spontaneous report received from a consumer concerned four female patients. The patient's weight, height, and medical history were not reported. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total dose was administered, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company was unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On unspecified date in 2021, the patients died from unknown cause of death after vaccination. The autopsy details were not provided. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death). This case, from the same reporter is linked to 20210320422.; Sender"s Comments: V0- 20210536600- Covid-19 vaccine ad26.cov2.s-death. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information

on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 Form:
 Version 2.0
 Onset:
 2021-03-28

 Age:
 Submitted:
 0000-00-00

 Sex:
 Unknown
 Entered:
 2021-05-22

**Location:** Massachusetts

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EW0164 / 2 LA / OT

Administered by: Unknown Purchased by: ?

Symptoms: Foetal growth restriction, Maternal exposure during pregnancy, Ultrasound scan

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Foetal disorders (narrow)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-04-23
Days after onset: 26
Permanent Disability? No
Recovered? No
Office Visit? Yes
ER Visit? No

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations:

Other Medications: ESTRACE; PROGESTERONE

Current Illness:

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: Test Date: 20210426; Test Name: ultrasound; Result Unstructured Data: Test Result:baby stopped growing 5 days after shot; Test Date: 20210506; Test Name: ultrasound; Result Unstructured Data: Test Result:baby stopped growing 5 days after shot

CDC Split Type: USPFIZER INC2021512724

Write-up: Baby stopped growing 5 days after shot, confirmed with ultrasounds on 4/26 and 5/6; Maternal exposure during pregnancy, first trimester; This is a spontaneous report from a contactable consumer (fetus"s mother). This consumer reported information for both mother and fetus. This is the fetus report. A patient (fetus) mother (35-years-old) received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration, administered in Arm Left on 18Apr2021 09:15 (Batch/Lot Number: EW0164) at the age of 35-years-old as single dose, dose 1 via an unspecified route of administration, administered in Arm Left on 28Mar2021 15:00 (Batch/Lot Number: Er8732) at the age of 35-years-old as single dose for covid-19 immunisation. Route of the administration for fetus was provided as Transplacental. The patient"s mother medical history was not reported. The patient"s mother sconcomitant medication included estradiol (ESTRACE) taken for an unspecified indication, start and stop date were not reported, progesterone taken for an unspecified indication, start and stop date were not reported. The patient"s mother did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The baby experienced maternal exposure during pregnancy, first trimester from 28Mar2021 15:00. On 23Apr2021, 14:00, the mother experienced miscarriage, the baby stopped growing 5 days after shot 23Apr2021 14:00, confirmed with ultrasounds 26Apr2021 and 06May2021, the event resulted in doctor or other healthcare professional office/clinic visit, there was no treatment for event. Mother's Last menstrual date was 10Mar2021. The outcome of the events was fatal.; Sender's Comments: Linked Report(s): US-PFIZER INC-2021509131 mother case; Reported Cause(s) of Death: Baby stopped growing 5 days after shot, confirmed with ultrasounds on 4/26 and 5/6; Maternal exposure during pregnancy, first trimester

 VAERS ID: 1340513 (history)
 Vaccinated:
 2021-04-01

 Form:
 Version 2.0
 Onset:
 2021-04-01

Age: Days after Sex: Male vaccination: 0

Location: California Submitted: 0000-00-00 Entered: 2021-05-22

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

Administered by: Unknown Purchased by: ?

Symptoms: Asthma, Death, Hypersensitivity, Loss of consciousness, Pain in extremity, Peripheral swelling

SMQs:, Torsade de pointes/QT prolongation (broad), Cardiac failure (broad), Anaphylactic reaction (broad), Angioedema (broad), Asthma/bronchospasm (narrow), Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Noninfectious encephalitis (broad), Noninfectious encephalitis (broad), Noninfectious meningitis (broad), Extravasation events (injections, infusions and implants) (broad), Haemodynamic oedema, effusions and fluid overload (narrow), Eosinophilic pneumonia (broad), Hypotonic-hyporesponsive episode (broad), Generalised convulsive seizures following immunisation (broad), Hypersensitivity (narrow), Tendinopathies and ligament disorders (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-01 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:

Preexisting Conditions: Medical History/Concurrent Conditions: Allergy; Asthma

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021561326

Write-up: lose his life after the vaccine; Passed out; swelling and pain in his side of his arm; swelling and pain in his side of his arm; asthma trigger; allergies; This is a spontaneous report from a contactable consumer (patient's wife). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) dose 1 via an unspecified route of administration on Apr2021 (Batch/Lot number was not reported) as 1st dose, single for covid-19 immunisation. The

patient medical history included bad allergies and has asthma. Concomitant medications were not reported. He lose his life after the vaccine in Apr2021. He took the vaccine in Apr2021. After 3 days he took the vaccine on Tuesday, then Friday he was gone, that first dose. That day he died, he had like the asthma trigger like 10 minute after then he passed out but Thursday he was saying that he had like swelling and pain in his side of his arm. He had night shift and then morning came, Friday came home and then he ate and then he slept and then he woke up at 10 am just to go to kitchen and thought he was saying like having had allergies and 10 minutes then he passed out and then that was it. The reporter was just wondering how come, he still passed. Seriousness for lose his life after the vaccine was reported as death. The outcome of event lose his life after the vaccine was fatal and other events was unknown. The patient died in Apr2021. The cause of death was unknown. It was unknown if an autopsy was performed. Information on the Lot/Batch number has been requested.; Reported Cause(s) of Death: lose his life after the vaccine

VAERS ID: <u>1343001</u> (history) 2021-02-27 Vaccinated: Form: Version 2.0 Onset: 2021-03-01

Days after Age: 2 vaccination: Sex: Female

Submitted: 0000-00-00 Location: New Jersey Entered: 2021-05-24

| Vaccination / Manufacturer                                   |    | Lot / Dose | Site / | Route |
|--|----|------------|--------|-------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTE | СН | EN6203 / 1 | -/     | IM    |

Administered by: Public Purchased by: ?

Symptoms: Confusional state, Death, General physical health deterioration, Pain, Skin discolouration

SMQs:, Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Dementia (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Hypotonic-hyporesponsive episode (broad), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-04 Days after onset: 3
Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? Yes Hospitalized? Yes, 2 days Extended hospital stay? No

Previous Vaccinations: Other Medications: Current Illness: **Preexisting Conditions:** 

Allergies: None

Diagnostic Lab Data: Multiple tests were done. To many to write down. I have a complete medical record of all treatments provided.

Write-up: Went to er on March 3rd around 2am with discoloration on body with confusion and pain. Was told possible ttp. Condition quickly declined and was transferred to hospital main campus around 12pm. Condition continued to rapidly decline and passed away on March 4th at 11am. There is much more to tell about this. To much to write down. I have called several times no one has called me back.

Vaccinated: 0000-00-00 VAERS ID: <u>1345714</u> (history) Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-05-25

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | - / UNK    | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210538222

Write-up: HEART ATTACK; This spontaneous report received from a consumer via a company representative, concerned a female patient of unspecified age, race and ethnic origin. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of administration was not reported, batch number: unknown and expiry: unknown) dose and therapy start date were not reported, 1 total, administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, in 2021 (11 hours post vaccination), the patient died due to heart attack. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of heart attack was fatal. This report was serious (Death).; Sender"s Comments: V0 20210538222covid-19 vaccine ad26.cov2.s-Myocardial infarction. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: **HEART ATTACK** 

 VAERS ID: 1345716 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-25

Location: Ohio

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDĆ Split Type: USJNJFOC20210538476

Write-up: DEATH; This spontaneous report received from a consumer via social media concerned a patient of unspecified age and sex. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, frequency one total ,start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the reporter reported that one patient died post vaccination from unknown cause of death. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died due to unknown cause on an unspecified date. This report was serious (Death). This case, from the same reporter is linked to 20210536753.; Sender"s Comments: V0: 20210538476-COVID-19 VACCINE AD26.COV2.S-Death. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1345770 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-25

Location: Unknown

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

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs:

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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210541733

Write-up: DEATH; This spontaneous report received from a consumer by a other manufacturer company (Pfizer Inc.) via social media post, was received on 14-MAY-2021 and concerned multiple patients (more than 3000). The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose, start therapy date were not reported, frequency 1 total dose administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. Noncompany suspect vaccine included: MRNA 1273 (form of admin, route of admin, and batch number were not reported), dose, start therapy date were not reported for an unspecified indication; and BNT 162 (form of admin, route of admin, and batch number were not reported), dose, start therapy date were not reported for an unspecified indication. No concomitant medications were reported. It was reported that on an unspecified date, more than 3000 patients died from vaccine. The cause of death was unknown. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210541733-covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1345844 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-05-25

Location: Colorado

 Vaccination / Manufacturer
 Lot / Dose Site / Route

 COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA
 - / UNK
 - /

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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 Visit? No ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Allergies: Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: Patient died 2 hours after getting the vaccine; This spontaneous case was reported by a non-health professional and describes the occurrence of DEATH (Patient died 2 hours after getting the vaccine) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant products were reported. The reporter was worried about the administration of the vaccine and wanted to know if there was a way for someone to help their community. Reporter had contacted everyone in Public health department of the rural hometown. With the amount of adverse reactions with vaccine reporter was concerned that the vaccine was not being stored properly or not been given properly and further reported that one person died and they were not reporting it because they did not trust the government. A patient died two hours after getting the Moderna vaccine. No treatment information provided. This is a case of sudden death in a female patient who died 2 hours after receiving a dose of vaccine. Very limited information regarding this event has been provided at this time.; Sender's Comments: This is a case of sudden death in a female patient who died 2 hours after receiving a dose of vaccine. Very limited information regarding this event has been provided at this time.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1345947 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-25

Location: New York

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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:

CDC Split Type: USJNJFOC20210545044

Write-up: BLOOD CLOTS; This spontaneous report received from a consumer by a other manufacturer company (Pfizer Inc.) received on14-MAY-2021 and concerned multiple (few) patients. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) frequency 1 total, dose, start therapy date were not reported for prophylactic vaccination. No concomitant medications were reported. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. Reporter stated that Johnson and Johnson vaccine caused blood clots and few people died. It was not reported whether autopsy was performed. On an unspecified date, the patients experienced blood clots. On an unspecified date, the patients died from blood clots. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death, and Other Medically Important Condition).; Sender's Comments: V0; 20210545044-covid-19 vaccine ad26.cov2.s Blood clots. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: BLOOD CLOTS

 VAERS ID: 1349042 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-05-26

Location: New York

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Brain injury, Cardiac disorder, Cerebrovascular accident, Death, Myocardial infarction, Thrombosis

SMQs:, Myocardial infarction (narrow), Ischaemic central nervous system vascular conditions (narrow), Haemorrhagic central nervous system vascular conditions (narrow), Émbolic and thrombotic events, arterial (narrow), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (broad), Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (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:

CDC Split Type: USJNJFOC20210544901

Write-up: DROPPING DEAD; HEART ATTACKS; BLOOD CLOTS; STROKES; BRAIN DAMAGE; HEART CONDITIONS; This spontaneous report received from a consumer who reported reading from many personal social media accounts which concerned multiple patients of unspecified age and sex. No past medical history or concurrent conditions were reported. The patients received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. It was reported that, the patients were suffering from blood clots, dropping dead, had strokes, heart attacks, heart conditions and brain damage after vaccination. It was also reported that, the patients were perfectly healthy before and now they would never be the same. On an unspecified date, the patient died from unknown cause of death. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patients died of unknown cause on an unspecified date, and the outcome of blood clots, strokes, heart attacks, heart conditions and brain damage was not reported. This report was serious (Death, and Other Medically Important Condition). This case, from the same reporter is linked to 20210534943.; Sender"s Comments: V0: 20210544901-covid-19 vaccine ad26.cov2.s -Dropping dead, brain damage, blood clots, heart attacks and strokes. This event(s) are considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

Vaccinated: 0000-00-00 VAERS ID: <u>1349117</u> (history) Version 2.0 Onset: 0000-00-00 Form: Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-05-26

Location: New York

| Vaccination / Manufacturer                   | Lot / Dose     | Site / Route |
|--|----------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODER | NA UNKNOWN / 1 | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (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:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: Dropped dead of a heart attack; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MYOCARDIAL INFARCTION (Dropped dead of a heart attack) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient experienced MYOCARDIAL INFARCTION (Dropped dead of a heart attack) (seriousness criteria death and medically significant). The reported cause of death was Heart attack. It is unknown if an autopsy was performed. No concomitant medication was reported. No treatment information was reported. It was reported that patient"s funeral was on 11 May 2021. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to MOD21-090166, US-MODERNATX, INC.-MOD-2021-128463, US-MODERNATX, INC.-MOD-2021-128999 (E2B Linked Report).; Sender"s Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. MOD21-090166: US-MODERNATX, INC.-MOD-2021-128463: Same reporter US-MODERNATX, INC.-MOD-2021-128999:; Reported Cause(s) of Death: Heart attack

VAERS ID: <u>1349751</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Unknown Entered: 2021-05-26 Sex:

Location: Unknown

Lot / Dose Vaccination / Manufacturer Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USJNJFOC20210546018

Write-up: DIED; This spontaneous report received from a consumer via a company representative concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose, start therapy date were not reported, 1 total dose administered for prophylactic vaccination. The batch no was not reported ,The company is unable to performed follow up to request batch /Lot numbers .No concomitant medications were reported. It was reported that on an unspecified date, the patient died from covid-19 vaccine ad26.cov2.s. The cause of death was unknown. it was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death); Sender"s Comments: V0: 20210546018-covid-19 vaccine ad26.cov2. s Death. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1353088</u> (<u>history</u>) Vaccinated: 0000-00-00 Version 2.0 0000-00-00 Form: Onset: Age: Submitted: 0000-00-00 Sex: Female Entered: 2021-05-27

Location: New York

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: Died in the car on the way home after receiving the second dose of the Moderna COVID-19; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Died in the car on the way home after receiving the second dose of the Moderna COVID-19) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant medication information not provided. Treatment information not provided. Action taken with mRNA in response to the event/s was not applicable. A patient called on 13MAY2021 to report adverse effects she experienced after receiving the Moderna COVID-19 vaccine. During the call, she reported a serious adverse effect for "another lady" who "died in the car on the way home" after receiving the second dose of the Moderna COVID-19 vaccine. The caller reported that the individual received the second dose of the vaccine. No additional information was provided. The Serious Adverse Event Reporting form has been completed. Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. This case was linked to US-MODERNATX, INC.-MOD-2021-128107, MOD21-090166, US-MODERNATX, INC. MOD-2021-128999 (E2B Linked Report).; Sender"s Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded. US-MODERNATX, INC.-MOD-2021-128107: MOD21-090166: US-MODERNATX, INC.-MOD-2021-128999:; Reported Cause(s) of Death: unknown cause of death

**VAERS ID:** <u>1357434</u> (<u>history</u>) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: 2021-05-28 Sex: Unknown Entered:

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death, Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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:

Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210550011

Write-up: DEATHS; BLOOD CLOTS; This spontaneous report received from a consumer who reported reading and seeing on the news concerned a patient of unspecified age, race, ethnic origin and sex. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number not reported, expiry not reported) frequency one total, dose, therapy start date were not reported administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the consumer stated that he read and saw on the news that this vaccine causes patient"s deaths, and blood clots. On an unspecified date, the patient died from unknown cause of death. It was not reported whether autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of deaths on an unspecified date, and the outcome of blood clots was not reported. This report was serious (Death, and Other Medically Important Condition).; Sender"s Comments: V0: 20210550011-covid-19 vaccine ad26.cov2.s-deaths, blood clots. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1360403 (history)
 Vaccinated:
 2021-03-17

 Form:
 Version 2.0
 Onset:
 2021-03-30

 Age:
 Days after
 12

Sex: Male vaccination:

 Location:
 Maine
 Submitted:
 0000-00-00

 Entered:
 2021-05-29

Administered by: Other Purchased by: ?

Symptoms: Death, Investigation, Maternal exposure during pregnancy, Meconium aspiration syndrome, Premature baby, Serology test

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Neonatal disorders (narrow), Respiratory failure (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-30 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: EUCRISA; LORATADINE

Current Illness: Preexisting Conditions:

Allergies:

Diagnostic Lab Data: Test Name: Ante-natal check-up; Result Unstructured Data: Test Result:20 wk fetal surgery, 25Mar2021, normal growing; Comments: 20 wk fetal surgery, 25Mar2021, normal growing, normal anatomy, male fetus; Test Name: serology test; Result Unstructured Data: Test Result:HIV negative, Rubeola immune, HBSag negative,; Comments: HIV negative, Rubeola immune, HBSag negative, VISRL no reactive

CDC Split Type: USPFIZER INC2021392328

Write-up: Maternal exposure during pregnancy, second trimester; Meconium Aspiration; baby died 2 hours; severe prematurity; The initial case was missing the following minimum criteria: no adverse event. Upon receipt of follow-up information on 24May2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable other HCP (parent). This other HCP reported information for both mother and fetus/baby case. This is the baby report. This 38-year-old female patient was pregnant of a male fetus and received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) intramuscular on 24Feb2021 08:15 (Batch/Lot Number: EL9261) and the second dose on 17Mar2021 (Batch/Lot Number: EL9261), both as single dose for COVID-19 immunisation. Relevant medical history of the mother included atopic dermatitis. Concomitant medications included crisaborole (EUCRISA) taken for dermatitis atopic from an unspecified start date and ongoing and loratadine taken for hypersensitivity, start and stop date were not reported. First day of last menstrual period: 29Oct2020. Estimated date of conception: 12Nov2020. Estimated delivery date: 05Aug2021. Gestational period at time of initial exposure: 16 weeks and 5 days. Second trimester. The male fetus had a premature birth on 30Mar2021 and experienced meconium aspiration on an unspecified date. The fetus died on 30Mar2021, 2 hours after the delivery. The mother went into preterm labor on 29Mar2021 which was 12 days after second Pfizer vaccine. She delivered on 30Mar2021 at 21 weeks and 5 days. She was diagnosed with chorioamnioitis due to a staph aureus infection. Leading up to the hospital admission and after first and second vaccines she had frequent headaches, fatigue which she related to the vaccine. She also had chills and body aches. On admission she had a fever. Results of serology tests, e.g., rubella, toxoplasmosis, etc: HIV negative, Rubeola immune, HBSag negative, VISRL no reactive. Ante-natal check-up (specify dates and results) e.g., fetal ultrasound, serum markers, etc: 20 wk fetal surgery, 25Mar2021, normal growing, normal anatomy, male fetus. The mother presented ruptured membrane with chorioamnionitis, treated with antibiotics, and changed postpartum day. Mode of delivery: Vaginal delivery. Outcome of pregnancy: Premature live birth: Baby lived 2 hours. Date of Outcome of Pregnancy: 30Mar2021. Gestational age at birth in weeks: 21 weeks and 5 days.; Sender's Comments: Based on the information currently available, there is not a reasonable possibility reported events were related to BNT162B2 vaccine administration. It was noted that patients mother was diagnosed with chorioamnionitis due to a staph aureus infection which could be contributory. Case will be reassessed upon receipt of additional information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics committees and Investigators, as appropriate.,Linked Report(s): US-PFIZER INC-2021392327 Mother/Fetus baby case;US-PFIZER INC-2021390010 Mother/Fetus baby case; Reported Cause(s) of Death: Unknown cause of death

https://medalerts.org/vaersdb/findfield.php

 VAERS ID: 1364021 (history)
 Vaccinated:
 2021-05-13

 Form:
 Version 2.0
 Onset:
 2021-05-13

Age: Days after Sex: Male vaccination:

 Location:
 Unknown
 Submitted:
 0000-00-00

 Entered:
 2021-06-01

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown

nown Purchased by: ?

Symptoms: Death

SMQs: Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-05-13
Days after onset: 0
Permanent Disability? No
Recovered? No

Office Visit? No ER Visit? No ER or Doctor Vi

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness: Preexisting Conditions: Allernies:

Allergies: Diagnostic Lab Data:

CDC Split Type: MODERNATX, INC.MOD2021163

Write-up: Had his second shot on 5/13 and passed away on that night or morning; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Had his second shot on 5/13 and passed away on that night or morning) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On 13-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on 13-May-2021 The patient died on 13-May-2021. The cause of death was not reported. It is unknown if an autopsy was performed. No relevant concomitant medications were reported. It was reported that patient passed away on that night of vaccination or next morning. The patient"s autopsy might be scheduled on 24-MAY-2021. No treatment information was provided. Action taken with mRNA-1273 in response to events was not applicable. Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender"s Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1364314 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Male
 Entered:
 2021-06-01

Location: Florida

|  |     | Site / Route |
|--|-----|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | -/1 | -/-          |

Administered by: Unknown Purchased by: ?

Symptoms: Cardiac arrest

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (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), Respiratory failure (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 Vis

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness: Preexisting Conditions: Allernies:

Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021599474

Write-up: Cardiac arrest; This is a spontaneous report received by a contactable consumer. A male patient of unknown age received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot number not provided), via an unknown route, on unknown date at single dose for COVID-19 immunisation. No relevant medical history and concomitant medications were provided. Recently the patient received the first shot of COVID-19 vaccine and subsequently went into cardiac arrest. He unfortunately passed away one week later. It was unknown if an autopsy was performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: cardiac arrest

 VAERS ID: 1366828 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-06-02

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USJNJFOC20210600235

Write-up: DEATH; This spontaneous report received from a consumer concerned a male of unspecified age. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) 1 total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient died due to unknown cause. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0:20210600235 -COVID-19 VACCINE AD26.COV2.S- Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s), Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1366906</u> (history) Vaccinated: 0000-00-00 Form: Onset: 0000-00-00 Version 2.0 Submitted: 0000-00-00 Age: Entered: 2021-06-02 Sex: Male

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | - / UNK    | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: Passed away; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Passed away) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. The patient"s wife reported that the patient passed away a few weeks after taking the Moderna vaccine. Concomitant medication and treatment information were not reported. Action taken with mRNA-1273 in response to the event was Not Applicable Company comment Very limited information regarding this event/s has been provided at this time. Further information has been requested. Reporter did not allow further contact; Sender"s Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1366907</u> (history) Vaccinated: 0000-00-00 Onset: 2021-05-23 Form: Version 2.0 Age: Submitted: 0000-00-00 Female Entered: 2021-06-02 Sex:

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / UNK

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-05-23 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:** 

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: Died; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Died) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on 23-May-2021 The patient died on 23-May-2021. The cause of death was not reported. It is unknown if an autopsy was performed. The reporter mentioned that grandma got Moderna vaccine and died yesterday (23 -May-2021) Concomitant medication and treatment information were not reported. Action taken with mRNA-1273 in response to the event was Not Applicable Company comment Very limited information regarding this event/s has been provided at this time. Further information has not been requested since follow up was denied. Reporter did not allow further contact; Sender"s Comments: Very limited information regarding this event/s has been provided at this time. Further information has not been requested since follow up was denied.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1366914</u> (history) Vaccinated: 0000-00-00 Version 2.0 Onset: 2021-05-23 Form: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-06-02

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / UNK - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMOs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-05-23 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:** 

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: got his grandma a covid-19 vaccine and she died /she"s not the first i have heard about that died; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (got his grandma a covid-19 vaccine and she died /she"s not the first i have heard about that died) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on 23-May-2021 The patient died on 23-May-2021. The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant medication was reported. It was reported that the reporter grandma received a covid-19 vaccine and died yesterday. Reporter also stated that it"s not the first he has heard about that someone died from the covid-19 vaccine. The reporter did not specify it was the morderna Covid-19 vaccine he was referring to. Company comment Very limited information regarding this event/s has been provided at this time. Further information has not been requested since reporter did not share any personal information.; Sender"s Comments: Very limited information regarding this event/s has been provided at this time. Further information has not been requested since reporter did not share any personal information.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1370319</u> (history) Vaccinated: 0000-00-00 0000-00-00 Form: Onset: Version 2.0 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-06-03

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: 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:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: Son died 10 days after his first moderna vaccine; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Son died 10 days after his first moderna vaccine) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant product was not provided by the reporter. Treatment information was not provided. Action taken with mRNA-1273 in response to the events was not applicable. A male patient of an unknown age who received mRNA-1273 died 10 days after his first dose of vaccine. No medical conditions or conmeds were provided. Very limited information regarding these events has been provided at this time. Further information is being pursued.; Sender"s Comments: A male patient of an unknown age who received mRNA-1273 died 10 days after his first dose of vaccine. No medical conditions or conmeds were provided. Very limited information regarding these events has been provided at this time. Further information is being pursued.; Reported Cause(s) of Death: Son died 10 days after his first moderna vaccine

VAERS ID: <u>1373283</u> (<u>history</u>) 2021-01-21 Vaccinated: Form: Version 2.0 Onset: 2021-01-21 Days after Age: 0

vaccination: Sex: Male

Submitted: 0000-00-00 Location: Unknown Entered: 2021-06-04

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death, Nause

SMQs:, Acute pancreatitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-11 Days after onset: 49 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:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: The patient is deceased; Nausea while eating; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (The patient is deceased) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional nonserious events is detailed below. No Medical History information was reported. On 21-Jan-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 21-Jan-2021, the patient experienced NAUSEA (Nausea while eating). The patient died on 11-Mar-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, NAUSEA (Nausea while eating) outcome was unknown. No concomitant medications were reported. It was reported that nausea would go away for a few hours and would come back while eating again. The patient was already in supplemental oxygen but was using more since he received the vaccine. The patient had been experiencing the events for four days. Company comment: Based on current available information and the temporal association between product use and the start date of the events a causal cannot be ruled out for the event of Nausea and is unlikely for the event of Death. The event of Oxygen therapy is invalid as it is a pre-existing condition. Most recent FOLLOW-UP information incorporated above includes: On 25-May-2021: Follow up received on 25 May 2021 includes serious event death.; Sender"s Comments: Based on current available information and the temporal association between product use and the start date of the events a causal cannot be ruled out for the event of Nausea and is unlikely for the event of Death. The event of Oxygen therapy is invalid as it is a pre-existing condition.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1373784</u> (<u>history</u>) Vaccinated: 2021-04-18 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 2021-06-04 Sex: Unknown Entered:

Location: California

| Vaccination / Manufacturer                                     | Lot / Dose | Site / F | Route |
|--|------------|----------|-------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EW161 / 1  | LA /     | OT    |

Administered by: Unknown Purchased by: ?

Symptoms: Congenital anomaly, Maternal exposure during pregnancy

SMQs:, Congenital, familial and genetic disorders (narrow), Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (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:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021602308

Write-up: Miscarriage on 13May2021/seriousness criterion was reported as "Congenital anomaly/birth defect"; Miscarriage on 13May2021/seriousness criterion was reported as "Congenital anomaly/birth defect"; This is a spontaneous report from a contactable consumer (patient). This is the baby case. A 34-year-old female patient received the 1st single dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, in left arm on 18Apr2021 (Batch/Lot Number: Ew161), and the 2nd single dose, always in the left arm, on 02May2021 (Batch/Lot Number: Ew0171), for COVID-19 immunisation. First and second dose were administered at the age of 34 years old. Relevant medical history was reported as none. The patient's last menstrual period was on 18Feb2021 and pregnancy due date was 26Dec2021. Concomitant medications included unspecified pre-natal vitamins. Relevant past drug history included sulfa. The patient had not received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was never diagnosed with COVID-19, and since the vaccination the patient had not been tested for COVID-19. The patient reported having miscarriage on 13May2021, diagnosed after the 2nd shot of BNT162b2. A doctor or other healthcare professional office/clinic visit was needed. The fetus had died sometime between the 1st and 2nd shot based on gestational age. Gestation period when the event was observed was reported as 4 weeks. The patient had to undergo dilation and curettage from which the patient was recovering. The seriousness criterion was reported as "Congenital anomaly/birth defect" (no further information reported about the congenital anomaly). No follow up attempts are needed. No further information expected.; Sender"s Comments: Linked Report(s): US-PFIZER INC-2021602163 mother/baby case; Reported Cause(s) of Death: Miscarriage; Congenital anomaly; Miscarriage; Congenital anomaly

VAERS ID: <u>1373801</u> (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Age: Submitted: 0000-00-00 Sex: Male Entered: 2021-06-04

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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: CDC Split Type: USPFIZER INC2021609860

Write-up: Death; This is a spontaneous report from a non-contactable consumer. An adult male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot Number: Unknown) as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient died on an unspecified date. It was not reported if an autopsy was performed. Follow-up attempts are completed. No further information is expected.; Reported Cause(s) of Death: Death

VAERS ID: <u>1373835</u> (history) Vaccinated: 0000-00-00 Version 2.0 Form: Onset: 0000-00-00 Age: Submitted: 0000-00-00 Entered: 2021-06-04 Sex: Unknown

Location: California

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021616779

Write-up: All died within the 5 weeks after there first shot; This is a spontaneous report from a contactable consumer. This consumer reported similar events for six patients. This is the sixth of six reports. An elderly patient of unknown gender received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date of 2021, as single dose for covid-19 immunization. The patient" s medical history and concomitant medications were not reported. Patient was residential home with 5 other elderly residents patient. Reporter stated that

they all got vaccinated with the first Pfizer shot (Confirmed as Covid 19 vaccine) and they all died within the 5 weeks after their first shot. By 18Mar2021 these residents in the house would have died. The reporter stated that they should not have died they just died. The reporter doesn" t know if it was a side effect, he knows if it was a reaction but all of the six residents that got vaccinated died within their first vaccination shot. Within the 5 weeks after the first vaccination. Reporter stated they died in their sleep supposedly. They died in their sleep. Outcome of the event was fatal. It was unknown if an autopsy was done. The information on the batch/lot number has been requested.; Sender"s Comments: Linked Report(s): US-PFIZER INC-2021617030 same reporter/SD/AE, different patients; Reported Cause(s) of Death: died within the 5 weeks after there first shot

 VAERS ID: 1373996 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Submitted: 0000-00-00

 Sex: Unknown
 Entered: 2021-06-04

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK - / -

Administered by: Other Purchased by: ? Symptoms: Cerebrovascular accident, Death

**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: 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:

Preexisting Conditions: Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210601307

Write-up: DEATH; STROKES; This spontaneous report received from a consumer via social media concerned multiple patients of unspecified gender. The patient "s weight, height, and medical history were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patients died of unknown cause. It was reported that the patients had stroke. Date of death and autopsy details were not reported. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died on an unspecified date and the outcome of strokes was not reported. This report was serious (Death, and Other Medically Important Condition).; Sender's Comments: V0- 20210601307-covid-19 vaccine ad26.cov2.s- Death, Stroke. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1374022 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-06-04

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death
SMQs:
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:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: Death; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Death) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant medication or treatment were reported by the reporter. Company Comment: This is an invalid case due to no identifiable patient. Also, very limited information regarding the event has been provided at this time. This case was linked to MOD-2021-102410 (Patient Link).; Sender's Comments: This is an invalid case due to no identifiable patient. Also, very limited information regarding the event has been provided at this time.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1374303 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-06-04

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 -/ OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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 Visit? No ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Allergies: Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Died) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant medications were reported. No treatment information was reported. Action taken with mRNA-1273 (Moderna COVID-19 Vaccine) in response to the event was not applicable. Company comment: Very limited information regarding this patient"s death has been provided at this time.; Sender"s Comments: Very limited information regarding this patient Death

 VAERS ID: 1380664 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-06-08

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ? Symptoms: Death, Dyspnoea, Speech disorder

SMQs:, Anaphylactic reaction (broad), Dementia (broad), Acute central respiratory depression (broad), Psychosis and psychotic disorders (broad), Pulmonary hypertension (broad), Guillain-Barre syndrome (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Cardiomyopathy (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: COVID-19 (admitted to the hospital for COVID); Hospitalization

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210607655

Write-up: DEATH; TROUBLE IN BREATHING; UNABLE TO SPEAK; This spontaneous report received from a patient via a company representative via social media concerned a female of unspecified age. The patient"s height, and weight were not reported. The patient"s medical history included covid-19 infection. The patient was admitted to the hospital with fully recovered Covid. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported) 1 total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported, per procedure no follow up will be requested for the case. No concomitant medications were reported. On an unspecified date, immediately after vaccine shot the patient experienced trouble in breathing, and next day patient was unable to speak. On an unspecified date, the subject died from unknown cause of death. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of trouble in breathing and unable to speak was not reported. This report was serious (Death).; Sender's Comments: V0: 20210607655-COVID-19 VACCINE AD26.COV2.S-Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1381213 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-06-08

Location: California

Vaccination / Manufacturer Lot / Dose Site / Route

COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH

Purchased by: ?

Administered by: Unknown Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021616788

Write-up: All died within the 5 weeks after there first shot; This is spontaneous report from a contactable consumer. This the second case out of six cases. An elderly male patient of unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date of 2021 as single dose for covid-19 immunisation. The patient medical history and the patient so concomitant medications were not reported. On unknown date the patient died within the 5 weeks after the first vaccination. It was not reported if an autopsy was performed. The patient was in a residential home with 5 other elderly residents. He/she died in sleep. Information related Lot/Batch number has been requested.; Sender"s Comments: Linked Report(s): US-PFIZER INC-2021617030 same reporter, same vaccine, same adverse event, different patient.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1381214</u> (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Age: Submitted: 0000-00-00 Sex: Unknown Entered: 2021-06-08

Location: California

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021616796

Write-up: all died within the 5 weeks after there first shot; This is spontaneous report from a contactable consumer. This the third case out of six cases. An elderly male patient of unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date of 2021 as single dose for covid-19 immunisation. The patient medical history and the patient so concomitant medications were not reported. On unknown date the patient died within the 5 weeks after the first vaccination. It was not reported if an autopsy was performed. The patient was in a residential home with 5 other elderly residents. He/she died in sleep. Information related Lot/Batch number has been requested.; Sender"s Comments: Linked Report(s): US-PFIZER INC-2021617030 same reporter, same vaccine, same adverse event, different patient.; Reported Cause(s) of Death: Unknown cause of death

**VAERS ID:** <u>1381215</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 2021-06-08 Sex: Unknown Entered:

Location: California

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021617301

Write-up: all died within the 5 weeks after there first shot; This is spontaneous report from a contactable consumer. This the fifth case out of six cases. An elderly patient of unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date of 2021 as single dose for covid-19 immunisation. The patient medical history and the patient"s concomitant medications were not reported. On unknown date the patient died within the 5 weeks after the first vaccination. It was not reported if an autopsy was performed. The patient was in a residential home with 5 other elderly residents. He/she died in sleep. Information related Lot/Batch number has been requested.; Sender"s Comments: Linked Report(s): US-PFIZER INC-2021617030 same reporter, same vaccine, same adverse event, different patient.; Reported Cause(s) of Death: all died within the 5 weeks after there first shot

Vaccinated: 0000-00-00 VAERS ID: <u>1381218</u> (<u>history</u>) Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-06-08

Location: California

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021618004

Write-up: All died within the 5 weeks after first shot; This is a spontaneous report from a contactable consumer. This consumer reported similar events for six patients. This is the fourth of six reports. An elderly patient of an unknown gender and age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration, on an unspecified date of 2021, as single dose for COVID-19 immunization. The patient" s medical history and concomitant medications were not reported. On unknown date, in 2021, the patient died within the 5 weeks after the first vaccination. It was not reported if an autopsy was performed. The patient was in a residential home with 5 other elderly residents. He/she died in sleep. The information on the lot number has been requested.; Sender's Comments: Linked Report(s): US-PFIZER INC-2021617030 same reporter/SD/AE, different patients; Reported Cause(s) of Death: All died within the 5 weeks after first shot

**VAERS ID:** <u>1384711</u> (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Age: Submitted: 0000-00-00 Male Entered: 2021-06-09 Sex:

Location: Indiana

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

Administered by: Unknown Purchased by: ?

Symptoms: Pneumonia

SMQs:, Eosinophilic pneumonia (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Infective pneumonia (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:** 

Allergies:

Diagnostic Lab Data:

CDČ Split Type: USPFIZER INC2021641564

Write-up: This patient had done the same thing, only he ended up taking pneumonia and dying with it; This is a spontaneous report from a contactable consumer or other non hcp. This is a split case report which was conservatively captured as per the statement "This patient had done the same thing". A 75-year-old male patient

received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Solution for injection; Lot Number and Expiration date was not reported), via an unspecified route of administration on an unspecified date as unknown, single for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced pneumonia on an unspecified date. It was reported that, when reporter saw her medical doctor, the day before reporting the event, who was very concerned because she had a recent patient that was about the same age as the reporter, he was 75 years old. The patient had done the same thing, only he ended up taking pneumonia and dying with it. The patient died on an unspecified date. It was not reported if an autopsy was performed. The outcome of the event was fatal on an unknown date. Information about Lot/Batch number has been requested.; Reported Cause(s) of Death: This patient had done the same thing, only he ended up taking pneumonia and dying with it

 VAERS ID: 1387787 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-06-10

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDČ Split Type: USPFIZER INC2021613680

Write-up: gave my mom the COVID vaccine and now she is dead; This is a spontaneous report from a non-contactable pharmacist. This pharmacist reported on behalf of a pharmacy technician"s mother (the patient). An elderly female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE, lot unknown, unknown if first or second dose) solution for injection intramuscular on an unknown date as a single dose for COVID-19 vaccination. Medical history was not reported. Concomitant medication included unspecified medication but has never taken morphine sulfate. The pharmacy technician stated, "I gave my mom the COVID vaccine and now she was dead." The outcome of the event was fatal. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender"s Comments: The information currently available is limited and does not allow a meaningful case evaluation. However, based on chronological connection to the vaccine a causal relationship between event of death (unknown cause) and BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE) cannot be completely excluded. The case will be reevaluated should additional information become available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: gave my mom the COVID vaccine and now she is dead

 VAERS ID: 1394058 (history)
 Vaccinated: 2021-03-17

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-06-12

Location: Pennsylvania

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA 037A21B / 1 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death, Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 0000-00-00
Permanent Disability? No
Recovered? 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: Current Illness:

Preexisting Conditions: Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: This spontaneous case was reported by a patient family member or friend (subsequently medically confirmed) and describes the occurrence of DEATH (She passed away) and THROMBOSIS (Clots in her leg) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 037A21B) for COVID-19 vaccination. No Medical History information was reported. On 17-Mar-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced DEATH (She passed away) (seriousness criteria death, nospitalization and medically significant) and THROMBOSIS (Clots in her leg) (seriousness criteria hospitalization and medically significant). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, THROMBOSIS (Clots in her leg) outcome was unknown. No concomitant medications reported. Description: The patient had clots in her leg and was hospitalized. There was talk of amputation, but she passed

away before that occurred. No treatment information provided. Company Comment: Very limited information regarding these events have been provided at this time. Further information cannot be requested.; Sender's Comments: Very limited information regarding these events have been provided at this time. Further information cannot be requested.; Reported Cause(s) of Death: Unknown cause of death

 VAERS ID: 1394084 (history)
 Vaccinated:
 2021-03-17

 Form:
 Version 2.0
 Onset:
 2021-04-07

Age: Days after Sex: Unknown vaccination: 21

 Location:
 Virginia
 Submitted:
 0000-00-00

 Entered:
 2021-06-12

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

Administered by: Work Purchased by: ?

Symptoms: Foetal death, Foetal exposure during pregnancy, Foetal growth restriction

SMQs:, Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (narrow), Foetal disorders (narrow), Termination of pregnancy and risk of sheating (narrow)

risk of abortion (narrow) Life Threatening? No Birth Defect? No Died? Yes

Date died: 0000-00-00 Permanent Disability? No Recovered? No Office Visit? Yes ER Visit? No

ER or Doctor Visit? Yes Hospitalized? No Previous Vaccinations: Other Medications: ZOLOFT Current Illness: Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021607425

Write-up: I ended up with a miscarriage; fetus I was pregnant with stopped growing at 5.5 weeks; I was pregnant with stopped growing at 5.5 weeks which happens to be the same time I had the vaccine.; This is a spontaneous report from a contactable consumer. This consumer (mother) reported similar events for self and the foetus. This report for foetus included that: A fetus received BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Solution for injection, via transplacental route, on 17Mar2021 13:30 as 1 st dose, single dose for covid-19 immunization. Also received BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Solution for injection, via transplacental route, on 07Apr2021 13:30 as 2 nd dose, single dose for covid-19 immunization. The patient medical history was not reported. The concomitant drugs included Prenatal Vitamin, Iron Supplement, Zoloft which patient had received within 2 weeks of vaccination. Facility where the most recent COVID-19 vaccine was administered was the workplace clinic. The patient had not received any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19 and had no allergies. The patient reported that on 07Apr2021 the foetus she was pregnant with stopped growing at 5.5 weeks which happened to be the same time she had the vaccine. She ended up with a miscarriage which resulted in doctor or other healthcare professional office/clinic visit. The patient had received the treatment. The outcome of the event was fatal. Follow-up attempts are needed. Further information is expected Follow-up (07Jun2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts completed. No further information is expected.; Sender"s Comments: Linked Report(s): US-PFIZER INC-2021536223 fetal case and maternal case; Reported Cause(s) of Death: Fetal death

 VAERS ID:
 1394136 (history)
 Vaccinated:
 2021-06-01

 Form:
 Version 2.0
 Onset:
 2021-06-01

Age: Days after Sex: Male vaccination:

 Location:
 Unknown
 Submitted:
 0000-00-00

 Entered:
 2021-06-12

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No

Died? Yes Date died: 2021-06-01

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:
Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: PFIZER INC2021655748

Write-up: This is a spontaneous report from a non-contactable nurse. An adult male patient of unspecified age received the second single dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) on an unspecified date in Jun2021, for COVID-19 immunization. The first dose of BNT162B2 vaccine was administered on an unknown date. Medical history and concomitant medications were not reported. The patient took the second dose of Covid 19 vaccine and died sometime in the same week, on an unspecified date in Jun2021. Cause of death was unknown. It was unknown if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender"s Comments: Event unknown cause of death is assessed as related until sufficient information is available to confirm an unrelated cause of death. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for

safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: The patient took the second dose of Covid 19 vaccine and died sometime in the same week

 VAERS ID: 1394140 (history)
 Vaccinated:
 2021-05-13

 Form:
 Version 2.0
 Onset:
 2021-05-14

Age: Days after Sex: Male vaccination:

Location: California Submitted: 0000-00-00
Entered: 2021-06-12

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EX8679 / 2 - / -

Administered by: Unknown Purchased by: ?

Symptoms: Myocarditis

SMQs:, Cardiomyopathy (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Immune-mediated/autoimmune disorders (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-05-14 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:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data:

CDC Split Type: PFIZER INC2021664604

Write-up: the cause of death is myocarditis; This is a spontaneous report from a contactable consumer reporting for her father. A 78-years-old male patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on 13May2021 (Batch/Lot Number: EX8679) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient died from myocarditis on 14May2021. The patient died on 14May2021. It was not reported if an autopsy was performed. Course of the event. The woman reported that her father, who was vaccinated in out of country, died after the second dose. He got his second dose on 13May2021 and died the next day (14May2021). The cause of death is myocarditis. Follow up information has been requested.; Reported Cause(s) of Death: the cause of death is myocarditis

 VAERS ID: 1398443 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-06-15

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | - / UNK    | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Adverse drug reaction

SMQs:

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:

Previous Vaccinations: Other Medications:

Current Illness: Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210619563

Write-up: SÉVERE SIDE EFFECTS; This spontaneous report received from a patient concerned a female of unspecified age. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) 1 total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient experienced severe side effects. On an unspecified date, the patient died from severe side effects. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0:20210619563 - Covid-19 Vaccine Ad26.Cov2.S - Severe Side Effects. This event is considered Unassessable. The event has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially

associated with the event.; Reported Cause(s) of Death: SEVERE SIDE EFFECTS

VAERS ID: 1398528 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-06-15

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / UNK - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (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:** Allergies: Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: heart attack; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (heart attack) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) unknown. On an unknown date, the patient experienced MYOCARDIAL INFARCTION (heart attack) (seriousness criteria death and medically significant). The reported cause of death was Myocardial infarction. It is unknown if an autopsy was performed. Concomitant medications were not reported. No treatment information was provided. Patient reported a family member died from a heart attack shortly after getting your vaccine. Very limited information regarding this event has been provided at this time. Further information has been requested,; Sender's Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Myocardial infarction

VAERS ID: <u>1401679</u> (history) Vaccinated: 0000-00-00 Version 2.0 0000-00-00 Form: Onset: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-06-16

Location: Michigan

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USJNJFOC20210626951

Write-up: DIED; This spontaneous report received from a company representative via Social media concerned a 35-year-old female, unspecified race and ethnicity. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. Post vaccination, after one week, on an unspecified date patient died, cause of death was unknown. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210626951- Covid-19 vaccine ad26.cov2.s-Died. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

Vaccinated: 0000-00-00 VAERS ID: <u>1401705</u> (<u>history</u>) Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 2021-06-16 Sex: Unknown Entered:

Location: Pennsylvania

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | UNKNOWN / UNK | - / OT       |

Administered by: Unknown Symptoms: Cardiac disorder

SMQs:

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:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Cardiac problems after receiving either Pfizer or Moderna vaccine; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a nurse and describes the occurrence of CARDIAC DISORDER (Cardiac problems after receiving either Pfizer or Moderna vaccine) in an elderly patient of an unknown gender who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced CARDIAC DISORDER (Cardiac problems after receiving either Pfizer or Moderna vaccine) (seriousness criterion death). The reported cause of death was Cardiac disorder NOS. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. Company Comment: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the event, a causal relationship cannot be excluded.; Reported Cause(s) of Death: Cardiac disorder NOS

VAERS ID: <u>1402006</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Entered: 2021-06-16 Sex: Female

Location: Unknown

Vaccination / Manufacturer Site / Route Lot / Dose COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Purchased by: ?

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USJNJFOC20210626664

Write-up: DEATH; This spontaneous report received from a consumer via a company representative concerned a female of unspecified age. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry: Not reported) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient died. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died due to unknown cause. This report was serious (Death).; Sender"s Comments: V0; 20210626664- COVID-19 VACCINE AD26.COV2.S-Death. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1402014</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-06-16

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USJNJFOC20210629311

Write-up: DEATH; This spontaneous report received from a consumer via a company representative concerned an adult male. Additional live follow up was received on 14-JUN-2021. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) one total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient was died. The cause of death was not reported. It was unknown whether the autopsy was done or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210629311- covid-19 vaccine ad26.cov2.sdeath. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

**VAERS ID: 1405294** (history) Vaccinated: 0000-00-00 Version 2.0 0000-00-00 Form: Onset: Age: Submitted: 0000-00-00 Sex: Unknown Entered: 2021-06-17

Location: Pennsylvania

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA UNKNOWN / UNK - / OT

Purchased by: ?

Administered by: Unknown

Symptoms: Cardiac disorder SMQs:

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: Current Illness:

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Cardiac problems after receiving either Pfizer or Moderna vaccine; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a health care professional and describes the occurrence of CARDIAC DISORDER (Cardiac problems after receiving either Pfizer or Moderna vaccine) in an elderly patient of an unknown gender who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced CARDIAC DISORDER (Cardiac problems after receiving either Pfizer or Moderna vaccine) (seriousness criteria death and life threatening). The reported cause of death was cardiac disorder. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No relevant concomitant medications were reported. It was reported that the reporter has seen that patients above 60 years of age who developed Cardiac problems after receiving either Pfizer or Moderna vaccine. Two patients even passed away post cardiac problems after vaccination. No treatment information was provided. Action taken with mRNA-1273 in response to the events was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Reported Cause(s) of Death: Cardiac disorder

**VAERS ID:** <u>1406251</u> (<u>history</u>) Vaccinated: 0000-00-00 Form: Version 2.0 0000-00-00 Onset: Submitted: 0000-00-00 Age: 2021-06-17 Sex: Male Entered:

Location: Florida

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN -/ UNK

Administered by: Other Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210626581

Write-up: BLOOD CLOT; This spontaneous report received from a physician concerned a 21 year old male of unspecified race and ethnicity. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient had blood clot at some point following vaccination and died due to it. It was not reported, if the autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death). This case is linked to 20210456400 and 20210457370 (same reporter). .; Sender's Comments: V0: 20210626581-covid-19 vaccine ad26.cov2.s-This case concerns a 21 year old male, Blood Clot. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: BLOOD CLOT

VAERS ID: <u>1406256</u> (history) Vaccinated: 0000-00-00 Version 2.0 0000-00-00 Form: Onset: Age: Submitted: 0000-00-00 Female Entered: 2021-06-17 Sex:

Location: Florida

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / 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: 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:

CDC Split Type: USJNJFOC20210628286

Write-up: STROKE; This spontaneous report received from a consumer via a company representative via social media platform concerned a female of unspecified age. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose at a frequency of 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient got stroke and patient died from stroke. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0:20210628286-JANSSEN COVID-19 VACCINE Ad26.COV2.S - stroke with fatal outcome- This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: STROKE

**VAERS ID:** <u>1409735</u> (history) Vaccinated: 0000-00-00 Version 2.0 0000-00-00 Form: Onset: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-06-18

Location: Unknown

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

Administered by: Unknown Purchased by: ? Symptoms: Death, Malaise, Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (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:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021683311

Write-up: died, received the Pfizer vaccine; massive heart attack; she wasn"t feeling well; This is a spontaneous report from a non-contactable consumer or other non hcp. A 74-years-old female patient received second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; formulation: Solution for injection, Lot Number: UNKNOWN), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation. The patient medical history and

concomitant medications were not reported. The patient had vaccine on an unspecified date and within one day, the patient stated she wasn"t feeling well. It was reported that she had massive heart attack. The reporter reported that the patient died on an unspecified date and do not know what happened. The patient died on an unspecified date for an unspecified reason. It was unknown weather autopsy was performed or not. The outcome of she wasn"t feeling well and massive heart attack was unknown. Request Name: REQ-347122 Product: PFIZER-BIONTECH COVID-19 VACCINE Question: Has anyone reported Heart attack or stroke? Response: Spoke from attached document: In the all-enrolled population of (total N=43,448), the proportions of participants who reported at least 1 SAE during the time period from Dose 1 to the data cutoff date (November 14, 2020) were 0.6% in the BNT162b2 vaccine group and 0.5% in the placebo group. The most common SAEs in the vaccine group which were numerically higher than in the placebo group were acute myocardial infarction (0.02%), and cerebrovascular accident (0.02%), and in the placebo arm numerically higher than in the vaccine arm were pneumonia (0.03%), atrial fibrillation (0.02%), and syncope (0.02%). Occurrence of SAEs involving system organ classes and specific preferred terms were otherwise balanced between treatment groups, including no imbalance overall in cardiovascular serious adverse events. Offered to email for review, caller declined. No follow-up attempts are possible, No further information is expected.

 VAERS ID: 1412223 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Unknown
 Entered:
 2021-06-19

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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:

CDC Split Type: USJNJFOC20210627096

Write-up: BLOOD CLOT; This spontaneous report received from a patient via social media via a company representative concerned a patient of unspecified age and sex. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient had blood clot and died. The cause of death is blood clot. It was unknown whether an autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death). This case, from the same reporter is linked to 20210627090.; Sender"s Comments: V0: 20210627096-covid-19 vaccine ad26.cov2.s-blood clot. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: BLOOD CLOT

 VAERS ID: 1412230 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-06-19

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Cerebral haemorrhage

SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Haemorrhagic central nervous system vascular conditions (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-06-10 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:

CDC Split Type: USJNJFOC20210628293

Write-up: BRAIN BLEED; This spontaneous report received from a consumer via social media via a company representative concerned a male of unspecified age. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry: Unknown) dose, start therapy date were not reported, 1 total, administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced brain bleed. On Thursday 10-JUN-2021, the patient died from brain bleed. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death). This case, from the same reporter is linked to 20210628379 and 20210628386.; Sender's Comments: V0-20210628293-Covid-19 vaccine ad26.cov2.s -BRAIN BLEED. This event(s) is

considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: BRAIN BLEED

 VAERS ID: 1413724 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-06-21

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: COVID-19, Death

SMQs:, Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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:

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210629346

Write-up: PÁSSED AWAY; COVID-19; This spontaneous report received from a consumer via a company representative via social media concerned a female of unspecified age. Initial information was processed with the additional information received from central complaint vigilance on 15-JUN-2021. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose not reported. I total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient got COVID-19 and passed away. The patient died from unknown cause of death. It was unknown if autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of COVID-19 was not reported. This report was serious (Death). This report was associated with product quality complaint: 90000182715. The suspected product quality complaint has been confirmed to be voided (did not meet PQC criteria) based on the PQC evaluation/investigation performed. This case, from the same reporter is linked to 20210635272.; Sender's Comments: V0; 20210629346-covid-19 vaccine ad26.cov2.s ?Passed away. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1413736 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Male
 Entered:
 2021-06-21

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Myocarditis

SMQs:, Cardiomyopathy (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Immune-mediated/autoimmune disorders (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:

Preexisting Conditions Allergies: Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210632922

Write-up: SUDDEN CARDIAC DEATH CAUSED BY MYOCARDITIS; This spontaneous report received via social media from a patient via a company representative concerned a 30 year old male. The patient"s weight, height and medical history were not reported. No past medical history or concurrent conditions were reported. On an unspecified date, the patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: not reported) 1 total dose administered, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, after eight days of vaccination, the patient died of sudden cardiac death caused by myocarditis. The reporter figured all this in the news and thought it could be related. The cause of death was myocarditis. It was unknown whether an autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0: 20210632922-covid-19 vaccine ad26.cov2.s-sudden cardiac death caused by myocarditis. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: MYOCARDITIS

VAERS ID: <u>1413743</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-06-21

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-05-01 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:

CDC Split Type: USJNJFOC20210634485

Write-up: DEATH; This spontaneous report received from a consumer via a company representative via social media concerned a female of unspecified age. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total, administered on 02-MAY-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date in MAY-2021, she died from unknown cause of death. It was reported that, patient"s obituary news was on paper on 17-MAY-2021. It was unspecified that if the autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0-20210634485- Covid-19 vaccine ad26.cov2.s-Death. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1413754</u> (<u>history</u>) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-06-17 Submitted: 0000-00-00 Age: Entered: 2021-06-21 Sex: Male

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-06-17 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: **Preexisting Conditions:** 

Allergies: Diagnostic Lab Data:

CDČ Split Type: USJNJFOC20210637036

Write-up: This spontaneous report received from a company representative concerned a male of unspecified age. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) 1 total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On 17-JUN-2021, the the died from unknown cause of death. The father suspected that the death might be related to the Janssen Covid-19 vaccine. An autopsy was planned to be performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0:20210637036- covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1416488</u> (<u>history</u>) Vaccinated: 0000-00-00 Version 2.0 0000-00-00 Form: Onset: Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-06-22

Location: Texas

Vaccination / Manufacturer Lot / Dose Site / Route

COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 -/ OT

Administered by: Unknown Purchased by: ?

Symptoms: Death, Seizure

SMQs:, Systemic lupus erythematosus (broad), Convulsions (narrow), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad),

Noninfectious meningitis (broad), Generalised convulsive seizures following immunisation (narrow), 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:

Current Illness:

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Passed away; Had seizures 2 days after receiving his first dose; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Passed away) and SEIZURE (Had seizures 2 days after receiving his first dose) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced DEATH (Passed away) (seriousness criteria death and medically significant) and SEIZURE (Had seizures 2 days after receiving his first dose) (seriousness criterion medically significant). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, SEIZURE (Had seizures 2 days after receiving his first dose) outcome was unknown. No concomitant medication information was provided. No treatment medication information was provided. Reporter stated she knows of someone and is not totally sure which vaccine was taken, but says Moderna. Action taken with respect to mRNA-1273 was not applicable. This is a case of a sudden death of a Male patient who reportedly had seizures 2 days after receiving his vaccine. Reporter is unsure of vaccine that patient received and this can be a confounding factor. Very limited information has been provided regarding these events. Most recent FOLLOW-UP information incorporated above includes: On 18-Jun-2021: Sender's Comments: This is a case of a sudden death of a Male patient who reportedly had seizures 2 days after receiving his vaccine. Reporter is unsure of vaccine that patient received and this can be a confounding factor. Very limited information has been provided regarding these events.; Reported Cause(s) of Death: unknown cause of death

 VAERS ID: 1416708 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Sex: Female
 Submitted: 0000-00-00

 Entered: 2021-06-22

Location: California

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Aortic thrombosi

SMQs:, Embolic and thrombotic events, arterial (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-05-29 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:

CDC Split Type: USJNJFOC20210628291

Write-up: BLOOD CLOT IN AORTIC ARTERY; This spontaneous report received from a consumer via a company representative concerned a female of unspecified age. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unk) dose not reported, 1 total administered on 27-MAR-202 for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient experienced a massive blood clot in her aortic artery blocking all the blood flow to her legs then, pieces broke off and went to her brain and heart. On 28-MAY-2021 13:45 in afternoon the patient"s life support was stopped. On 29-MAY-2021 at 2:01, 9 weeks after vaccination the patient died from blood clot in aortic artery. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s

13:45 in afternoon the patient"s life support was stopped. On 29-MAY-2021 at 2:01, 9 weeks after vaccination the patient died from blood clot in aortic artery. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: This spontaneous report from consumer concerns a female patient of unspecified age/race/ethnicity who developed "massive blood clot in her aortic artery blocking all the blood flow to her legs then, pieces broke off and went to her brain and heart" 62 days after receiving Janssen COVID-19 vaccine. The patient died on 63rd day post vaccination. No other details reported. The information available precludes a complete and meaningful assessment. Considering the temporal relationship, the events are assessed to have an indeterminate relationship with the vaccination.; Reported Cause(s) of Death: BLOOD CLOT IN AORTIC ARTERY

 VAERS ID: 1419747 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-06-23

 Location:
 Unknown

Vaccination / Manufacturer Lot / Dose Site / Route

COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death, Suspected COVID-19, Vaccination failure

SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210635272

Write-up: PASSED AWAY; SUSPECTED CLINICAL VACCINATION FAILURE; SUSPECTED COVID-19 INFECTION; This spontaneous report received from a consumer via a company representative via social media concerned a patient of unspecified age, sex, unknown race and ethnicity. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: not reported, expiry: unknown) dose was not reported, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, patient had suspected Covid-19, suspected clinical vaccination failure and patient passed away from unknown cause. It was unknown if the autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient was passed away on an unspecified date. The outcome of suspected covid-19 infection and suspected clinical vaccination failure was not reported. This report was serious (Death, and Other Medically Important Condition). This case, from the same reporter is linked to 20210629346.; Sender''s Comments: V0: 20210635272-Covid-19 vaccine ad26.cov2.s-Passed away This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). 20210635272-Covid-19 vaccine ad26.cov2.-Suspected Clinical Vaccination Failure . This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: SPECIAL SITUATIONS.; Reported Cause(s) of Death: UNKNOWN CAUSE OF **DEATH** 

VAERS ID: <u>1419824</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: 2021-06-23 Sex: Unknown Entered:

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | - / UNK    | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Died; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Died) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant medications were provided. It was reported that a person died after receiving a COVID-19 vaccine. No further details were provided. Very limited information regarding this event has been provided at this time. Further information has been requested.; Sender"s Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1419839</u> (history) Vaccinated: 2021-04-16

Form: Version 2.0 Onset: 2021-04-23

Davs after Age: vaccination: Sex: Male

Submitted: 0000-00-00 Location: Unknown Entered: 2021-06-23

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | - / UNK    | - / OT       |

Administered by: Unknown Purchased by: ? Symptoms: Death, Feeling abnormal, Illness

SMQs:, Dementia (broad) Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-05-26 Days after onset: 33 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: Surgery (Bladder surgery on 25 Feb.)

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Stated going downhill; He died; Got a little sick,he stated going downhill; This spontaneous case was reported by a patient family member or friend and describes the occurrence of DEATH (He died) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Surgery (Bladder surgery on 25 Feb.). On 16-Apr-2021, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 23-Apr-2021, the patient experienced ILLNESS (Got a little sick,he stated going downhill). On an unknown date, the patient experienced FÉELING ABNORMAL (Stated going downhill). The patient died on 26-May-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, ILLNESS (Got a little sick,he stated going downhill) and FEELING ABNORMAL (Stated going downhill) outcome was unknown. Treatment and concomitant information was not provided by the reporter. Patient had the modera shot on 16-Apr-2021 and he was recovering from a bladder surgery. Very limited information regarding this events has been provided at this time. Further information has been requested.; Sender"s Comments: Very limited information regarding this events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1419925</u> (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Unknown Entered: 2021-06-23 Sex:

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: 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:

CDC Split Type: USPFIZER INC2021702371

Write-up: patient died recently after getting the vaccine; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient died recently after getting the vaccine. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information about lot/batch number has been requested.; Reported Cause(s) of Death: patient died recently after getting the vaccine

VAERS ID: <u>1419934</u> (history) Vaccinated: 0000-00-00 0000-00-00 Form: Onset: Version 2.0 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-06-23

Location: Indiana

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PEIZER-BIONTECH)) / PEIZER/BIONTECH | - / UNK    | -/-          |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC2021711228

Write-up: with no health conditions died after the vaccine; This is a spontaneous report from a contactable consumer (patient"s friend). A 25-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date as dose number unknown, single for covid-19 immunisation. The patient medical history and concomitant medications were not reported. A friend"s 25 year old daughter (the patient) with no health conditions died after the vaccine. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: with no health conditions died after the vaccine

VAERS ID: <u>1420118</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-06-23

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USJNJFOC20210644799

Write-up: DEATH: This spontaneous report received from a parent via a company representative via social media concerned a 30 year old male, unknown race and ad26.cov2.s (suspension for injection, route of admin not reported, batch number: not reported, expiry: unknown) dose was not reported, 1 total, administered on APR-2021 for prophylactic vaccination. The batch number was not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: not reported, expiry: unknown) dose was not reported, 1 total, administered on APR-2021 for prophylactic vaccination. The batch number was not reported. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient was died. The patient died from unknown cause of death. It was unknown if the autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210644799-COVID-19 VACCINE AD26.COV2.S-Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

Vaccinated: 0000-00-00 VAERS ID: <u>1422827</u> (history) Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Unknown 2021-06-24 Entered: Sex:

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 RA / SYR

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-20 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: CDC Split Type: Write-up: Death

Vaccinated: 0000-00-00 VAERS ID: 1423008 (history) Form: Version 2.0 Onset: 2021-06-14 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-06-24

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death, Nightmare

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

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:

Date died: 2021-06-14

**Preexisting Conditions:** Allergies:

**Current Illness:** 

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210633197

Write-up: DEATH; SHEER NIGHTMARE THE SPIKE PROTEINS; This spontaneous report received from a patient via a company representative concerned a female of unspecified age, race and ethnicity. The patient sheight, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, expiry: UNKNOWN) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up was requested for this case. No concomitant medications were reported. On 14-JUN-2021, the patient experienced sheer nightmare the spike proteins and died from unknown cause of death on 14-JUN-2021, and the outcome of sheer nightmare the spike proteins was not reported. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210633197-covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1423010</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Female Entered: 2021-06-24 Sex:

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | - / UNK    | -/-          |

Administered by: Other Purchased by: ? Symptoms: Cerebral thrombosis, Coma, Death

SMQs:, Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Ischaemic central nervous system vascular conditions (narrow), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (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: **Current Illness:** 

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210637172

Write-up: DEATH; COMA; BLOOD CLOTS ON BRAIN; This spontaneous report received from a consumer via a company representative concerned a female of unspecified age. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot number. No concomitant medications were reported. On an unspecified date, the subject experienced death, coma, and blood clots on brain. On an unspecified date, the patient died from blood clots on brain, and coma. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0-20210637172-COVID VACCINE AD26.COV2.S-Death, Coma, Blood clots on brain. This events are considered un-assessable. The events have a compatible/suggestive temporal relationship, are unlabeled, and have unknown scientific plausibility. There is no information on any other factors potentially associated with the events.; Reported Cause(s) of Death: BLOOD CLOTS ON BRAIN; COMA

VAERS ID: 1423016 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-06-24

Location: Maine

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: COVID-19, SARS-CoV-2 test positive, Vaccination failure

SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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: Rheumatoid arthritis (Treated by immune-suppressing drug (Unspecified))

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data: Test Name: SARS-CoV-2 test positive; Result Unstructured Data: Positive

CDC Split Type: USJNJFOC20210644468

Write-up: DIED FROM COVID-19; SUSPECTED CLINICAL VACCINATION FAILURE; This spontaneous report received from a company representative and a physician via social media concerned a 74 year old female. The patient"s height, and weight were not reported. The patient"s concurrent conditions included rheumatoid arthritis and patient was taking unspecified immune-suppressing medication. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: not reported) dose, start therapy date were not reported for an unspecified indication. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date the patient experienced Covid-19, and suspected clinical vaccination failure. The patient tested positive for Covid-19 four weeks after receiving the vaccine & later died from Covid-19. Her case was extremely rare. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of Covid-19 on an unspecified date and the outcome of suspected clinical vaccination failure was not reported. This report was serious (Death, and Other Medically Important Condition).; Sender"s Comments: V0: 20210644468-COVID-19 VACCINE AD26.COV2.S-DIED FROM COVID-19. This event is considered Unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. 20210644468-COVID-19 VACCINE AD26.COV2.S-SUSPECTED CLINICAL VACCINATION FAILURE. This event(s) is considered not related. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There are other factors more likely to be associated with the event(s) than the drug. Specifically: SPECIAL SITUATIONS.; Reported Cause(s) of Death: COVID-19

VAERS ID: <u>1423057</u> (<u>history</u>) Vaccinated: 0000-00-00 Version 2.0 Form: Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-06-24

Location: California

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Dyspnoea

SMQs:, Anaphylactic reaction (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Cardiomyopathy (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: Polio **Preexisting Conditions:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Problems breathing; This spontaneous case was reported by an other health care professional and describes the occurrence of DYSPNOEA (Problems breathing) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Concurrent medical conditions included Polio. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient experienced DYSPNOEA (Problems breathing) (seriousness criterion death). The reported cause of death was problems breathing. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown), the reporter did not provide any causality assessments. Concomitant medications was not provided. Treatment medications was not provided. Action taken with mRNA-1273 in response to events was not applicable. As a young child, patient was in an iron lung. This is a case of fatal Dyspnoea in a male subject with a hx of polio, who died after receiving the second dose of vaccine. Very limited information has been provided at this time.; Sender''s Comments: This is a case of fatal Dyspnoea in a male subject with a hx of polio, who died after receiving the second dose of vaccine. Very limited information has been provided at this time.; Reported Cause(s) of Death: Problems breathing

**VAERS ID: 1423112** (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-06-24

Location: Maryland

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

Administered by: Unknown Purchased by: ? Symptoms: Cardiac disorder, Cardiac failure congestive SMQs:, Cardiac failure (narrow), Cardiomyopathy (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:

CDC Split Type: USPFIZER INC2021673157

Write-up: congestive heart failure; Heart problem/heart down; This is a spontaneous report from a Pfizer-sponsored program. A contactable consumer reported that a 90-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as dose 1, single and via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as dose 2, single for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient experienced congestive heart failure and heart problem/heart down. The patient had a heart problem after the Pfizer Covid vaccine. The patient had congestive heart failure and was 90 years old. The hospital said for the patient to get the second shot and it shut her heart down and the patient passed away. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on Lot/Batch number has been requested.; Reported Cause(s) of Death: congestive heart failure; Heart problem/heart down

VAERS ID: <u>1423115</u> (<u>history</u>) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-06-24

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021674301

Write-up: died because of the vaccine; This is a spontaneous report from a Non-contactable consumer (patient's grandson). A male patient of an unspecified age received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunization. The patient"s medical history and concomitant medications were not reported. The patient died because of the vaccine on an unspecified date. The cause of death was not reported. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: died because of the vaccine

VAERS ID: 1423128 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-06-24

Location: Pennsylvania

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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: CDC Split Type: USPFIZER INC2021719708

Write-up: Died 3-5 days after getting the Pfizer COVID vaccine; This is a spontaneous report from a contactable consumer. An elderly female patient received bnt162b2 (Pfizer COVID vaccine), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as dose number unknown, single for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Consumer stated that her aunt, who was going to be 100 years old, died 3-5 days after getting the Pfizer COVID vaccine. Consumer stated that they were healthy people. She stated that she is a transfusion medical specialist. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on lot/batch number has been requested.; Reported Cause(s) of Death: Died 3-5 days after getting the Pfizer COVID vaccine

VAERS ID: 1426843 (history) Vaccinated: 2021-03-26 Version 2.0 Onset: 0000-00-00 Form: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-06-25

Location: New Hampshire

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EL9269 / 1

Administered by: Senior Living Purchased by: ?

Symptoms: Chest pain, Dyspnoea

SMQs:, Anaphylactic reaction (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (broad), Cardiomyopathy (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:

CDC Split Type: USPFIZER INC2021415137

Write-up: chest pain; had some acute shortness of breath; This is a spontaneous report from a contactable nurse (Registered Nurse) via Medical Information Team. This nurse reported for 7 patients. This report is 7 of 7 patient. A female patient of an unspecified age received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection) via an unspecified route of administration on 26Mar2021 (Lot number: EL9269, Expiry date: 01May2021) as single dose for Covid-19 immunisation. The patient's medical history and concomitant medications were not reported. On an unspecified date, the patient had some acute shortness of breath and chest pain. Reportedly she was calling from the nursing home stated that she was trying multiple times and she needed to speak to someone to report adverse reactions, she had been reporting to the VAERS system since they started giving vaccines in January, stated: "she had summitted probably 30 reports at that point of all different various things in any of the patients even if they were in hospice if they had a vaccine and proceeded to pass away, she done all the reporting. She had a very abnormal large volume of patients that got vaccinated on 16th of April, with the first doses of Pfizer (PFIZER-BIONTECH COVID-19 VACCINE) one specific of number and she had 7 adverse events in one group of patients out of 30. And it was way too complicated to get that information quickly, so she spoke to somebody as there was a chance that those could be a significant event and needed to tell somebody what was going on". Caller stated: "because all the reports involving one lot it was more suspicious than even all the other reports that she had ever done. It was just one whole group and now she had 3 deaths. She had 3 deaths and have 2 strokes in this group". Caller stated that she would file reports online she just wanted someone to call her back about the side effects and the lot involved. Stated "she got the whole group, who were due to get their second dose on Friday, two days from now, so obviously she not giving it to any of these people there was a 7 of them out of 33. She had 20 staff that have received it the same day she did not have any side effects in any of the staff but definitely little weary at the moment." Offered to forward provide information to safety. Caller provided lot EL9269, Expiry date 01May2021 (stated that it was weird because it was very close to the expiration date). Caller stated: "All those people were dosed on March 26th. Caller stated that she was going to give just basics (in terms of information to start the process) and that she would file a form online. Caller stated: "That day 31 patients received a vaccine and she had 7 patients worth investigating (caller stated that she had that portion written if there was a way to forward. Explained that there was an option to contact through our website but for adverse reports specifically she would refer them to Pfizer safety explained that she also had a fax, but caller declined she already had that information. Verified that she was reporting adverse events (7 patients, gender: 5 females and 2 males). Caller stated "three patients were send out and subsequently passed away in the hospital, one patient with bradycardia, hypotension and she passed away in the ER, critical labs, she did not even make it one day, we send her out and she passed away in the ER. She had one male patient who had acute stroke she did not have all the details because he was still hospitalized in ICU. She have one (patient) who we sent to the ER hypoxic, hypotensive, short of breath, she ended up passing away in the hospital, her diagnosis there was hypoxia and acute CHF. She had another male patient who had an acute CVA we send him to the hospital he had acute CVA, he had a right artery occlusion, he passed away. She had another female patient who was sent out with shortness of breath and increased confusion, she wound up in the ER with hypoxia and sepsis and she passed away. She was sure that she did not have hospital records, only know what she was told. And then had two others one that was send to the ER with shortness of breath and elevated D-dimer, she actually returned to us her scans were negative, so she was one of those we are not really 100 percent sure, but she did get send out to the ER. And we have another one (female) chest pain, shortness of breath, she was not sent out her D-dimer and her studies that we have done here were within normal limits but definitely had some acute shortness of breath and chest pain. Done troponin and bunch of cardiac labs there, she did not go out. So those were the seven that she had at the moment that were concerning. Outcome of the events was unknown. No follow up attempts are possible. No further information is expected.

VAERS ID: 1426917 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-06-25

Location: Kentucky

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

Administered by: Unknown Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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:

CDC Split Type: USPFIZER INC2021683252

Write-up: pass away recently due to blood clots; This is a spontaneous report from a contactable nurse (parent) and consumer. The nurse reported similar events for three patients. This is the first of three reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as DOSE NUMBER UNKNOWN, SINGLE for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. The patient pass away recently due to blood clots on an unspecified date. The patient died on an unspecified date. It was not reported if an autopsy was performed. It was reported that even though the event was outside of reporting timelines & deemed by the PI to be unrelated to study drug. Information on batch and lot number is requested.; Sender's Comments: Based on available information, a possible contributory role of the subject product, BNT162B2 vaccine, cannot be excluded for the reported event of thrombosis with fatal outcome due to temporal relationship. However, the reported event may possibly represent intercurrent medical condition in this patient. There is limited information provided in this report. Additional information is needed to better assess the case, including complete medical history, diagnostics including vascular imaging studies, coagulation panel and autopsy results, counteractive treatment measures and concomitant medications. This case will be reassessed once additional information is available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate., Linked Report(s): PFIZER INC-2021688670 same reporter, event and suspect drug; different patient; PFIZER INC-2021688671 same reporter, event and suspect drug; different patient; Reported Cause(s) of Death: blood clots

**VAERS ID:** <u>1426921</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-06-25

Location: Kentucky

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

Administered by: Unknown Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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:

CDC Split Type: USPFIZER INC2021688670

Write-up: Patient died due to Blood clots; This is a spontaneous report from a contactable nurse. This nurse reported similar events for 3 patients. This is the 2nd of 3 reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as unknown dose, single for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient pass away recently due to blood clots. The agency also stated that all 3 of these nurses had received the Pfizer vaccine. Document submitted for patient even though the event was outside of reporting timelines and deemed by the PI to be unrelated to study drug. It is not reported if autopsy was performed. information about lot/batch number has been requested.; Sender"s Comments: Based from current drug profile, the event thrombosis is assessed as unrelated to suspected drug BNT162B2. It is difficult to provide possible cause of the event due to limited patient medical information or background.,Linked Report(s): PFIZER INC-2021688252 same reporter, same drug, same event, different patient; PFIZER INC-2021688671 same reporter, same drug, same event, different patient; Reported Cause(s) of Death: Blood clots

 VAERS ID: 1429304 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Unknown
 Entered:
 2021-06-26

Location: Unknown

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK
 - /

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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

Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210648705

Write-up: PEOPLE HAD DIED; This spontaneous report received from a consumer via social media concerned multiple patients of unspecified ages with unknown ethnicity and race. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown, Expiry: Unknown) dose not reported, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, reporter stated that people had died from vaccine and they were healthy before the vaccination. Patients were died from unknown cause of death. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of the event patient had died was fatal. This report was serious (Death). This case, from the same reporter is linked to 20210648176; Sender"s Comments: V0: 20210648705- covid-19 vaccine ad26.cov2.s-People had died . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1429416 (history)
 Vaccinated:
 2021-03-26

 Form:
 Version 2.0
 Onset:
 2021-04-01

 Age:
 Days after vaccination:
 6

 Location:
 Illinois
 Submitted:
 0000-00-00

**Location:** Illinois **Submitted:** 0000-00-00 **Entered:** 2021-06-26

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

Administered by: Unknown Purchased by: ?

Symptoms: COVID-19, Death, Drug ineffective, SARS-CoV-2 test

SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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:

Previous Vaccinations: Other Medications: Current Illness: Preexisting Conditions: Allergies:

Diagnostic Lab Data: Test Date: 202104; Test Name: Covid-19; Result Unstructured Data: Test Result:Contracted COVID

CDC Split Type: USPFIZER INC2021694061

Write-up: Contracted COVID in April before they could receive the 2nd dose and were hospitalized for 2 weeks; Contracted COVID in April before they could receive the 2nd dose and were hospitalized for 2 weeks; Husband passed away; This is a spontaneous report from a contactable pharmacist. This pharmacist (Patient's wife) reported for a male patient (Reporter's husband). A 70-years-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection. Lot number: unknown), dose 1 via an unspecified route of administration on 26Mar2021 as dose 1, single for COVID-19 immunization. No medical and concomitant medication history were reported. She and her husband (who also received the vaccine) contracted COVID in April 2021 before they could receive the second dose and were hospitalized for 2 weeks. The husband passed away on an unspecified date, while the patient recovered from a severe (not mild) COVID infection. She was asking if she can get the second dose and when should she receive the second dose. The patient underwent lab tests and procedures which included SARS-CoV-2 test contracted COVID-19 in Apr2021. It was not reported if an autopsy was performed. The outcome of the event death was fatal and rest on events was unknown. information about lot/batch number has been requested.; Sender's Comments: As there is limited information in the case provided, the causal association between the event and the suspect drug cannot be excluded. The case will be reassessed once new information is available. The impact of this report on the benefit/risk profile of the Pfizer drug is evaluated as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: husband passed away

 VAERS ID: 1432774 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-06-29

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ? Symptoms: Myocardial infarction, Thrombosis

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (narrow), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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:

CDC Split Type: USJNJFOC20210648060

Write-up: HEART ATTACK; MULTIPLE BLOOD CLOTS; This spontaneous report received from a consumer via a company representative concerned a female of unspecified age. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, start therapy date were not reported ,1 total administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. The reporter stated that, On an unspecified date her mother had multiple blood clots due to which she had heart attack. Patient was on blood thinners and did not survive. It was unknown if autopsy was performed or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died from heart attack and had not recovered from multiple blood clots. This report was serious (Death).; Sender"s Comments: V0: 20210648060-covid-19 vaccine ad26.cov2.s -multiple blood clots, heart attack. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: HEART ATTACK

 VAERS ID: 1432778 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-06-29

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death
SMQs:
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 Vis

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness: Preexisting Conditions:

Allergies: Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210648251

Write-up: DEATH; This spontaneous report received from a consumer via a company representative from social media concerned a female of unspecified age. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN) dose, frequency 1 total, start therapy date were not reported administered for prophylactic vaccination. Batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient died. It was reported by consumer that his niece was died due to vaccine. No further information was provided. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210648251-JANSSEN COVID-19 VACCINE Ad26.COV2.S- Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1432788 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-06-29

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death, Hospitalisation

SMQs:

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: Current Illness: Preexisting Conditions: Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210650080

Write-up: IN THE HOSPITAL 3 DAYS AFTER JANSSEN VACCINE; DEATH (LOST THE FIGHT 3 WEEKS LATER); This spontaneous report received from a consumer via a company representative concerned a female of unspecified age and unknown race and ethnicity. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, one total administered, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported, it was reported that on an unspecified date, the patient was in the hospital fighting for her life 3 days after taking the vaccine. She lost the fight 3 weeks later (death). It was mentioned that the patient believed the propaganda and lost her life. The patient died due to unknown cause. It was unknown if autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0:20210650080-COVID-19 VACCINE AD26.COv2.S-In the Hospital 3 days after Jannsen vaccine, Death(Lost the Fight 3 weeks later). This event(s) is considered un-assessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1432789 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset:
 2021-03-14

 Age:
 Submitted:
 0000-00-00

 Sex:
 Male
 Entered:
 2021-06-29

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Cardiac arrest

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (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), Respiratory failure (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-14 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:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210650125

Write-up: CARDIAC ARREST; This spontaneous report received from a consumer via a company representative and concerned a 32 year old male of unspecified race and ethnic origin. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total administered on13-MAR-2021 for prophylactic vaccination.. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On 14-MAR-2021 with in 12 hours, the patient developed cardiac arrest and died due to it. On an unspecified date, an autopsy was performed but the result where not reported The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0:20210650125-JANSSEN COVID-19 VACCINE Ad26.COV2.S- cardiac arrest-This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: CARDIAC ARREST

 VAERS ID: 1432800 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-06-29

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Symptoms: Death

SMQs: 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:

CDC Split Type: USJNJFOC20210651615

Write-up: DEATH; This spontaneous report received from a consumer concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: UNKNOWN) frequency 1 total, dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient died from unknown cause of death. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210651615-COVID-19 VACCINE AD26.COV2.S -Death. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

**VAERS ID:** <u>1432866</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-06-29

Location: Florida

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA -/1 - / OT

Purchased by: ?

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: 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:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Her son has died; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Her son has died) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. No relevant concomitant medications were reported. No treatment information was provided. This is a case of death in a male subject who died after receiving first dose of vaccine Very limited information has been provided at this time.; Sender's Comments: This is a case of death in a male subject who died after receiving first dose of vaccine Very limited information has been provided at this time.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1432900</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Unknown Entered: 2021-06-29 Sex:

Location: Michigan

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: 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:

CDC Split Type: USPFIZER INC2021765175

Write-up: and have a question about a death being reported as possible link to COVID-19 vaccine; This is a spontaneous report from a contactable consumer. An unspecified age and gender patient received an unspecified dose of BNT162B2 via an unspecified route of administration on an unspecified date for COVID-19 immunization. Medical history and concomitant medication were not reported. On an unknown date, the patient experienced death and it was been reported as possible link to COVID-19 vaccine. The reporter stated that was reported a teen dead several days after gotten a vaccine. Since only Pfizer vaccine is available to teens and reporter wanted to know whether have a statement about this. The CDC was investigated any potential link. The outcome of event was fatal. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: and have a question about a death being reported as possible link to COVID-19 vaccine

VAERS ID: <u>1435925</u> (<u>history</u>) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Entered: 2021-06-30 Sex: Unknown

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | - / UNK    | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Product contamination, Pyrexia, Septic shock

SMQs:, Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Toxic-septic shock conditions (narrow), Drug reaction with eosinophilia and

systemic symptoms syndrome (broad), Sepsis (narrow), Opportunistic infections (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:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Fatal fevers; Septic shock; Product contamination; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a non-health professional and describes the occurrence of PYREXIA (Fatal fevers), SEPTIC SHOCK (Septic shock) and PRODUCT CONTAMINATION (Product contamination) in an elderly patient of an unknown gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) at an unspecified dose. On an unknown date, the patient experienced PYREXIA (Fatal fevers) (seriousness criterion death), SEPTIC SHOCK (Septic shock) (seriousness criteria death and medically significant) and PRODUCT CONTAMINATION (Product contamination) (seriousness criterion death). The cause of death was not reported. It is unknown if an autopsy was performed. Concomitant product use was not provided. 104 Patients received the vaccine. Treatment information was not provided. Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: 1435953 (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: 2021-06-30 Sex: Female Entered:

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: Life Threatening? No

Birth Defect? No Died? Yes

Date died: 0000-00-00 Permanent Disability? No

Office Visit? No ER Visit? No

Recovered? No

ER or Doctor Visit? No Hospitalized? No

**Previous Vaccinations:** Other Medications:

Current Illness: **Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Death; This spontaneous case was reported by a non-health professional and describes the occurrence of DEATH (Death) in a female patient of an

unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Sender"s Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

Vaccinated: 0000-00-00 VAERS ID: <u>1439574</u> (<u>history</u>) Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Unknown 2021-07-01 Sex: Entered:

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | -/UNK      | -/-          |

Purchased by: ?

Administered by: Other

Symptoms: Death

SMQs:

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:

CDC Split Type: USJNJFOC20210666298

Write-up: DEATH; This spontaneous report received from a consumer via other company Pfizer concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported) one total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patient was died. The cause of death was not reported. It was unknown whether the autopsy was done or not. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: 20210666298-Covid-19 vaccine ad26.cov2.s -Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1440065</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-07-01

Location: Unknown

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PEIZER-BIONTECH)) / PEIZER/BIONTECH | -12        | -/-          |

Administered by: Unknown Purchased by: ?

Symptoms: Autopsy, Cardiomegaly, Death, Pericardial effusion

SMQs:, Cardiac failure (broad), Systemic lupus erythematosus (broad), Haemodynamic oedema, effusions and fluid overload (narrow), Cardiomyopathy (broad), 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: autopsy; Result Unstructured Data: Test Result:enlarged heart and fluid surrounding the heart; Comments: caused by the Covid

CDC Split Type: USPFIZER INC2021760279

Write-up: died three days after Covid vaccination; Autopsy showed enlarged heart and fluid surrounding the heart; Autopsy showed enlarged heart and fluid surrounding the heart; This is a spontaneous report from a contactable consumer or other non-health care professional in response to mail sent regarding the confirmation of below mentioned query. A 13-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Batch/Lot number and Expiration date not reported) via an unspecified route of administration in an unspecified anatomical location on an unspecified date as single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. The patient previously received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Batch/Lot number and Expiration date not reported) via an unspecified route of administration in an unspecified anatomical location on an unspecified date as single dose for COVID-19 immunisation. On an unspecified date, the patient after receiving his second Covid vaccine from Pfizer died three days later. The patient underwent lab tests and procedures which included autopsy: enlarged heart and fluid surrounding the heart caused by the Covid vaccination. The outcome of the events was fatal. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: enlarged heart and fluid surrounding the heart

Vaccinated: 0000-00-00 VAERS ID: <u>1442349</u> (<u>history</u>) 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: 2021-07-02 Unknown Entered: Sex:

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK -/-

Administered by: Other Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210666397

Write-up: BLOOD CLOTS; This spontaneous report received from a consumer via a Business partner (Pfizer Inc.) on 25-JUN-2021 concerned three patients of unspecified age and gender. The patient's weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown and expiry date: unknown) dose was not reported, 1 total, start therapy date was not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, three patients were developed blood clot after vaccination. The patient died from blood clots on an unspecified date. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0:20210666397-Covid-19 vaccine ad26.cov2.s -Blood clots. This event is considered unassessable. The event has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: BLOOD CLOTS

VAERS ID: <u>1442361</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Sex: Female Entered: 2021-07-02

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs: 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:

CDC Split Type: USJNJFOC20210667006

Write-up: DEATH; This spontaneous report received from a consumer via a company representative concerned a female of unspecified age, race and ethnicity. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient died from the vaccine due to unknown cause of death and could never got the second shot. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210667006-JANSSEN COVID-19 VACCINE Ad26.COV2.S- Death. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1445751</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Unknown Entered: 2021-07-03 Sex:

Location: New York

Site / Route Vaccination / Manufacturer Lot / Dose COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA UNKNOWN / UNK - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 0000-00-00 Permanent Disability? No

Recovered? No Office Visit? Yes ER Visit? No ER or Doctor Visit? No Hospitalized? No **Previous Vaccinations:** Other Medications:

Current Illness: **Preexisting Conditions:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Received the Moderna Shot and within 7-8 weeks after passed away; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a patient family member or friend and describes the occurrence of DEATH (Received the Moderna Shot and within 7-8 weeks after passed away) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unknown) for COVID-19 vaccination. The patient"s past medical history included No adverse event. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant medication was reported by reporter. Patient died on an unknown date approximately 7 to 8 weeks after receiving vaccination.; Sender"s Comments: Very limited information regarding this event has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: unknown casuse of death

Vaccinated: 0000-00-00 **VAERS ID:** <u>1446010</u> (history) Version 2.0 0000-00-00 Form: Onset: Submitted: 0000-00-00 Age: Entered: 2021-07-03 Sex: Unknown

Location: Unknown

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

Administered by: Unknown Purchased by: ? Symptoms: Death, Headache, Loss of consciousne

SMQs:, Torsade de pointes/QT prolongation (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), Hypotonic-hyporesponsive episode (broad), Generalised convulsive seizures following immunisation (broad), Hypoglycaemia (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: **Current Illness: Preexisting Conditions:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021746877

Write-up: death; lost consciousness; headache; This is a spontaneous report from a non-contactable consumer via a regulatory authority. A 33-year-old patient of an unspecified gender received bnt162b2 (BNT162b2), via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunisation. The patient"s medical history and concomitant medications were not reported. On an unknown date, the patient experienced lost consciousness, headache, and death. The event, lost consciousness, was life-threatening. The event, death, was serious for death. The clinical course was as follows: the patient was a pilot who had been vaccinated with bnt162b2. A strong headache occurred immediately after starting the flight. Two hours later, the patient almost lost consciousness and made an emergency landing. (withheld) inoculated and killed three pilots. It's been a fuss, but it doesn"t stop anymore. The patient did not know when it will fall when the patient flies (as reported). The clinical outcome of the events, lost consciousness and headache, was unknown. The clinical outcome of the event, death, was fatal. The patient died on an unspecified date due to an unknown cause of death. 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: death

VAERS ID: <u>1446013</u> (<u>history</u>) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-07-03

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Thrombocytopenia

SMQs:, Haematopoietic thrombocytopenia (narrow), Systemic lupus erythematosus (broad), 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:

CDC Split Type: USPFIZER INC2021749751

Write-up: thrombocytopenia; This is a Literature report. The full publication has been requested. A patient of unspecified age and gender received BNT162B2 (lot number unknown), via an unspecified route of administration, on an unknown date at single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. The patient experienced thrombocytopenia and eventual death on an unknown date. The patient died on an unknown date. The cause of death was thrombocytopenia. It was unknown if an autopsy was performed. The outcome of the event was fatal. The recent report of thrombocytopenia and eventual death of a healthy person who received an mRNA-based COVID-19 vaccine has again raised concerns about whether vaccines trigger ITP. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender"s Comments: Based on a very limited information provided in the report, lacking time to onset, history of pre-existing medical conditions, baseline laboratory data, conmeds and course of events, the Company did not consider the event, fatal thrombocytopenia, as secondary to BNT162B2.; Reported Cause(s) of Death: thrombocytopenia

VAERS ID: <u>1449426</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 2021-07-06 Entered: Sex: Unknown

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Purchased by: ?

Administered by: Other

Symptoms: Death

SMQs:

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:

CDC Split Type: USJNJFOC20210703030

Write-up: DIED; This spontaneous report received from a consumer via a company representative via social media concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) one total, dose not reported, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure no follow up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced died. On an unspecified date, the patient was died from unknown cause of death. It was unknown whether the autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0 20210703030-JANSSEN COVID-19 VACCINE-died. This event is considered unassessable. The event has a compatible suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

**VAERS ID:** <u>1453619</u> (history) Vaccinated: 2021-04-20 2021-04-20 Form: Onset: Version 2.0

Age: Days after vaccination: Sex: Female

Submitted: 0000-00-00 Location: Washington Entered: 2021-07-07

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death, Dizziness, Hot flush

SMQs:, Anticholinergic syndrome (broad), Vestibular disorders (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:

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Hot flashes; Dizziness; Death; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Death) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. No Medical History information was reported. On 20-Apr-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On 20-Apr-2021, the patient experienced HOT FLUSH (Hot flashes) and DIZZINESS (Dizziness). The patient died on an unknown date. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, HOT FLUSH (Hot flashes) and DIZZINESS (Dizziness) outcome was unknown. Concomitant medication use was not provided by reporter. Treatment information was not provided by reporter. Very limited information regarding this patient"s death has been provided at this time. Based on the current available information and temporal association between the use of the product and the start date of the rest of the events, a causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 29-Jun-2021: Followed up Received on 29jun-2021 that includes TCR: patient passed away.; Sender's Comments: Very limited information regarding this patient's death has been provided at this time. Based on the current available information and temporal association between the use of the product and the start date of the rest of the events, a causal relationship cannot be excluded.; Reported Cause(s) of Death: unknown cause of death

VAERS ID: 1453698 (history) Vaccinated: 2021-03-05 Form: Version 2.0 Onset: 2021-03-01 Submitted: 0000-00-00 Age: Entered: 2021-07-07 Sex: Male

Location: Pennsylvania

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EN6203 / 1 LA / OT

Administered by: Unknown Purchased by: ? Symptoms: Completed suicide, Fatigue, Tinnitus

SMQs:, Suicide/self-injury (narrow), Hearing impairment (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-01 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: MS **Preexisting Conditions:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021577024

Write-up: Tinnitus; Committed suicide; Fatigue; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Lot Number: ER8730), on 05Mar2021 11:15 and second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection; Lot Number: ER8730), on 26Mar2021 10:30; both via an intramuscular route of administration, administered in Arm left (left shoulder), as single dose, for covid-19 immunization. Medical history included multiple sclerosis (MS) from 07Jul2002 and ongoing. Patient's prior vaccination was none. The patient's concomitant medications were not reported. Caller reported the side effects after the administration of the Covid-19 vaccine. On unknown date in Mar2021, after the first shot his tinnitus started and he was also fatigued; and he committed suicide eventually. The caller went to a specialist and was told that he had heard about that symptom before from 6 patients who reported the same thing. Later the reporter mentioned he didn"t know the guy other than he was a founder of one organization (name no provided) and he committed suicide. Had spoken with one of his friends who knew of a friend who also had tinnitus shortly after getting Covid and it was serious because the guy committed suicide. The guy was about his age and he ended up committing suicide and he had similar symptoms. This all happened around the same time in March when he had his vaccine and it"s kind of eerie. It stated on the guy"s obituary he had covid and tinnitus, but caller unable to clarify if guy had covid virus or vaccine. He didn"t know the guy, but his other friend who have friends that were doctors said that you could go crazy. No further details provided for this person or other persons. This was the report two of three. Upon receipt of the follow up, it was stated that approximately 1-2 days after just vaccine, the patient started with hissing second on both ears which stated was diagnosed as tinnitus. As of today, 12Jun2021, the "hissins" was consistent or worse than the start and it fall day and night. On an unspecified date in Mar2021, the patient died, and the autopsy was not performed. The outcome of the events committed suicide and tinnitus was fatal while the outcome of the event fatigue was unknown. Follow-up attempts are completed. No further information is expected.; Reported Cause(s) of Death: Tinnitus; committed suicide

VAERS ID: <u>1456637</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-07-08

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / UNK

Administered by: Unknown Purchased by: ?

Symptoms: Death, Epistaxis

SMQs:, Haemorrhage terms (excl laboratory terms) (narrow)

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: Current Illness:

Preexisting Conditions: Comments: No medical history was reported.

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20211

Write-up: healthy woman dying within 48 h of vaccination; blood coming out of her nose; This spontaneous case was reported by a physician and describes the occurrence of DEATH (healthy woman dying within 48 h of vaccination) and EPISTAXIS (blood coming out of her nose) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On an unknown date, the patient experienced DEATH (healthy woman dying within 48 h of vaccination) (seriousness criteria death, medically significant and life threatening) and EPISTAXIS (blood coming out of her nose) (seriousness criteria death and life threatening). The cause of death was not reported. It is unknown if an autopsy was performed. For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments. No concomitant medications were provided by the reporter. The subject stated that "there are many deaths related to the Covid vaccine and autopsies have been ordered." The subject also stated that many deaths have occurred within 48 hours of the vaccination. He also reported that a healthy young woman was found deceased in her apartment within 48 hours of vaccination. The deceased was found with blood coming out of her nose. No treatment information was provided by the reporter. Very limited information regarding this events has been provided at this time. Details regarding the exact brand of vaccine received, dosing dates, Medical history, concomitant medication, and date/cause of death are required for further evaluation. Further information has been requested.; Sender's Comments: Very limited information regarding this events has been provided at this time. Details regarding the exact brand of vaccine received, dosing dates, Medical history, concomitant medication, and date/cause of death are required for further evaluation. Further information has been requested.; Reported Cause(s) of Death: Many deaths related to the COVID vaccine

Vaccinated: 2021-03-03 VAERS ID: <u>1456646</u> (history) Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-07-08

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EN6203 / 2

Administered by: Unknown Purchased by: ?

Symptoms: Antibody test, COVID-19, Coombs test, Death, SARS-CoV-2 antibody test negative SMQs:, Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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: Hodgkin"s disease (and they took his spleen out so he is a little immunocompromised.)

Diagnostic Lab Data: Test Date: 20210407; Test Name: IG; Test Result: Negative; Comments: AbIG Quantitative; Test Date: 20210524; Test Name: IG; Test Result: Negative; Comments: IGgAb, ABIGm; Test Date: 20210407; Test Name: COB TEST; Test Result: Negative; Test Date: 20210407; Test Name: COB TEST; Test Result: Negative; Test Date: 2021; Test Name: COB TEST; Test Result: Negative; Test Date: 20210524; Test Name: COB TEST; Test Result: Negative; Test Date: 20210407; Test Name: COVID-19 test; Test Result: Negative; Test Date: 20210407; Test Name: COVID-19 test; Test Result: Negative; Test Date: 20210407; Test Name: SARS test; Test Result: Negative; Test Date: 20210407; Test Name: SARS test; Test Result: Negative; Test Date: 20210407; Test Name: SARS test; Test Result: Negative; Test Date: 20210407; Test Name: SARS test; Test Result: Negative; Test Name: SARS test; Test Result: Negative; Test Name: SARS test; Test

CDC Split Type: USPFIZER INC2021640296

Write-up: passed away; The initial case was missing the following minimum criteria: adverse event. Upon receipt of follow-up information on 01Jul2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable consumer (patient) and patient's wife. A 69-years-old male patient received first dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: EN6201), via an unspecified route on 10Feb2021 (at the age of 69-years) as dose 1, single and second dose of BNT162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Lot Number: EN6203), via an unspecified route on 03Mar2021 (at the age of 69-years) as dose 2, single for covid-19 immunisation. The patient medical history included Hodgkin's disease from 1978 (they took his spleen out, so he was a little immunocompromised and they took out his spleen and appendix after diagnosis) and unknown if ongoing. The patient concomitant medications were not reported. On unspecified date, the patient experienced had 3 antibody tests- one that was a 15minutes finger prick and two others that were all 2-3 weeks apart. Patient stated all 3 tests were negative for antibodies and his doctors don"t know why. His doctors said maybe it did not detect antibodies to the vaccine. In 1978, he had Hodgkin's disease and they took his spleen out, so he was a little immunocompromised. However, the infectious disease doctor said since he got both doses he should still be protected. Reporter was concerned that he didn"t had great immune system when three negative tests came back, he just want to make sure that everybody thinks he was not okay because he was going out over usual instructions because of them. His primary care physician (PCP) said he talked to another doctor and said if he had the vaccine it should be covered but the test came back negative. Reporter stated that the "last test he had was on 24May2021, it was COVID-19 antibody test, SARS test, COB test 2, AbIG Quantitative. This one was done on maybe 10th (unspecified date in 2021) it was rapid test for SARS, COB-2, IGg antibody. That was done on 07Apr201 and stated if Pfizer want, he can give that also, SARS, COVID, COB-2, IGgAb, AblGm, they all came back negative". Patient"s wife stated her husband passed away and at the time of the vaccination she and her daughter got adverse reactions she would like to fill the form for both her and her daughter. The patient died on unspecified date in 2021 with unknown cause of death and autopsy results was unknown. The outcome of the event was fatal. Follow up needed, further information has been requested.; Reported Cause(s) of Death: passed away

VAERS ID: <u>1458799</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-07-09

Location: Tennessee

| Vaccination / Manufacturer                     | Lot / Do | se Site / Route |
|--|----------|-----------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1      | - / OT          |

Administered by: Unknown 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: 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: Egg allergy; Tuberculosis (Tuberculosis in their kidney.)

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: they believe the cause of death was stroke; This spontaneous case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (they believe the cause of death was stroke) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Pneumonia vaccine. Past adverse reactions to the above products included Pneumonia with Pneumonia vaccine. Concurrent medical conditions included Egg allergy and Tuberculosis (Tuberculosis in their kidney.). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced CEREBROVASCULAR ACCIDENT (they believe the cause of death was stroke) (seriousness criteria death and medically significant). The reported cause of death was Stroke. It is unknown if an autopsy was performed. This spontaneous case was reported by a consumer and describes the occurrence of CEREBROVASCULAR ACCIDENT (they believe the cause of death was stroke) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. Previously administered products included for Product used for unknown indication: Pneumonia vaccine. Past adverse reactions to the above products included Pneumonia with Pneumonia vaccine. Concurrent medical conditions included Egg allergy and Tuberculosis in their kidney.). On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced CEREBROVASCULAR ACCIDENT (they believe the cause of death was stroke) (seriousness criteria death and medically significant). The reported cause of death was Stroke. It is unknown if an autopsy was performed. The patient was on blood pressure medications. The reporter reports that two days after they received their first dose of the Moderna COVID-19

 VAERS ID: 1459256 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-07-09

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs: 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:

CDC Split Type: USPFIZER INC2021827105

Write-up: already has 1 acquaintance who passed the msm and died; This is a spontaneous report from a contactable physician. This physician reported for an unknown patient. A patient of unspecified age and gender received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as dose number unknown, single for COVID-19 immunization. The patient medical history and were not reported. The patient experienced already has 1 acquaintance who passed the msm and died on an unspecified date. Reporter stated, First of all, I want to say that I'm going to file an investigation against everything that's going on. when I chose Pfizer it was because you said the vaccine was good for patients and cancer, chronic diseases. I lived working paying my bills and taking care of my children until the day I got this vaccine. and then all my exams started to change. I know you don't want to be responsible for anything, because only money matters. already has 1 acquaintance who passed the msm and died, so what does pfizer do to support it? nothing? I'm like 1 vegetable and what are you going to do for me? Somehow I'm going to sue you because a lawyer also finds fault with you for that. very disappointed and living hell and even depression because of my health. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information on the lot/batch number has been requested.; Sender's Comments: Based on available information and temporal relationship, a possible contributory role of BNT162B2 vaccine cannot be excluded for the reported event of Death. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regula

VAERS ID: <u>1459429</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-07-09

Location: Michigan

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / UNK - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Cerebral thrombosis

SMQs:, Ischaemic 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: 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:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Died with a blood clot in her brain; This spontaneous case was reported by a consumer and describes the occurrence of CEREBRAL THROMBOSIS (Died with a blood clot in her brain) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced CEREBRAL THROMBOSIS (Died with a blood clot in her brain) (seriousness criteria death and medically significant). The reported cause of death was died with a blood clot in her brain. It is unknown if an autopsy was performed. The action taken with mRNA-1273 (Moderna COVID-19 Vaccine) (Unknown) was unknown. Concomitant product use was not provided by the reporter. No treatment information was provided. Company Comment: Very limited information on this fatal case. However, based on the current available information and assumed temporal association between the use of the unspecified Moderna Vaccine product and the start date of the event, a causal relationship cannot be excluded. Reporter did not allow further contact; Sender"s Comments: Very limited information on this fatal case. However, based on the current available information and assumed temporal association between the use of the unspecified Moderna Vaccine product and the start date of the event, a causal relationship cannot be excluded. Reported Cause(s) of Death: Died with a blood clot in her brain

VAERS ID: <u>1463008</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-05-21 Age: Submitted: 0000-00-00 2021-07-11 Sex: Male Entered:

Location: New York

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Purchased by: ? Administered by: Other

Symptoms: Blood glucose, Blood pressure measurement, Brain death, Fall, Incorrect dose administered, Intracranial aneurysm, Needle issue, Thrombosis SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (broad), Accidents and injuries (narrow), Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (narrow), Medication errors (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-05-25 Days after onset: 4 Permanent Disability? Yes

Recovered? No Office Visit? No ER Visit? No ER or Doctor Visit? Yes

Hospitalized? Yes, 5 days Extended hospital stay? No Previous Vaccinations:

Other Medications:

Current Illness: Blind; Cancer; Congestive heart failure; Diabetes; Penicillin allergy

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: Test Name: Glucose; Result Unstructured Data: glucose 112; Test Name: Blood pressure; Result Unstructured Data: BP 120/75

CDC Split Type: USJNJFOC20210708201

Write-up: BRAIN ANEURYSM; BRAIN DEAD; BLOOD CLOT; FALL; NEEDLE BROKE OFF THE SYRINGE; NEEDLE BROKE OFF THE SYRINGE UNSURE OF THE FULL VOLUME THAT WAS INJECTED; This spontaneous report received from a consumer concerned a 57 year old White Hispanic/Latino male.. The patient's height, and weight were not reported. The patient"s concurrent conditions included blind, diabetes, cancer, congestive heart failure, and penicillin allergy. Nurse came to patients house to administer the vaccine due to patient disability, patient usually does have a home aid. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. Upon administering the vaccine, the needle broke off the syringe, unsure of the full volume that was injected. On 21-MAY-2021 patient experienced dizziness, vomiting, and fall. Blood pressure and sugar was fine after the wife had checked it (BP 120/75, glucose 112). They called the ambulance because the symptoms were unrelenting and a headache began on 21-MAY-2021. Patient required and emergency surgery to relieve pressure on the brain, drilling of the skull where ultimately patient was pronounced brain dead. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of brain aneurysm due to blood clot and brain dead on 25-MAY-2021, and the outcome of fall, blood clot, needle broke off the syringe, needle broke off the syringe unsure of the full volume that was injected was not reported. This report was serious (Death, Hospitalization Caused / Prolonged, Other Medically Important Condition, and Disability Or Permanent Damage).; Sender s Comments: V0: 20210708201-COVID-19 VACCINE AD26.COV2.S-Brain Aneurysm, Brain Dead, Blood Clot, Fall. This event(s) is considered unassessable. The event(s) has a

compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: BRAIN ANEURYSM DUE TO BLOOD CLOT

VAERS ID: <u>1463018</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-07-11

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Purchased by: ?

Administered by: Other

Symptoms: Death SMQs:

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:

CDC Split Type: USJNJFOC20210713544

Write-up: PÉRISHED APPROX 9 WEEKS POST INJECTION OF YOUR PRODUCT; This spontaneous report received from a company representative via social media and concerned a male patient of unspecified age, race and ethnic origin. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number not reported, expiry not reported frequency one total, dose, therapy start date were not reported administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient perished approximately 9 weeks (2021) post injection and cause of death was unknown. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210713544-covid-19 vaccine ad26.cov2.s -Perished approx. 9 weeks post injection of your product. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: 1463262 (history) Vaccinated: 0000-00-00 0000-00-00 Version 2.0 Onset: Form: Submitted: 0000-00-00 Age: 2021-07-11 Sex: Male Entered:

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Drug ineffective, SARS-CoV-2 test, Suspected COVID-19

SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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:** 

Allergies:

Diagnostic Lab Data: Test Name: PCR Test; Test Result: Negative ; Test Name: PCR Test; Test Result: Negative CDC Split Type: USPFIZER INC2021785213

Write-up: suspected covid 19; drug ineffective; This is a spontaneous report from a non-contactable consumer (patient daughter) through a Pfizer sponsored program. A male patient of an unspecified age received bnt162b2 (Pfizer-BioNTech Covid-19 Vaccine), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as DOSE NUMBER UNKNOWN, SINGLE for covid-19 immunisation. The patient medical history was not reported. The patient's concomitant medications were not reported. As per the reporter, her father (orthopedic surgeon) died of covid-19 vaccine on an unspecified date. The patient underwent lab tests and procedures which included had 2 negative PCR test 14 days later. The patient died on an unspecified date. It was not reported if an autopsy was performed. No follow-up attempts are possible; batch/lot number cannot be obtained. No further information is expected.; Reported Cause(s) of Death: suspected covid

VAERS ID: 1466124 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-07-13

Location: Washington

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

Administered by: Unknown Purchased by: ?

Symptoms: Thrombosis

SMQs:, Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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:

CDC Split Type: USPFIZER INC2021807766

Write-up: blood clots; This is a spontaneous report from a contactable physician via a sales representative. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as DOSE NUMBER UNKNOWN, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. Patient died one week after receiving Pfizer COVID vaccine, autopsy confirmed blood clots. Event took place after use of product. Information on the lot/batch number has been requested.; Sender"s Comments: A possible contributory role of the suspect drug to the reported event "blood clots" cannot be completely excluded based on temporal association. This case will be re-assessed when additional information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identifies as part of this review, as well as any appropriate action in response, will be promptly notifies to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: blood clots

VAERS ID: <u>1469612</u> (<u>history</u>) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-04-14 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-07-14

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs: Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-06-14 Days after onset: 61 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:

CDC Split Type: USJNJFOC20210710773

Write-up: DIED AFTER RECEIVING YOUR VACCINE; This spontaneous report received from a consumer via a company representative concerned a female of unspecified age, race and ethnicity. The patient"s height and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown and expiry: unknown) 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow up will be requested for this case. No concomitant medications were reported. On 14-APR-2021, the patient died after receiving vaccine and cause of death was unknown. It was unspecified if autopsy performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210710773-covid-19 vaccine ad26.cov2.s - DIED AFTER RECEIVING YOUR VACCINE. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s). Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

**VAERS ID:** <u>1481067</u> (history) Vaccinated: 0000-00-00 2021-04-01 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Male Entered: 2021-07-17 Sex:

Location: New York

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death, Headache

SMQs: Life Threatening? No

Birth Defect? No Died? Yes Date died: 2021-06-19

Days after onset: 79 Permanent Disability? No Recovered? No Office Visit? No

ER Visit? No ER or Doctor Visit? No Hospitalized? No **Previous Vaccinations:** Other Medications:

Preexisting Conditions: Comments: Unknown

Allergies:

Current Illness:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210710119

Write-up: DEATH; SLIGHT HEADACHE; This spontaneous report received from a patient via social media (Blog) by a company representative concerned a 53 year old male. Initial information was processed along with the additional information received on 06-JUL-2021. The patient"s weight, height, and medical history were not reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, and expiry: unknown) dose was not reported, 1 total administered on or around 13-APR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On APR-2021, after vaccination the patient experienced slight headache. On 19-JUN-2021, nine weeks after vaccination, the patient died from unknown cause of death. It was unknown if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died on 19-JUN-2021, and the outcome of slight headache was not reported. This report was serious (Death). This case, from the same reporter is linked to 20210711387.; Sender's Comments: V0: 20210710119-COVID-19 VACCINE AD26.COV2.S -Death. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: 1481132 (history) Vaccinated: 0000-00-00 Version 2.0 Form: Onset: 0000-00-00 Submitted: 0000-00-00 Age: Unknown Entered: 2021-07-17 Sex:

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ? Symptoms: Vaccine breakthrough infection

SMQs:

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: Current Illness: **Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210724474

Write-up: BREAKTHROUGH CASE; This spontaneous report received from a health care professional via social media concerned a patient of unspecified age and sex. The patient's height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose,1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient was hospitalized at the time of death and was a vaccine breakthrough case. On an unspecified date, the patient died. It was unknown autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome was fatal. This report was serious (Death, and Hospitalization Caused / Prolonged). This report was associated with product quality complaint:90000185655; Sender"s Comments: V0; 20210724474 -covid-19 vaccine ad26.cov2- vaccine breakthrough case. This event is considered unassessable. The event has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event. Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

Vaccinated: 0000-00-00 VAERS ID: <u>1481184</u> (history) Version 2.0 Onset: 0000-00-00 Form: Age: Submitted: 0000-00-00 2021-07-17 Male Entered: Sex:

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Purchased by: ?

Administered by: Other Symptoms: Death

SMQs: 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:

CDC Split Type: USJNJFOC20210726824

Write-up: DEATH; This spontaneous report received from a consumer via social media company representative concerned a male of unspecified age, race and ethnic origin. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received Covid-19 vaccine ad26.cov2. s (suspension for injection, route of admin not reported, batch number: Unknown expiry: Unknown) dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient died from unknown cause of death. It was reported that, the patient death occurred after getting the vaccine. It was unknown, if an autopsy was performed. The action taken with Covid-19 vaccine ad26.cov2. s was not applicable. This report was serious (Death)., Sender S Comments: V0: 20210726824-Covid-19 vaccine ad26.cov2. s -Death. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1481259</u> (history) Vaccinated: 0000-00-00 Version 2.0 Onset: 0000-00-00 Form: Age: Submitted: 0000-00-00 Male Entered: 2021-07-17 Sex:

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death SMQs: 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:

CDC Split Type: USJNJFOC20210730562

Write-up: PASSED AWAY DUE TO THE JOHNSON AND JOHNSON VACCINE; This spontaneous report received from a patient concerned a 4 decade old male. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown), 1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient passed away due to the Johnson and Johnson vaccine and cause of death was unknown. It was unspecified if autopsy performed. Reporter just got off the phone with her cousin it was her best friend who passed away. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0: 20210730562-covid-19 vaccine ad26.cov2.s-passed away due to the Johnson and Johnson vaccine. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).

**VAERS ID:** <u>1481694</u> (history) Vaccinated: 2021-02-01 Form: Version 2.0 Onset: 2021-02-02 Davs after

Age: 1 Sex: Male vaccination:

Submitted: 0000-00-00 Location: North Carolina Entered: 2021-07-18

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA 012M20A / 1 - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Abdominal discomfort, Arthralgia, C-reactive protein, C-reactive protein increased, Death, Decreased appetite, Haemorrhage, Renal disorder SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Arthritis (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-03-23 Days after onset: 48 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? No Hospitalized? No **Previous Vaccinations:** Other Medications:

Current Illness: Cardiac disorder NOS

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: Test Date: 20210203; Test Name: CRP; Result Unstructured Data: 128 it gradually increased to 246 and 259

CDC Split Type: USMODERNATX, INC.MOD20210

Write-up: Had given him vitamin K to stop the bleeding; kidneys started shouting down; Died; Raised C-reactive protein; Shoulder pain; Loss of appetite; Stomach discomfort; This case was initially received via an unknown source (no reference has been entered for a health authority or license partner) on 26-Feb-2021. The most recent information was received on 08-Jul-2021 and was forwarded to Moderna on 08-Jul-2021. This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of DEATH (Died) and HAEMORRHAGE (Had given him vitamin K to stop the bleeding) in a 73-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 012M20A) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included Cardiac disorder NOS. On 01-Feb-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 02-Feb-2021, the patient experienced DECREASED APPETITE (Loss of appetite), ABDOMINAL DISCOMFORT (Stomach discomfort) and ARTHRALGIA (Shoulder pain). On 03-Feb-2021, the patient experienced C-REACTIVE PROTEIN INCREASED (Raised C-reactive protein). On an unknown date, the patient experienced HAEMORRHAGE (Had given him vitamin K to stop the bleeding) (seriousness criterion medically significant) and RENAL DISORDER (kidneys started shouting down). The patient was treated with VITAMIN K NOS for Bleeding, at an unspecified dose and frequency. The patient died on 23-Mar-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, HAEMORRHAGE (Had given him vitamin K to stop the bleeding), RENAL DISORDER (kidneys started shouting down), DECREASED APPETITE (Loss of appetite), ABDOMINAL DISCOMFORT (Stomach discomfort), C-REACTIVE PROTEIN INCREASED (Raised C-reactive protein) and ARTHRALGIA (Shoulder pain) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): On 03-Feb-2021, C-reactive protein: 128 (High) 128 it gradually increased to 246 and 259. Concomitant medications were not provided. The patient was given a steroid shot for raised c-reactive protein. On 01-Mar-2021 the patient"s kidneys started to shut down. On an unreported date, the patient was given Vitamin -K to stop unspecified bleeding. On 23-Mar-2021 the patient died, specific cause of death was not reported. Treatment included Vitamin K. Very limited information regarding these events has been provided at this time. Further information has been requested. Further information is not expected This case was linked to MOD-2021-252597 (Patient Link). Most recent FOLLOW-UP information incorporated above includes: On 08-Jul-2021: Additional events reported: Patient died; kidneys started to shut down and bleeding. Current conditions updated to include "heart patient". Date of vaccine confirmed as first dose.; Sender"s Comments: Very limited information regarding these events has been provided at this time. Further information has been requested. Further information is not expected; Reported Cause(s) of Death: Unknown cause of death

**VAERS ID:** <u>1481741</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-06-27 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-07-18

Location: Connecticut

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | -/1        | - / OT       |

Administered by: Unknown Purchased by: ? Symptoms: Coma, Death, Disorientation, Mala

SMQs:, Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Dementia (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Hypoglycaemia (broad), Dehydration (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-06-27 Days after onset: 0 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: **Current Illness:** Preexisting Conditions:

Allergies: Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: feeling very ill; in an induced coma; in a complete disorientation; passed away; This spontaneous case was reported by a patient family member or friend and describes the occurrence of DEATH (passed away), MALAISE (feeling very ill), COMA (in an induced coma) and DISORIENTATION (in a complete disorientation) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. On an unknown date, the patient experienced MALAISE (feeling very ill) (seriousness criterion hospitalization), COMA (in an induced coma) (seriousness criterion medically significant) and DISORIENTATION (in a complete disorientation) (seriousness criterion medically significant). The patient died on 27-Jun-2021. The cause of death was not reported. It is unknown if an autopsy was performed. At the time of death, MALAISE (feeling very ill), COMA (in an induced coma) and DISORIENTATION (in a complete disorientation) outcome was unknown. Action taken with mRNA-1273 (Moderna COVID-19 Vaccine) was not applicable. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender"s Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1481806</u> (history) Vaccinated: 2021-01-01 Form: Version 2.0 Onset: 2021-01-01

Days after Age: vaccination: Sex: Female

Submitted: 0000-00-00 Location: Arkansas Entered: 2021-07-18

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | - / 1      | LA / -       |

Administered by: Unknown Purchased by: ?

Symptoms: Blood disorder, Blood test, Body temperature, Cough, Fatigue, Impaired work ability, Myocardial infarction, Pyrexia, Sinusitis, Thrombosis, Vaccination site pain, Vomitino

SMQs:, Anaphylactic reaction (broad), Acute pancreatitis (broad), Haematopoietic cytopenias affecting more than one type of blood cell (broad), Neuroleptic malignant syndrome (broad), Myocardial infarction (narrow), Anticholinergic syndrome (broad), Embolic and thrombotic events, arterial (narrow), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (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: 2021-02-21 Davs after onset: 51 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: Blood disorder; Dialysis; Renal failure

Diagnostic Lab Data: Test Name: Blood test; Result Unstructured Data: normal; Test Date: 202102; Test Name: Temperature; Result Unstructured Data: started running a temperature CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Thick blood; Missed a whole week of work; second shot:-heart attack; second shot: tired; second shot- started running a temperature; second dosethrowing up; Sinus infection; second dose-coughing; second dose-blood clots; left arm was hurting; This spontaneous case was reported by a consumer and describes the occurrence of MYOCARDIAL INFARCTION (second shot:-heart attack) and THROMBOSIS (second dose- blood clots) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient spast medical history included Renal failure. Concurrent medical conditions included Dialysis and Blood disorder. In January 2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) dosage was changed to 1 dosage form. On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. In January 2021, the patient experienced VACCINATION SITE PAIN (left arm was hurting). On 14-Feb-2021, the patient experienced SINUSITIS (Sinus infection), COUGH (second dose-coughing) and VOMITING (second dose-throwing up). On 15-Feb-2021, the patient experienced FATIGUE (second shot: tired) and PYREXIA (second shot: started running a temperature). In February 2021, the patient experienced FATIGUE (second shot: tired) and PYREXIA (second shot: started running a temperature). experienced THROMBOSIS (second dose- blood clots) (seriousness criteria death and medically significant). On 21-Feb-2021, the patient experienced MYOCARDIAL INFARCTION (second shot:-heart attack) (seriousness criteria death and medically significant). On an unknown date, the patient experienced BLOOD DISORDER (Thick blood) and IMPAIRED WORK ABILITY (Missed a whole week of work). The patient was treated with IBUPROFEN for Fever, at an unspecified dose and frequency and ONDANSETRON (ZOFRAN MELT) for Stomach pain, at an unspecified dose and frequency. On 21-Feb-2021, SINUSITIS (Sinus infection), COUGH (second dose-coughing), VOMITING (second dose- throwing up) and FATIGUE (second shot: tired) outcome was unknown and PYREXIA (second shot- started running a temperature) had resolved with sequelae. The patient died on 21-Feb-2021. The reported cause of death was blood clots leading to heart attack. An autopsy was not performed. At the time of death, BLOOD DISORDER (Thick blood), IMPAIRED WORK ABILITY (Missed a whole week of work) and VACCINATION SITE PAIN (left arm was hurting) outcome was unknown. DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available): In February 2021, Body temperature: abnormal (abnormal) started running a temperature. On an unknown date, Blood test: normal (normal) normal. Patient took first dose of moderna vaccine in JAN 2021 and second dose in FEB 2021. Patients body temperature was 98-104 after taking ibuprofen for few days. Patient" blood was thick as pancake syrup. Patient was on dialysis for 5 years before the shot. On 16 FEB 2021 Dialysis and blood work was done. Patient went to doctor on 19 FEB 2021. Patient missed her work a week from 15 FEB 2021 to 21 FEB 2021. Very limited information regarding this event/s has been provided at this time. Further information has been requested. This case was linked to MOD-2021-256627 (Patient Link).; Sender"s Comments: Very limited information regarding this event/s has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Blood clots leading to heart attack

VAERS ID: 1483260 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Entered: 2021-07-18 Sex: Female

Location: Unknown

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

Purchased by: ? Administered by: Unknown

Symptoms: Death, Headache

SMQs: 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:

CDC Split Type: USPFIZER INC2021818626

Write-up: Ended up passing away about seven days after she received the second shot of the vaccine; Extreme headache; This is a spontaneous report from a noncontactable consumer. A female patient (reporter"s mother) of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), dose 2 via an unspecified route of administration on an unspecified date as DOSE 2, SINGLE for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient previously received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), for covid-19 immunisation. Patient actually took both of the vaccines and she experienced extreme headache after she received her second vaccine and she ended up passing away, she ended up passing away about seven days after she received the second shot of the vaccine. The outcome of headache was unknown, while other event was fatal. The patient died on an unspecified date. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Ended up passing away about seven days after she received the second shot of the vaccine

VAERS ID: <u>1483478</u> (history) Vaccinated: 2021-02-08 Form: Version 2.0 Onset: 2021-02-08

Days after Age: Sex: Male vaccination:

Submitted: 0000-00-00 Location: New York

Entered: 2021-07-18

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

Administered by: Unknown Purchased by: ?

Symptoms: Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-02-08 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: Preexisting Conditions:** 

Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021831962

Write-up: Heart attack; This is a spontaneous report from a contactable consumer. A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on 08Feb2021 as a Dose number unknown, single for COVID-19 immunization. The patient"s medical history and concomitant medications were not reported. The reporter stated that, came to know a man who walked outside of the center and died right after the Covid vaccine from a heart attack. The reporter was unsure if it was Pfizer. People were there to help the patient right away and he still died. The reporter can't find much information about this event on the internet because of censorship. On 08Feb2021, the patient collapsed and later died after leaving the vaccination site. The patient died 25 mins after receiving the vaccine. First responders got to the man in seconds, and he passed away in the hospital. It was not reported if an autopsy was performed or not. Information on the lot/batch number had been requested.; Reported Cause(s) of Death: Heart attack

VAERS ID: <u>1483486</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 2021-06-16 Submitted: 0000-00-00 Age: Male Entered: 2021-07-18 Sex:

Location: Michigan

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No

Birth Defect? No

Died? Yes

Date died: 2021-06-16 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:** 

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021832027

Write-up: died in his sleep 3 days after taking the Pfizer covid vaccine; This is a spontaneous report from a contactable consumer. A 13-years-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as dose 2, single for covid-19 immunisation. The patient"s medical history and concomitant medications were not reported. Historical Vaccine included the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) for COVID-19 immunisation. The patient experienced died in his sleep, 3

days after taking Pfizer COVID vaccine on 16Jun2021. This is coincidental, this is not causative. Cause of death was unknown. No investigation assessment. The patient died on 16Jun2021. The county health department confirmed the investigation and the autopsy was being performed. The information is being sent the CDC to see if there is a correlation. The reporter mentions that we all know a lot of 13-year-old falling over for that. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: Cause of death was unknown

VAERS ID: <u>1483490</u> (history) Vaccinated: 0000-00-00 Version 2.0 0000-00-00 Form: Onset: Submitted: 0000-00-00 Age: Male 2021-07-18 Sex: Entered:

Location: Pennsylvania

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021832116

Write-up: I read a headline online that said a thirteen year old died in his sleep after taking the Pfizer vaccine and the CDC is investigating. Another article headline may have said it was a boy but; This is a spontaneous report from a contactable consumer via Pfizer Colleague. A 13-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection,Batch/Lot number was not reported) via an unspecified route of administration on an unspecified date as dose number unknown, single for covid-19 immunisation. The patient medical history and concomitant medications were not reported. On an unspecified date, the reporter read a headline online that said a thirteen-year-old died in his sleep after taking the Pfizer vaccine and the CDC was investigating. Another article headline may have said it was a boy, but reporter can"t find that article again. The reporter don"t have a subscription to newsweek so could not read the article and get more specifics. The patient died on an unspecified date. It was unknown if an autopsy was performed. The outcome of event was reported as fatal. Follow up needed, further information was requested.; Reported Cause(s) of Death: a thirteen year old died in his sleep after taking the Pfizer vaccine

Vaccinated: 0000-00-00 VAERS ID: <u>1483624</u> (history) 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: 2021-07-18 Sex: Female Entered:

Location: Unknown

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

Administered by: Unknown Purchased by: ? Symptoms: Cerebrovascular accident, Investigation

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: 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: Organ test; Result Unstructured Data: Test Result:Normal Results; Comments: she was perfectly fine

CDC Split Type: USPFIZER INC2021873485

Write-up: Stroke; This is a spontaneous report received from a contactable consumer. This consumer reported for a female patient (reporters friend"s mom) that an unspecified age elder female patient received second dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date was not reported), via unspecified route of administration on an unspecified date in 2021 as dose 2, single for COVID-19 immunization. The patient medical history and concomitant medication was not reported. The patient previously took first dose BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, lot number and expiration date was not reported), via unspecified route on an unspecified date as single dose for COVID-19 immunization. On an unspecified date patient died she had a stroke, and they were trying to say that because she was older, she just passed her organ test, and she was perfectly fine and 2 days later after her second shot she had a stroke (Not clarified hence split not made) and it was like they keep on and understood that there were multiple reasons that someone could have a stroke specially if patient was older. The outcome of evet was fatal Information on the lot/batch number has been requested. Additional information is requested.; Reported Cause(s) of Death: stroke

 VAERS ID: 1483629 (history)
 Vaccinated: 2021-03-29

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Sex: Female
 Submitted: 0000-00-00

 Entered: 2021-07-18

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Atrial fibrillation, Cytokine storm, Deep vein thrombosis, Haemophagocytic lymphohisticcytosis, Nervous system disorder, Platelet count

SMQs:, Supraventricular tachyarrhythmias (narrow), Embolic and thrombotic events, venous (narrow), Thrombophlebitis (broad), Hypersensitivity (broad), Tumour

lysis syndrome (broad), Immune-mediated/autoimmune disorders (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-06-12
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: Current Illness:

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: Test Name: Platelets; Result Unstructured Data: Test Result:15,000

CDC Split Type: USPFIZER INC2021879891

Write-up: Neurologic damage (Shaking/memory/speech/motorskills); DVT; Afib; Secondary hlh; Cytokine Storm; This is a spontaneous report from a Pfizer-sponsored program. A female patient of an unspecified age received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on 29Mar2021 as single dose for covid-19 immunization. The patient medical history was not reported. The patient's concomitant medications were not reported. Historical vaccine included first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection; Lot number: unknown), via an unspecified route of administration on unspecified date as single dose for COVID-19 immunization. The patient experienced neurologic damage (Shaking/memory/speech/motorskills), DVT, Afib, secondary hlh, cytokine storm on 2021. The patient was hospitalized for neurologic damage (Shaking/memory/speech/motorskills), dvt, Afib, Secondary hlh and cytokine storm from 12Apr2021 to an unknown date. The patient underwent lab tests and procedures which included platelet count: 15,000. The patient died on 12Jun2021. It was not reported if an autopsy was performed. The outcome of all the events was Fatal. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Based on temporal association, the causal relationship between BNT162B2 and the events cannot be excluded. The information available in this report is limited and does not allow a medically meaningful assessment. This case will be reassessed once additional information becomes available.,Linked Report(s): US-PFIZER INC-2021879892 same source, different reporter/ patient; Reported Cause(s) of Death: The Pfizer shots killed my beautiful mother

 VAERS ID: 1486322 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Sex: Female Entered: 2021-07-20

Location: Michigan

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

Administered by: Unknown 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: 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:

CDC Split Type: USPFIZER INC2021856673

Write-up: stroke; This is a spontaneous report from a contactable other hcp. The other hcp reported for both the husband and wife, this is the case for wife. A female patient of an unspecified age received bnt162b2 (COVID-19 VACCINE - MANUFACTURER UNKNOWN), via an unspecified route of administration on unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient experienced stroke on unspecified date and died. It was not reported if an autopsy was performed. Information about batch/lot number has been requested.; Sender"s Comments: Based on known drug safety profile, there is reasonable possibility of causal association between the event Cerebrovascular accident and the suspect drug bnt162b2. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s): US-PFIZER INC-2021856461 Same reporter/ drug/event, different patients; Reported Cause(s) of Death: stroke

 VAERS ID: 1489529 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2021-04-01

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-07-21

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK - / -

Administered by: Other Purchased by: ?

Symptoms: COVID-19 pneumonia, Death, Dependence on respirator

SMQs:, Acute central respiratory depression (broad), Respiratory failure (broad), Infective pneumonia (narrow), Opportunistic infections (broad), COVID-19 (narrow)

Life Threatening? Yes Birth Defect? No Died? Yes

Date died: 2021-05-02 Days after onset: 31 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:
Current Illness:

Preexisting Conditions: Comments: The patient had no health problems

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210731688

Write-up: PATIENT PLACED ON VENTILATOR; DEATH; COVID PNEUMONIA; This spontaneous report received from a consumer via a company representative via social media concerned a 49 year old female of unspecified race and ethnic origin. The patient"s height, and weight were not reported. The patient had no health problems. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry unknown) dose was not reported, administered in late APR-2021 for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. In late APR-2021, on the night of vaccination, the patient experienced flu like symptoms. She was hospitalized and was in intensive care unit (ICU) (date unspecified), she never got better from flu like symptoms. It was claimed that the patient had Covid pneumonia. On an unspecified date, patient experienced sever lung damage and lung complications, and the patient was placed on ventilator. On 02-MAY-2021, the patient died from unknown cause of death It was unknown if the autopsy was performed. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient died of death on 02-MAY-2021, and the outcome of covid pneumonia and patient placed on ventilator was not reported. This report was serious (Death, Hospitalization Caused / Prolonged, and Life Threatening).; Sender"s Comments: V0 -20210731688-Covid-19 vaccine ad26.cov2.s-Death, Covid Pneumonia, Patient placed on ventilator. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1489537 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Sex: Male Entered: 2021-07-21

Location: Unknown

| Va            | ccination / Manufacturer          | Lot / Dose | Site / | Route |
|---------------|-----------------------------------|------------|--------|-------|
| COVID19: COVI | D19 (COVID19 (JANSSEN)) / JANSSEN | - / UNK    | -      | / -   |

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210733844

Write-up: DEATH; This spontaneous report received from a consumer concerned a 5 decade old male of unknown race and ethnicity. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin, and batch number were not reported, UNKNOWN expiry) dose, 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient died from unknown cause of death. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death). It was unknown whether the Autopsy was performed.; Sender"s Comments: V0: 20210733844-covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s); Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

VAERS ID: <u>1489604</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-07-21

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / UNK - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Death; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Death) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vacciné) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. Not Provided Concomitant product was not reported. Treatment was not reported. Company Comment: Very limited information regarding these events has been provided at this time. Further information has been requested.; Sender's Comments: Very limited information regarding these events has been provided at this time. Further information has been requested.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: 1493247 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Female Entered: 2021-07-22 Sex:

Location: South Carolina

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

Administered by: Pharmacy Purchased by: ?

Symptoms: Antibody test, COVID-19, Cough, Drug ineffective, Dyspnoea, SARS-CoV-2 test

SMQs:, Anaphylactic reaction (broad), Lack of efficacy/effect (narrow), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Cardiomyopathy (broad), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-07-10 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: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Bypass surgery (She had bypass 19 years ago); COPD

Diagnostic Lab Data: Test Name: Antibody Test; Result Unstructured Data: Test Result:no antibody at all; Test Date: 2021; Test Name: Covid-19; Test Result: Positive; Comments: She caught Covid and died.

CDC Split Type: USPFIZER INC2021881403

Write-up: My mother in law received the vaccine 4-5 months ago. She caught Covid and died; My mother in law received the vaccine 4-5 months ago. She caught Covid and died; Just couldn't breathe; A little cough; This is a spontaneous report received from a contactable consumer via Pfizer sponsored program. The caller is calling on behalf of her deceased Mother-in-law. A 73-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Solution for injection, Batch/Lot number was not reported, Expiration Date: Unknown), via an unspecified route of administration on an unspecified date as dose number unknown, single for COVID-19 immunization. Medical history included COPD from an unknown date and unknown if ongoing, Bypass (She had bypass 19 years ago) from an unknown date and unknown if ongoing. The reporter stated that "I don"t know what else was she taking." The patient"s concomitant medications were not reported. Reporter wants to know if Pfizer was giving a placebo or the actual vaccine. She believes her mother-in-law had received a placebo vaccine. My mother-in-law received the vaccine 4-5 months ago. She caught Covid and died (2021). The doctor confirmed she did not have any antibodies. We all had been exposed to her. We are currently in quarantine. My father-in-law is 80 years old and was nervous. He was wondering why did he take the vaccine if it did not protect his wife or him. Reported doctor had basically tested her and they had found no antibodies. At the moment she was nervous because her father-in-law lived with them and they were both quarantined and he was 80 years old. Reporter stated they said she had no antibody is like she never got the vaccine. Reporter stated I do not know the name of antibody Test, but the hospital did it and they said she had no antibody at all. Date of Death: Reporter stated, I am not sure my father-in-law did knows exactly when they got vaccinated but it was 3 or 5 months ago. Reporter stated, "No, she went to the hospital on Thursday evening, and she had been on the ventilator like 3 hours later and she died on Saturday morning 2 O"clock. She had no fever, she had a little cough not major stuff, it was like flu the fever and usual cough she did not had any of that. She had no flu, she just couldn"t breathe (2021). Anatomical Site of Administration: Reporter stated, I just know that she received it 4 months ago. The patient underwent lab tests and procedures which included antibody test: no antibody at all, Covid-19: positive on 2021 (She caught Covid and died). Therapeutic measures were taken as a result of my mother in law received the vaccine 4-5 months ago. she caught covid and died, just couldn"t breathe. The patient died on

10Jul2021. An autopsy was not performed. The outcome of events just couldn"t breathe and cough was unknown, while other events was fatal. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: My mother in law received the vaccine 4-5 months ago. She caught Covid and died

 VAERS ID: 1493251 (history)
 Vaccinated:
 2021-02-02

 Form:
 Version 2.0
 Onset:
 2021-02-05

Age: Days after Sex: Male vaccination:

 Location:
 Unknown
 Submitted:
 0000-00-00

 Entered:
 2021-07-22

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

Administered by: Military Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-02-05 Days after onset: 0 Permanent Disability? No Recovered? No

Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? Yes
Hospitalized? Yes, ? days
Extended hospital stay? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions:

Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021884595

Write-up: states her husband died 5 months ago with the second shot, after he had his second shot in 5 days; This is a spontaneous report from a contactable consumer (patient wife). A male patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Batch/Lot number: Unknown), via an unspecified route of administration on 02Feb2021 as dose 2, single for COVID-19 immunisation. No medical history and concomitant medications were reported. The patient previously received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Formulation: Solution for injection, Batch/Lot number: Unknown), via an unspecified route of administration on an unspecified date as dose 1, single for COVID-19 immunisation. The reporter stated that on 05Feb2021, her husband died 5 months ago with the second shot, after he had his second shot in 5 days and reporter confirmed that her husband had the Pfizer Covid-19 vaccine. She stated that her husband was in the hospice before that, he died a little bit over 5 months. Reporter stated she was a nursing student and said no to completing a report, by saying that her husband was gone, he died but because she looked at the medical statement that the Medicare paid for him the first time \$35 and the second time \$35 but she sees he took the second shot on 02Feb2021 and he died on 05Feb2021. He was in the emergency right after the shot, she thought, on the same day he had the shot on 02Feb2021 and he died in the hospital, but he was in the nursing home facility paid for seven months and hospice for seven months. She stated they wouldn't let her visit him and she was not able to visit him for a while before he died. The patient died on 05Feb2021. Cause of death was not provided. The outcome of event was fatal. Information on Lot/Batch information has been requested.; Reported Cause(s) of Death: states her husband died 5 months ago with the second shot, after he had his second shot in 5 days

 VAERS ID: 1493382 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-07-22

Location: New York

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | - / UNK    | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: Knows of some people and friends that have died after receiving Moderna"s COVID-19 vaccine; Based on the current case data, this case has been classified as invalid. This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Knows of some people and friends that have died after receiving Moderna"s COVID-19 vaccine) in a patient of an unknown age and gender who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. It is unknown if an autopsy was performed. Very limited information regarding this event has been provided at this time. No further follow-up information is expected. Reporter did not allow further contact; Sender"s Comments: Very limited information regarding this event has been provided at this time. No further follow-up information is expected.; Reported Cause(s) of Death: Unknown cause of death

VAERS ID: <u>1497584</u> (<u>history</u>) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Unknown Entered: 2021-07-23 Sex:

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Haemorrhagic stroke, Immune thrombocytopenia

SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Systemic lupus erythematosus (broad), Haemorrhagic central nervous system vascular conditions (narrow), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Hypersensitivity (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Immune-mediated/autoimmune disorders (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:** 

Allergies: Diagnostic Lab Data:

CDC Split Type: USPFIZER INC2021898328

Write-up: refractory ITP; hemorrhagic stroke; This is a literature report from the 2021, Patient died after receiving COVID-19 vaccine under investigation. Full Publication has been requested. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid-19 immunisation. The patient medical history was not reported. The patient"s concomitant medications were not reported. The patient experienced refractory ITP and hemorrhagic stroke, on an unspecified date. The patient died several weeks after receiving the Pfizer-BioNTech vaccine due to refractory ITP and hemorrhagic stroke. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information about lot/batch number cannot be obtained.; Sender"s Comments: As there is limited information in the case provided, the causal association between the events Immune thrombocytopenia, hemorrhagic stroke and the suspect drug BNT162B2 cannot be excluded. The case will be reassessed once new information is available. The impact of this report on the benefit-risk profile of the Pfizer product and on the conduct of the study is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: refractory ITP; hemorrhagic stroke

VAERS ID: <u>1497692</u> (<u>history</u>) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Entered: 2021-07-23 Sex: Unknown

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ? Symptoms: Cerebrovascular accident, Death

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: 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:

CDC Split Type: USJNJFOC20210741198

Write-up: DEATH; STROKE; This spontaneous report received from other health professional via a company representative from social media concerned a patient of unspecified age and sex. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose, frequency 1 total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient experienced stroke. On an unspecified date, the patient died from unknown cause of death. It was unknown if autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The outcome of stroke was not reported. This report was serious (Death, and Other Medically Important Condition). This case, from the same reporter is linked to 20210740986 and 20210740726.; Sender's Comments: V0: This social media received cased concerns a patient of unspecified age, gender, and ethnicity who had a "stroke" and died from an unspecified cause on unspecified date after receiving. No other pertinent details reported. Information is very limited in this case. The information available precludes a complete and meaningful assessment; hence, the causality is considered unclassifiable due to insufficient information.; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1500621 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-07-24

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Diea? 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:

CDC Split Type: USPFIZER INC2021868584

Write-up: Died in his sleep; This is a follow-up spontaneous report from a Pfizer Sponsored Program. A contactable consumer reported a 16-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date (at unknown age) as single dose for COVID-19 immunization. The patient medical history and concomitant medications were not reported. Caller stated that a 16-year-old boy died in his sleep after receiving his Covid-19 vaccine per Caller. Caller thinks it was the Pfizer Covid-19 vaccine. States that people died and adverse events happen after receiving the Pfizer Covid-19 vaccine. Regarding the 16 -ear-old male, caller is asking how could that happen to a young man that seems to be healthy? The patient died on an unspecified date. It was unknown if an autopsy was performed. information on the lot/batch number has been requested.; Sender's Comments: Linked Report(s): US-PFIZER INC-2021868538 same reporter/ drug, different AE/ patient; Reported Cause(s) of Death: Died in his sleep

 VAERS ID: 1504860 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Sex: Unknown
 Entered: 2021-07-27

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death, SARS-CoV-2 test, Suspected COVID-19

SMQs:, Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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 Current Illness:

Preexisting Conditions: Comments: over 80 years old patients had underlying health issues.

Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Result Unstructured Data: Positive

CDC Split Type: USJNJFOC20210741034

Write-up: DEATH; SUSPECTED COVID 19 INFECTION; This spontaneous report received from a company representative via Manufacturer on 16-JUL-2021 concerned multiple patients. Initial information was processed along with the additional information received on 21-JUL-2021. The patient"s height, and weight were not reported. Two patient"s over 80 years old had underlying health issues, and pre-existing medical conditions of other 8 patient"s were not reported. The patient"s received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose, 1 in total, start therapy date were not reported for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, two patient"s over 80 years old died from an unknown cause after being hospitalized, and eight patients also required hospitalization (hospitalization date unspecified). All patient"s had contracted the virus more than two weeks after being fully vaccinated. The cases are confirmed with a positive test COVID-19 (coronavirus disease) (confirmatory test was not reported) (suspected covid 19 infection). Laboratory data (dates unspecified) included: COVID-19 virus test (NR: not provided) Positive. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died of death on an unspecified date, and the outcome of suspected covid 19 infection was not reported. This report was serious (Death, and Hospitalization Caused / Prolonged). This report was associated with product quality complaint, 90000186727.; Sender"s Comments: V0 20210741034-COVID-19 VACCINE AD26.COV2.S-Death and suspected covid 19 infection. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1504869 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-07-27

Location: Unknown

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | - / UNK    | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations: Other Medications: Current Illness: Preexisting Conditions:

Allergies:
Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210746676

Write-up: DEATH; This spontaneous report received from a patient concerned multiple patients. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin were not reported)1 total dose, start therapy date were not reported for prophylactic vaccination. The batch number was not reported. The Company is unable to perform follow-up to request batch/lot numbers. No concomitant medications were reported. On an unspecified date, the patient died from unknown cause of death. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender's Comments: V0: 20210746676-covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1505007 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-07-27

Location: Virginia

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Adverse event, Death

SMQs:

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: Comments: The patient was healthy.

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210745184

Write-up: DEATH; FEEL SIDE EFFECTS/SYMPTOMS; This spontaneous report received from a consumer concerned a 49 year old male an unspecified race and ethnic origin. The patient"s height, and weight were not reported. The patient was healthy. The patient received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown; expiry date: Unknown) dose, start therapy date were not reported 1 total administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date (1 day after receiving vaccine), the patient experienced side effects/symptoms. Four day later, he passed away. It was not reported, if the autopsy was performed or not. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. The patient died of death on an unspecified date, and the outcome of feel side effects/symptoms was not reported. This report was serious (Death). This case is linked to 20210608311 (same reporter).; Sender's Comments: V0 - 20210745184-Covid-19 vaccine ad26.cov2.s-Death. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF

 VAERS ID: 1507809 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-07-28

 Location:
 Florida

| Vaccination / Manufacturer                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN | UNKNOWN / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210747770

Write-up: DEATH; This spontaneous report received from a consumer concerned multiple patients of unspecified age, sex, race and ethnic origin. The weight, height, and medical history of patients were not reported. The patients received Covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown, expiry: unknown) dose, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported and has been requested. No concomitant medications were reported. On an unspecified date, the patients died from unknown cause of death. The autopsy details were not provided. The action taken with Covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: V0: 20210747770-Covid-19 vaccine ad26.cov2.s -Death. This event(s) is considered unassessable. The event(s) has an unknown/unclear temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1507888 (history)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Sex: Female Entered: 2021-07-28

Location: Unknown

| Vaccination / Manufacturer                                | I      | Lot / Dose | Site / Route |
|---|--------|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIO | ONTECH | - / UNK    | -/-          |

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: USPFIZER INC202100913512

Write-up: Caller states that 5 deaths, from that vaccine was reported; This is a spontaneous report from a contactable consumer. This is the 1st of 5 reports. A female patient of an unspecified age received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, formulation: solution for injection, Lot number: unknown) via an unspecified route of administration on an unspecified date as dose number unknown, single for Covid-19 immunization. The patients medical history and concomitant medications were not reported. On an unspecified date, Consumer stated that 5 deaths, from that vaccine was reported and over 50% of people reported a debilitating disease, or cannot function, and have thousands of dollars in medical bills. The outcome of event was fatal. Autopsy was unknown. Information on the lot/ batch number has been requested.; Reported Cause(s) of Death: Caller states that 5 deaths, from that vaccine was reported

 VAERS ID: 1507903 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-07-28

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death
SMQs:

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: CDC Split Type: USPFIZER INC202100944572

Write-up: Death; This is a spontaneous report from a non-contactable consumer. This is one of 5 reports A patient of unspecified age and gender received bnt162b2 (BNT162B2) dose number unknown, via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient died on an unknown date from an unknown cause. It was not reported if an autopsy was performed. The reporter stated that the vaccine was kept in ice box for like 5 hours. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender's Comments: Linked Report(s): US-PFIZER INC-202100944710 same reporter/drug/event, different patient; US-PFIZER INC-202100944708 same reporter/drug/event, different patient; US-PFIZER INC-202100944711 same reporter/drug/event, different patient pa /event, different patient; US-PFIZER INC-202100944709 same reporter/drug/event, different patient; Reported Cause(s) of Death: Death

VAERS ID: <u>1507904</u> (<u>history</u>) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: Unknown Sex: Entered: 2021-07-28

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs: 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:

CDC Split Type: USPFIZER INC202100944708

Write-up: Death; This is a spontaneous report from a non-contactable consumer. This is one of 5 reports A patient of unspecified age and gender received bnt162b2 (BNT162B2) dose number unknown, via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as single dose for covid-19 immunisation . The patient medical history and concomitant medications were not reported. The patient died on an unknown date from an unknown cause. It was not reported if an autopsy was performed. The reporter stated that the vaccine was kept in ice box for like 5 hours. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.; Sender"s Comments: Linked Report(s): US-PFIZER INC-202100944572 same reporter/drug/event, different patient; Reported Cause(s) of Death: Death

VAERS ID: <u>1508935</u> (history) Vaccinated: 2021-02-01 Form: Version 2.0 Onset: 2021-02-01

Days after Age: vaccination: Female Sex:

Submitted: 0000-00-00 Location: Arkansas Entered: 2021-07-28

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

Administered by: Unknown Purchased by: ?

Symptoms: Blood test, Blood viscosity increased, Body temperature, Cough, Fatigue, Myocardial infarction, Product use issue, Pyrexia, Sinusitis, Thrombosis,

SMQs:, Anaphylactic reaction (broad), Acute pancreatitis (broad), Neuroleptic malignant syndrome (broad), Myocardial infarction (narrow), Anticholinergic syndrome (broad), Embolic and thrombotic events, arterial (narrow), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow), Thrombophlebitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Vasculitis (broad), Medication errors (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-02-21

Days after onset: 20 Permanent Disability? No Recovered? No Office Visit? Yes ER Visit? No

ER or Doctor Visit? No Hospitalized? No **Previous Vaccinations:** Other Medications:

Current Illness: Dialysis (she had been on dialysis for 5 years before the shot)

Preexisting Conditions: Medical History/Concurrent Conditions: Renal failure (had renal failure before the shot.)

Diagnostic Lab Data: Test Date: 20210216; Test Name: blood work; Result Unstructured Data: Test Result:it was fine; Test Date: 202102; Test Name: temperature;

Result Unstructured Data: Test Result:98-104 CDC Split Type: USPFIZER INC2021885179

Write-up: Stated that the coroner wrote the cause of death as a blood clot that caused a heart attack.; tired; coughing; sinus infection; throwing up; fever/started running a temperature; Stated that the coroner wrote the cause of death as a blood clot that caused a heart attack; Stated that she went from her blood being thin to as thick as pancake syrup after the second shot; Patient previously received first dose of Moderna shot; This is a spontaneous report from a contactable consumer. A 62-year-old female patient received BNT162B2 [COVID-19 Vaccine-Manufacturer Unknown; Solution for injection; Lot number: unknown] via an unspecified route in left arm on an unspecified date in Feb2021 as single dose for COVID-19 immunization. Medical history of the patient included renal failure [she had been on dialysis for 5 years before the shot. Stated that she had renal failure before the shot, dialysis blood work done on 16Feb2021] and dialysis. Concomitant medications were not reported. Patient previously received first dose of Moderna shot via an unspecified route on an unspecified date in Jan2021 as single dose for COVID-19 immunization and experienced first shot left arm hurt. On an unspecified date in Feb2021, after receiving second dose of vaccination, patient started running a temperature which lasted for five days. On 14Feb2021, patient experienced coughing, throwing, sinus infection and on 15Feb2021 experienced being tired. Reportedly, four days after receiving second dose of vaccination patient started running temperature. The doctor asked patient to rotate with ibuprofen for a few days and during that time it was 98-104. Patient was given medicine for coughing and Zofran to settle her stomach because she was throwing up, all of this was after the second shot. On Friday, patient went to the doctor and they never drew blood work, but patient had blood work from where she does dialysis. The doctor said it was fine, patient worked 40 hours per week and with dialysis and was told that she was healthy despite renal failure. Patient was told that she would be okay in 3-4 days. Two days later on Sunday night at 20:05 patient passed away. The coroner wrote the cause of death as a blood clot that caused a heart attack. Patient did not have an autopsy done. Patient blood was as thick as pancake syrup. Reporter mentioned that sometimes they would pull the needle on dialysis and it would take 30 minutes to stop the bleeding because her blood was so thin. Patient went from her blood being thin to as thick as pancake syrup after the second shot on an unspecified date in 2021.

Reporter said it was odd all of the coughing, throwing up, fever and blood thickening that happened after the second shot was given. Patient had been on dialysis for 5 years before the shot and had renal failure before the shot. Dialysis blood work was done on 16Feb2021. Reporter (patient husband) was very observant of wife and takes care of her. After the second shot patient missed whole a week of work [from 15Feb through 21Feb] and had never missed work. Patient was tired, fever, coughing and throwing up. Reporter believes that the medication caused all of these issues. Patient received treatment in response to the events fever, coughing, sinus infection and throwing up. Outcome of the event blood clot that caused a heart attack was fatal, for fever was recovered/resolved with sequel and for other events were unknown. Information on Lot/Batch information has been requested.; Reported Cause(s) of Death: blood clots leading to heart attack; blood clots leading to heart attack

VAERS ID: <u>1509030</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Submitted: 0000-00-00 Age: 2021-07-28 Entered: Sex: Unknown

Location: Unknown

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

Administered by: Unknown Purchased by: ?

Symptoms: Death

SMQs:

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:

CDC Split Type: USPFIZER INC2021889151

Write-up: passed away; This is a spontaneous report from a contactable consumer. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date at a single dose for covid-19 immunisation. Medical history and concomitant medications were unknown. No patient identifiers were provided but the reporter has firsthand knowledge of the patient and was reporting on a specific patient. The reporter felt people will get healthier with their own immune systems and that Covid was a cover up. She knew people that have died after getting vaccinated and the CDC had changed their guidelines many times now. She read if 50% were vaccinated and the other half combined with the virus but now that had changed to 70%. The body had been proven for antibodies to work and it"s no different than the flu shot. The reporter had a 16 year old girl come to her door today letting her know that her neighbor passed away and she asked the 16-year-old if she could hug her and the little girl said "yes I"ve been vaccinated". It was unknown if autopsy was performed. Outcome of the event was fatal. The lot number for the vaccine [BNT162B2] was not provided and will be requested during follow up.; Reported Cause(s) of Death: passed away

VAERS ID: 1511553 (history) Vaccinated: 0000-00-00 0000-00-00 Form: Onset: Version 2.0 Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2021-07-29

Location: Texas

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK

Administered by: Other Purchased by: ?

Symptoms: Death, Suspected COVID-19, Vaccination failure

SMQs:, Lack of efficacy/effect (narrow), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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: Current Illness:

Preexisting Conditions: Comments: Unknown

Allergies:

Diagnostic Lab Data:

CDC Split Type: USJNJFOC20210748471

Write-up: DEATH; SUSPECTED CLINICAL VACCINATION FAILURE; SUSPECTED COVID-19 INFECTION; This spontaneous report received via social media (news article) and concerned 26 multiple patients. Initial information was processed along with the additional information received from Regulatory Authority on 23-JUL-2021 and 27-JUL-2021. The patient"s weight, height, and medical history were not reported. The patient"s received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: unknown) dose was not reported, start therapy date were not reported, 1 total administered for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patients had a breakthrough infection after being vaccinated (suspected clinical vaccination failure and suspected covid-19 infection). It was reported that it was only 25 to 54 days after that last dose of the vaccine when the patients got sick. It was also reported that, on an unspecified date vaccinated patients were hospitalized and four experienced death from unknown cause of death. The number of days hospitalization was not reported. It was unknown if an autopsy was performed to the patients. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. The patient died on an unspecified date, and the outcome of suspected clinical vaccination failure and suspected covid-19 infection was not reported. This report was serious (Death, and Hospitalization Caused / Prolonged). This report was associated with product quality complaint number: 90000186897.; Sender"s Comments: V0:20210748471-COVID-19 VACCINE AD26.COV2.S-Death, suspected COVID-19 infection . This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s) than the drug.

 VAERS ID: 1511577 (nistory)
 Vaccinated: 0000-00-00

 Form: Version 2.0
 Onset: 0000-00-00

 Age: Submitted: 0000-00-00
 Sex: Unknown

 Entered: 2021-07-29

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (JANSSEN)) / JANSSEN UNKNOWN / UNK - / -

Purchased by: ?

Administered by: Other

Symptoms: Death

SMQs:

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:

CDC Split Type: USJNJFOC20210756409

Write-up: DIED 24 HOURS LATER AFTER TAKING VACCINE; This spontaneous report received from a company representative via Pfizer. via social media was received on 23-JUL-2021 and concerned a 21 year old of an unspecified sex. The patient"s height, and weight were not reported. No past medical history or concurrent conditions were reported. The patient received covid-19 vaccine ad26.cov2.s (suspension for injection, route of admin not reported, batch number: Unknown) dose was not reported, 1 total, start therapy date was not reported for prophylactic vaccination. The batch number was not reported. Per procedure, no follow-up will be requested for this case. No concomitant medications were reported. On an unspecified date, the patient died 24 hours later after taking vaccine. On an unspecified date, the patient died from unknown cause of death. It was unspecified if an autopsy was performed. The action taken with covid-19 vaccine ad26.cov2.s was not applicable. This report was serious (Death).; Sender"s Comments: 20210756409-Covid-19 vaccine ad26.cov2.s -died 24 hours later after taking vaccine. This event(s) is considered unassessable. The event(s) has a compatible/suggestive temporal relationship, is unlabeled, and has unknown scientific plausibility. There is no information on any other factors potentially associated with the event(s).; Reported Cause(s) of Death: UNKNOWN CAUSE OF DEATH

 VAERS ID: 1511611 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Female
 Entered: 2021-07-29

Location: Unknown

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA - / UNK - / OT

Administered by: Unknown Purchased by: ?

Symptoms: Death SMQs:

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:

CDČ Split Type: USMODERNATX, INC.MOD20212

Write-up: Death after vaccination; This spontaneous case was reported by a consumer and describes the occurrence of DEATH (Death after vaccination) in a female patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) for COVID-19 vaccination. No Medical History information was reported. On an unknown date, the patient received dose of mRNA-1273 (Moderna COVID-19 Vaccine) (unknown route) 1 dosage form. Death occurred on an unknown date The cause of death was not reported. An autopsy was not performed. Concomitant medication and treatment information were not reported. Company Comment: Very limited information regarding this event has been provided at this time. Further information is not expected (Follow up contact denied) Reporter did not allow further contact; Sender"s Comments: Very limited information regarding this event has been provided at this time. Further information is not expected (Follow up contact denied); Reported Cause(s) of Death: unknown cause of death

VAERS ID: <u>1511620</u> (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Entered: 2021-07-29 Sex: Female

Location: Unknown

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

Administered by: Unknown Purchased by: ? Symptoms: Cerebral haemorrhage, Neoplasm malignant

SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Haemorrhagic central nervous system vascular conditions (narrow), Non-haematological malignant

tumours (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:** Allergies:

Diagnostic Lab Data:

CDC Split Type: USPFIZER INC202100911615

Write-up: Caller states that the woman in the study had brain hemorrhaging and a cancerous growth, after the vaccine.; Caller states that the woman in the study had brain hemorrhaging and a cancerous growth, after the vaccine.; This is a spontaneous report from a Pfizer-sponsored program Support reported by a contactable consumer or other non-health care professional. A female patient of an unspecified age received unknown dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number and Expiration date not reported), via an unspecified route of administration in an unspecified anatomical location on an unspecified date as a single dose for COVID-19 immunisation. The patient medical history and concomitant medications were not reported. Reporter stated that cardiologist gave him a study which reported a woman, who had the vaccine, died on the operating table, after her brain was haemorrhaging and they found a cancerous growth. The patient died on an unspecified date. It was not reported if an autopsy was performed. Information about Lot/ Batch number have been requested.; Reported Cause(s) of Death: after her brain was hemorrhaging; and they found a cancerous growth

VAERS ID: <u>1514458</u> (history) Vaccinated: 2021-07-22 Onset: 2021-07-22 Form: Version 2.0

Age: Days after 0 vaccination: Male Sex:

Submitted: 0000-00-00 Location: Unknown Entered: 2021-07-30

| Vaccination / Manufacturer                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA | UNK / 1    | - / OT       |

Administered by: Unknown Purchased by: ?

Symptoms: Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-07-22 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:** 

**Preexisting Conditions:** 

Allergies: Diagnostic Lab Data:

CDC Split Type: USMODERNATX, INC.MOD20212

Write-up: heart attack; This spontaneous case was reported by a consumer (subsequently medically confirmed) and describes the occurrence of MYOCARDIAL INFARCTION (heart attack) in a male patient of an unknown age who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. Unk) for COVID-19 vaccination. No Medical History information was reported. On 22-Jul-2021, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 22-Jul-2021, the patient experienced MYOCARDIAL INFARCTION (heart attack) (seriousness criteria death and medically significant). The patient died on 22-Jul-2021. The cause of death was not reported. It is unknown if an autopsy was performed. No concomitant medications were reported. No laboratory data was provided. No treatment information was provided. Very limited information regarding this event has been provided at this time. No further information is expected at this time. Reporter did not allow further contact; Sender"s Comments: Very limited information regarding this event has been provided at this time. No further information is expected at this time.; Reported Cause(s) of Death: unknown cause of death

**VAERS ID:** <u>907575</u> (history) **Vaccinated:** 0000-00-00 Version 2.0 Onset: 0000-00-00 Form: Submitted: 0000-00-00 Age: Sex: Unknown Entered: 2020-12-23

Location: Foreign

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

Administered by: Other Purchased by: ?

Symptoms: Death, Diarrhoea

SMQs:, Pseudomembranous colitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Noninfectious diarrhoea (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-10 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:

CDC Split Type: GBPFIZER INC2020505569

Write-up: Diarrhoea, This is a spontaneous report from a contactable other healthcare professional via Agency and downloaded from the Regulatory Authority GB-MHRA-WEBCOVID-20201212222117, Safety Report Unique Identifier GB-MHRA-ADR 24542707 and EU-EC-10007191252. An elderly patient of an unspecified gender received bnt162b2 (batch/lot number not provided), via an unspecified route of administration in 2020 at single dose for COVID-19 immunisation. The patient"s medical history and concomitant medications were not reported. The patient experienced diarrhoea in 2020. The patient died due to diarrhoea on 10Dec2020. It was not reported if an autopsy was performed. No follow-up attempts are possible. Information on the lot/batch number not obtainable. No further information is expected.; Reported Cause(s) of Death: diarrhoea

VAERS ID: 908245 (history) Vaccinated: 2020-12-13 Version 2.0 2020-12-13 Form: Onset: Days after Age:

vaccination: Sex: Female Submitted: 0000-00-00 Location: Foreign Entered: 2020-12-24

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

Administered by: Other Purchased by: ?

Symptoms: Cardiac arrest, Circulatory collapse, Death

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (narrow), Arrhythmia related investigations, signs and symptoms (broad), Shockassociated 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), Acute central respiratory depression (broad), Cardiomyopathy (broad), Hypersensitivity (narrow), Respiratory failure (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-13 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:** 

**Preexisting Conditions:** Allergies: Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2020505572

Write-up: Asystole; Circulatory collapse; This is a spontaneous report from a contactable pharmacist received from Agency and downloaded from the Regulatory Authority-WEB GB-MHRA-WEBCOVID-20201214111558, Safety Report Unique Identifier GB-MHRA-ADR 24542972 and EU-EC-10007191566 received via Regulatory Authority. An adult female patient received bnt162b2 (batch/lot number not provided), via an unspecified route of administration on 13Dec2020 at single dose for COVID-19 vaccination. The patient"s medical history was not reported. Concomitant medication included sildenafil, acetylsalicylic acid, allopurinol, levothyroxine, spironolactone, amiloride hydrochloride, furosemide and desogestrel. The patient experienced asystole on 13Dec2020, circulatory collapse on 13Dec2020. The patient died due to asystole and circulatory collapse on 13Dec2020. It was not reported if an autopsy was performed. No follow-up attempts are possible. Information about batch number is not obtainable. No further information is expected.; Reported Cause(s) of Death: circulatory collapse; Asystole

 VAERS ID: 918721 (history)
 Vaccinated:
 2020-12-28

 Form:
 Version 2.0
 Onset:
 2020-12-28

Age: Days after Sex: Male vaccination:

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-04

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

Administered by: Other Purchased by: ?

Symptoms: Cardiac death, Loss of consciousness, Malaise

**SMQs:**, Torsade de pointes/QT prolongation (broad), Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), 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: 2020-12-28
Days after onset: 0
Permanent Disability? No
Recovered? 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: Cancer (NOS); Heart disease, unspecified; Heart failure, unspecified

Allergies:

Diagnostic Lab Data:

CDC Split Type: ILPFIZER INC2020517122

Write-up: cardiac arrest; heart failure; did not feel well, lost consciousness and died; did not feel well, lost consciousness and died; This is a spontaneous report from a contactable consumer. A 75-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 28Dec2020 08:30 at single dose for covid-19 immunisation. Medical history included suffered from the past from heart attacks, active heart disease, malignant diseases. The patient''s concomitant medications were not reported. A man of 75 years old, who suffers from many different background diseases, died (this morning 28Dec2020) from cardiac arrest, two hours after he received the injection. The man received the injection at 8.30am, and after he was feeling okay he was released to go home. After a while when he was home he did not feel well, lost consciousness and died, and he was pronounced dead from heart failure. The patient died on 28Dec2020. It was not reported if an autopsy was performed. The outcome of the event cardiac arrest and heart failure was fatal while the outcome of the other events was unknown. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Sender's Comments: Linked Report(s): IL-PFIZER INC-2020517177 same reporter, same vaccine, reporting similar events in different patients.; Reported Cause(s) of Death: heart failure; cardiac arrest

 VAERS ID: 918722 (history)
 Vaccinated:
 2020-12-24

 Form:
 Version 2.0
 Onset:
 2020-12-28

Age: Days after Sex: Male vaccination:

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-04

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EK4175 / 1 | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death
SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-28
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:

Preexisting Conditions: Medical History/Concurrent Conditions: Bladder tumor resection; Emphysema; Heavy smoker (for almost 50 years); Schizophrenia Allergies:

Diagnostic Lab Data:

CDC Split Type: ILPFIZER INC2020517177

Write-up: found dead in his bed; This is a spontaneous report from a contactable healthcare professional received via the Ministry of Health department of epidemiology. The department of epidemiology reported similar events for two patients. This is the second of two reports. A 61-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK4175), via an unspecified route of administration on 24Dec2020 as a single dose for COVID-19 immunization. Medical history included schizophrenia, very heavy smoker for almost 50 years, emphysema, and tumor resection in the bladder. The patient's concomitant medications were not reported. On 28Dec2020, the patient was found dead in his bed. It was reported that the patient did not have any complaints in the days following the vaccination. Then, on 28Dec2020, the patient was found dead. The cause of death was unknown. It was not reported if an autopsy was performed; Sender's Comments: A reasonable possibility that the event unknown cause of death is related to vaccination with BNT162B2 cannot be completely excluded until further information regarding clinical course and death cause is provided. Of note, the patient did not have any complaints in the days following the vaccination. The case was confounded by the patient's underlying conditions. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as

part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s): IL-PFIZER INC-2020517122 same reporter, same vaccine, reporting similar events in different patients.; Reported Cause(s) of Death: found dead in his bed

VAERS ID: 918727 (history) Vaccinated: 0000-00-00 Form: Version 2.0 Onset: 0000-00-00 Age: Submitted: 0000-00-00 Entered: 2021-01-04 Sex: Unknown

Location: Foreign

| Vaccination / Manufacturer                                    | Lot / Dose | Site / Route |
|---|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTEC | CH -/1     | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Cardiac death, Illness

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac

conditions (excl torsade de pointes) (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:** Allergies:

Diagnostic Lab Data:

CDC Split Type: SEPFIZER INC2020519895

Write-up: died the day after receiving the first injection of vaccine against Covid-19 in suspected cardiac arrest; This is a spontaneous report from a web page with a contactable physician as publisher. A multi-sick, elderly patient of an unspecified gender received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for covid vaccination. The patient medical history was not reported. The patient "s concomitant medications were not reported. The patient died the day after vaccination of a suspected heart stop. The patient died the day after receiving the first injection of vaccine against covid-19. The patient died on an unspecified date. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about LOT/batch number cannot be obtained.; Sender"s Comments: The information available in this report is limited and does not allow a medically meaningful assessment of the case. In particular the following relevant information is not available: complete medical history and complete demographics, treatment dates and dose, concomitant medications (if any), event descriptors, autopsy report. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: suspected heart stop

VAERS ID: <u>923219</u> (<u>history</u>) Vaccinated: 2020-12-30 Form: Version 2.0 Onset: 2021-01-01 Days after Age:

2 Sex: Female vaccination: 0000-00-00 Submitted: Location: Foreign Entered: 2021-01-06

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

Administered by: Other Purchased by: ?

Symptoms: Death, Sudden death, Unresponsive to stimuli

SMQs:, Torsade de pointes/QT prolongation (broad), Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Guillain-Barre syndrome (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Cardiomyopathy (broad), Hypotonic-hyporesponsive episode (broad), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-01 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:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Hypertension

Allergies:

Diagnostic Lab Data:

CDC Split Type: PTPFIZER INC2021002036

Write-up: Sudden death; This is a spontaneous report from a contactable physician and consumer. A 41-year-old female patient received the first dose of BNT162B2 (COMIRNATY; Lot Number: UNKNOWN), via an unspecified route of administration on 30Dec2020 at 0.3 mL single dose for COVID-19 immunisation. Medical history included hypertension. The patient's concomitant medications were not reported. On 01Jan2021, the patient experienced sudden death. The clinical course was as follows: The patient didn"t experience any adverse event at the moment of inoculation with COVID-19 vaccine or the following days. On 01Jan2021, at lunch time, two days after receiving the vaccine, the patient was found unresponsive in her bed by her partner. The cause of death was unknown. It was reported that an autopsy would be performed in the next days; the results were not yet available. The lot number for the vaccine, BNT162B2, was not provided and will be requested during follow up.; Sender"s Comments: The reported information is limited and does not allow a meaningful assessment of the case. It will be reassessed upon receipt of

follow up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: Sudden death

 VAERS ID: 925616 (history)
 Vaccinated: 2020-12-30

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-01-07

Location: Foreign

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

Administered by: Other Purchased by: ?

Symptoms: Cardiac arrest, Death

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (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), Respiratory failure (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: Asthma; Overweight

Allergies:

Diagnostic Lab Data:

CDC Split Type: ILPFIZER INC2021000681

Write-up: cardiac arrest; This is a spontaneous report from a contactable physician. A 64-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), via an unspecified route of administration on 30Dec2020 as single dose for covid-19 immunization. Medical history included asthma and a little overweight from an unknown date. The patient"s concomitant medications were not reported. The patient experienced cardiac arrest on an unspecified date, which was serious as it lead to death. The patient died on an unspecified date. It was not reported if an autopsy was performed. This batch/lot number is not available despite the follow-up attempts made. No further information is expected.; Sender"s Comments: The reported information is limited and does not allow a meaningful assessment of the case. It will be reassessed upon receipt of follow up information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.; Reported Cause(s) of Death: cardiac arrest

 VAERS ID: 928992 (history)
 Vaccinated: 2020-12-18

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-01-08

Location: Foreign

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EJ0553 / UNK - / OT

Administered by: Other Purchased by: ?

Symptoms: Atrial fibrillation, Condition aggravated, Death, Malaise

SMQs:, Supraventricular tachyarrhythmias (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-20 Permanent Disability? No Recovered? No

Office Visit? No ER Visit? No ER or Doctor Visit? Yes Hospitalized? Yes ? day

Hospitalized? Yes, ? days Extended hospital stay? No Previous Vaccinations: Other Medications: ; ; ; ;

Current Illness: Atrial fibrillation; Diabetes; Frailty; Hypothyroidism; Osteoporosis

Preexisting Conditions: Allergies:

Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021003922

Write-up: Atrial fibrillation; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority. The regulatory authority report number is GB-MHRA-EYC 00236011. An 87-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EJ0553), intramuscular on 18Dec2020 at 0.3 mL, single for covid-19 immunization. Medical history included ongoing hypothyroidism, ongoing diabetes, ongoing atrial fibrillation, ongoing frailty and, ongoing osteoporosis, all from unknown dates. Concomitant medication included prednisolone (MANUFACTURER UNKNOWN), levothyroxine (MANUFACTURER UNKNOWN), salbutamol (MANUFACTURER UNKNOWN), omeprazole (MANUFACTURER UNKNOWN), doxycycline (MANUFACTURER UNKNOWN). The patient experienced atrial fibrillation on an unspecified date, which was serious as it was medically significant, involved hospitalization and lead to death. Clinical course was as follows: the patient was vaccinated. Consent was obtained and a pre immunization checklist was completed. She was observed following the administration of the vaccine, and no adverse effects were noted. She returned home. She became unwell and was admitted to hospital approximately 24 hours later. The patient was admitted to the hospital 24 hours following the vaccination, and subsequently died later, while in the hospital. The full clinical details were unknown, but the diagnosis from Accident & Emergency was atrial fibrillation. It is not clear if this had any relation to the vaccine that was administered, but could not be excluded, per the reporter. The patient died on 20Dec2020. It was not reported if an autopsy was performed. No follow-up activities are possible. No further information is expected.; Reported Cause(s) of Death: Atrial fibrillation

**VAERS ID:** <u>929016 (history)</u> Vaccinated: 2020-12-29 Version 2.0 2020-12-29 Form: Onset:

Days after Age: vaccination: Female Sex:

Submitted: 0000-00-00 Location: Foreign 2021-01-08 Entered:

Lot / Dose Site / Route Vaccination / Manufacturer COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EJ1677 / UNK

Administered by: Other Purchased by: ?

Symptoms: Death, Diarrhoea, SARS-CoV-2 test negative, Vomiting

SMQs:, Acute pancreatitis (broad), Pseudomembranous colitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Noninfectious

diarrhoea (narrow), COVID-19 (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-30 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: INFLUENZA VIRUS

**Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Delirium (History of); Dementia; Urinary tract infection (History of) Allergies:

Diagnostic Lab Data: Test Date: 20201208; Test Name: COVID-19 virus test; Test Result: Negative; Comments: No - Negative CDC Split Type: GBPFIZER INC2021009768

Write-up: Death; Loose stools; Vomited; This is a spontaneous report from a contactable other healthcare professional by Pfizer from the Regulatory Agency (UK-MHRA). The regulatory authority report number is GB-MHRA-WEBCOVID-20201230164020. An elderly female patient received BNT162B2 (COVID-19 MRNA) VACCINE BIONTECH, Batch: EJ1677, Expiration date: Feb2021) via an unspecified route on 29Dec2020 at single dose for Covid-19 vaccination. Medical history included dementia and a history of urinary tract infection and delirium, all from an unknown date and unknown of ongoing. Concomitant medication included influenza vaccine (INFLUENZA VIRUS, Batch: 4924B1A) for influenza immunization. Patient has not had symptoms associated with COVID-19. Patient is not enrolled in clinical trial. No known allergies. The patient had not tested positive for COVID-19 since having the vaccine. On the 29Dec2020 the patient experienced loose stools and vomited. The patient underwent lab tests and procedures which included COVID-19 virus test: no -negative on 08Dec2020. The patient died on the 30Dec2020 at 11:25 am in the morning. It was unknown if a postmortem was going to be carried out, after talking to the general practice surgery they advised that the general practitioner was only passed notification of the patient"s death that afternoon (04Jan2021). It was advised that they may go to the coroner but couldn"t give a definitive answer until the general practitioner had looked at the notification. 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: Death

Vaccinated: 2020-12-25 VAERS ID: <u>929027 (history)</u> Form: Version 2.0 Onset: 2020-12-01 Age: Submitted: 0000-00-00 2021-01-08 Sex: Male Entered:

Location: Foreign

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EK4175 / UNK

Administered by: Other Purchased by: ?

Symptoms: Acute myocardial infarction, Death, Pain in extremity, Peripheral swelling

SMQs:, Cardiac failure (broad), Angioedema (broad), Myocardial infarction (narrow), Embolic and thrombotic events, arterial (narrow), Extravasation events (injections, infusions and implants) (broad), Haemodynamic oedema, effusions and fluid overload (narrow), Tendinopathies and ligament disorders (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-28 Days after onset: 27 Permanent Disability? No Recovered? No Office Visit? No ER Visit? No ER or Doctor Visit? No

Hospitalized? No **Previous Vaccinations:** Other Medications:

Preexisting Conditions: Medical History/Concurrent Conditions: Alcohol use; Aortic stenosis; Atrial fibrillation; Carotid artery stenosis; Chemotherapy; COPD; Diabetes; Diabetic nephropathy; Diabetic neuropathy; Diabetic retinopathy; DVT; Hepatitis; Hodgkin"s lymphoma; Mobility decreased; Smoker

Allergies:

Diagnostic Lab Data:

CDC Split Type: ILPFIZER INC2021009751

Write-up: At night they found him lifeless. Probably following acute MI; pain in the arm and swelling in the arm of vaccination; pain in the arm and swelling in the arm of vaccination; This is a spontaneous report from a contactable other healthcare professional via Division of Health. The other healthcare professional reported similar events for three patients. This is the second of three reports. A male patient of an unspecified age received BNT162B2 (lot# EK4175), via an unspecified route of administration on 25Dec2020 at single dose for Covid-19 immunisation. Medical history included chronic obstructive pulmonary disease (COPD) with smoking background, atrial fibrillation, aortic stenosis, diabetes with damage to all target organs (nephropathy, retinopathy, neuropathy), carotid stenosis, deep vein thrombosis (DVT) history, history of alcohol use with hepatitis, history of Hodgkin"s lymphoma after successful chemotherapy treatment, got around on a scooter. The patient"s concomitant medications were not reported. The patient was vaccinated on 25Dec2020 and passed away at home on 28Dec2020. Before his death, according to his daughter, he complained about pain in the arm and swelling in the arm of vaccination on an unspecified date of Dec2020. At night they found him lifeless. Probably following acute myocardial infarction (MI). The outcome of pain in the arm and swelling in the arm of vaccination was unknown, acute MI was fatal. It was not reported

if an autopsy was performed. Follow-up attempts are completed. No further information is expected.; Sender's Comments: Fatal acute myocardial infarction is more likely attributed to the patient underlying medical conditions including vascular stenosis and diabetes with complications. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate,Linked Report(s): IL-PFIZER INC-2020519349 same reporter/product, similar event, different patient; Reported Cause(s) of Death: acute MI

 VAERS ID: 929028 (history)
 Vaccinated:
 2020-12-30

 Form:
 Version 2.0
 Onset:
 2021-01-01

Age: Days after Sex: Male vaccination: 2

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-08

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

Administered by: Other Purchased by: ?

Symptoms: Death, Endotracheal intubation, Pleural effusion, Pyrexia, Respiratory distress, Sepsis, Vomiting

SMQs:, Anaphylactic reaction (broad), Acute pancreatitis (broad), Angioedema (broad), Neuroleptic malignant syndrome (broad), Systemic lupus erythematosus (broad), Anticholinergic syndrome (broad), Acute central respiratory depression (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Haemodynamic oedema, effusions and fluid overload (narrow), Hypersensitivity (broad), Respiratory failure (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Infective pneumonia (broad), Sepsis (narrow), Opportunistic infections (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-04 Days after onset: 3 Permanent Disability? No Recovered? No Office Visit? No ER Visit? No ER or Doctor Visit? Yes Hospitalized? Yes, ? days

Extended hospital stay? No Previous Vaccinations: Other Medications: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Bladder cancer; Blood pressure abnormal; Diabetes

Allergies:

Diagnostic Lab Data:

CDC Split Type: ILPFIZER INC2021009752

Write-up: SÉPSIS; respiratory distress; PLEURAL EFFUSION; This is a spontaneous report received from other healthcare professional via the Division of epidemiology of the Ministry of Health. The other healthcare professional reported similar events for three patients. This is the third of three reports. A 91-year-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 30Dec2020 at single dose for covid-19 immunisation. Medical history included known background of blood pressure disease, diabetes, malignant bladder from an unknown date and unknown if ongoing. The patient's concomitant medications were not reported. Patient was received at the emergency room 3 days after receiving the corona vaccine in Jan2021, with fever, vomiting more than 40 times, in respiratory distress, was hospitalized in internal medicine department with sepsis diagnosis due to respiratory distress and pleural effusion, intubated, his condition was serious, patient passed away on 04Jan2021. Cause of death was reported as sepsis, respiratory distress and pleural effusion. It was not reported if an autopsy was performed. Follow-up attempts are completed. No further information is expected. Information about batch/lot number cannot be obtained; Sender's Comments: Based on the information currently provided, the fatal events sepsis, respiratory distress and pleural effusion are more likely attributed to intercurrent infectious conditions associated with the advanced old patient underlying diseases. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in responses, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.,Linked Report(s): IL-PFIZER INC-2020519349 same reporter, product, simil

 VAERS ID: 933230 (history)
 Vaccinated:
 2020-12-20

 Form:
 Version 2.0
 Onset:
 2020-12-21

Age: Days after Sex: Male vaccination:

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-11

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

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2020-12-21 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:
Preexisting Conditions: Medical History/Concurrent Conditions: Cardiac disorder; Lung disease

Allergies:

Diagnostic Lab Data:

CDČ Split Type: GBPFIZER INC2021004572

Write-up: Death within 24 hours after dose; This is a spontaneous report from a contactable consumer downloaded from the regulatory authority (GB-MHRA-EYC 00236003 and GB-MHRA-ADR 24545815). A 78-year-old male patient received BNT162B2 (COMIRNATY), via an unspecified route of administration, on 20Dec2020 at 16:00 as a single dose for COVID-19 immunization. Medical history included cardiac disease and lung disease. The patient had no known allergies. Concomitant medications included an unspecified hypertensive taken for hypertension, an unspecified drug for ischaemic heart disease, and an unspecified drug for chronic obstructive pulmonary disease (COPD). The patient experienced death within 24 hours after dose on 21Dec2020. The event was reported as fatal. The clinical course was reported as follows: The patient was observed for 15 minutes after the dose was given and had no side effects. In the evening, the patient felt well. The patient received the vaccination as he was a high risk patient, elderly, and with a background of cardiac and lung disease. The clinical outcome of death within 24 hours after dose was fatal. The patient died on 21Dec2020. The cause of death was unexplained. It was unknown if an autopsy was performed. The reporter assessed the causality between the vaccination and death as unlikely. No follow-up attempts possible; information on lot and batch numbers cannot be obtained.; Reported Cause(s) of Death: Death unexplained

 VAERS ID: 933232 (history)
 Vaccinated:
 2020-12-17

 Form:
 Version 2.0
 Onset:
 2020-12-17

Age: Days after Sex: Male vaccination:

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-11

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

Administered by: Other Purchased by: ?

Symptoms: Death, Dizziness, Epistaxis, Haematemesis, Haemoptysis, Headache

SMQs:, Haemorrhage terms (excl laboratory terms) (narrow), Anticholinergic syndrome (broad), Gastrointestinal haemorrhage (narrow), Vestibular disorders (broad),

Infective pneumonia (broad)
Life Threatening? No

Birth Defect? No Died? Yes

Date died: 2020-12-20 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: ; VENTOLINE [SALBUTAMOL SULFATE]

Current Illness

Preexisting Conditions: Medical History/Concurrent Conditions: Asthma; Vitamin D3 deficiency

Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Result Unstructured Data: Test Result:No - Negative COVID-19 test

CDC Split Type: GBPFIZER INC2021004563

Write-up: Death; Head ache and dizziness; Head ache and dizziness; Spitting blood; Vomiting blood; Nose bleed; This is a spontaneous report a contactable consumer downloaded from the Regulatory Authority(GB-MHRA-WEBCOVID-20201220100831 and GB-MHRA-ADR 24545199). A male patient of an unspecified age received BNT162B2 (COMIRNATY), via an unspecified route of administration, on 17Dec2020 as a single dose for COVID-19 immunisation. Medical history included vitamin D3 deficiency and asthma. Concomitant medications included colecalciferol (MANUFACTURER UNKNOWN) for vitamin deficiency and salbutamol sulfate (VENTOLINE) for asthma. The patient experienced nose bleed on 17Dec2020, head ache and dizziness, spitting blood, and vomiting blood on 18Dec2020, and death on 20Dec2020. All of the events were reported as fatal. It was reported that a healthcare professional advised the patient to take unspecified pain medication after explaining mild and strong side effects to help with pain. The patient underwent lab tests and procedures which included COVID-19 virus test: No - negative COVID-19 test on an unspecified date. Therapeutic measures were taken as a result of nose bleed, head ache and dizziness, spitting blood, and vomiting blood as aforementioned. The clinical outcome of nose bleed, head ache and dizziness, spitting blood, and death was fatal. The patient died on 20Dec2020. The cause of death was unexplained. It was not reported if an autopsy was performed. It was also reported that since the vaccination, the patient had not been tested positive for COVID-19. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Death unexplained

 VAERS ID: 934465 (history)
 Vaccinated:
 2020-12-28

 Form:
 Version 2.0
 Onset:
 2020-12-29

Age: Days after
Sex: Male vaccination:

**Location:** Foreign **Submitted:** 0000-00-00 **Entered:** 2021-01-11

| Vaccination / Manufacturer                                     | Lot / Dose   | Site / Route |
|--|--------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EK4237 / UNK | -/-          |

Administered by: Other Purchased by: ? Symptoms: Circulatory collapse, Death

**SMQs:**, Anaphylactic reaction (narrow), 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), Hypersensitivity (narrow)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2020-12-29 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: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Atrial fibrillation; Cardiac disorder; Cardiac pacemaker insertion; Dementia; Heart failure; Penicillin allergy

Allergies:

Diagnostic Lab Data: Test Date: 20201229; Test Name: pulse; Result Unstructured Data: Test Result:no pulse

CDC Split Type: ILPFIZER INC2020519349

Write-up: patient died after collapsing in his home several hours after he received the vaccine; patient died after collapsing in his home several hours after he received the vaccine; The initial case was missing the following minimum criteria: the reporter does not have first-hand knowledge of the reported events and was not identifiable. Upon receipt of follow-up information on 06Jan2021, this case now contains all required information to be considered valid. This is a spontaneous report from a contactable healthcare professional via regulatory Authority. The regulatory authority reported similar events for three patients. This is the first of three reports. An 88-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EK4237), via an unspecified route of administration on 28Dec2020 as a single dose for COVID-19 immunization. Medical history included dementia, cardiac background with pacemaker, atrial fibrillation, heart failure, and penicillin allergy. The patient was not allergic to polyethylene glycol. The patient"s concomitant medications were not reported. On 29Dec2020, the patient died after collapsing in his home several hours after he received the vaccine. Outcome of collapsing was not recovered. The patient had no pulse when he arrived at the hospital. It was not reported if an autopsy was performed. The cause of death was unknown. Follow-up attempts are completed. No further information is expected.; Sender"s Comments: The advance old patient had underlying cardiac background with pacemaker, atrial fibrillation and heart failure, therefore the pre-existing cardiovascular medical conditions more likely provide explanations for collapsing lead to the patient death. More information especially death cause and autopsy results are needed for further meaningful assessment. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adv

 VAERS ID: 934760 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 0000-00-00

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-01-11

Location: Foreign

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

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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:

CDC Split Type: DEPFIZER INC2021006905

Write-up: Death in connection with the vaccination and/or Covid19 disease / positivity; Death in connection with the vaccination and/or Covid19 disease / positivity; This is a spontaneous report from a contactable physician. This physician reported similar events for two patients. This is the second of two reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. The patient"s medical history and concomitant medications were not reported. It was reported 2 deceased were autopsied, death in connection with the vaccination or Covid19 disease / positivity; Sender"s Comments: The information currently provided is too limited to make a meaningful medical assessment hence, the events are conservatively assessed as related to the suspect drug BNT162B2 until further information becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to RAs, Ethics Committees, and Investigators, as appropriate, Linked Report(s): DE-PFIZER INC-2021006738 same reporter, same product, same event, different patient; Reported Cause(s) of Death: Death in connection with the vaccination and/or Covid19 disease / positivity; Death in connection with the vaccination and/or Covid19 disease / positivity

 VAERS ID: 934763 (history)
 Vaccinated:
 2020-12-30

 Form:
 Version 2.0
 Onset:
 2021-01-01

 Age:
 Days after
 2

Sex: Female vaccination:

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-11

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EJ6797 / 1 | - / OT       |

Administered by: Other Purchased by: ?

Symptoms: Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-01 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: ELIQUIS;

Current Illness: Atrial fibrillation; Dementia; Depression; Obstipation (Periodic treated)

Preexisting Conditions: Medical History/Concurrent Conditions: Tibia fracture (conservative treatment)

Allergies:

Diagnostic Lab Data:

CDC Split Type: DKPFIZER INC2021013445

Write-up: Sudden death; This is a spontaneous report downloaded from the regulatory authority DK-DKMA-WBS-0028211. Report was received from a contactable nurse via regulatory authority. A 94-years-old female patient received BNT162B2 (COMIRNATY) (Lot # EJ6797, exp date 30Apr2021), via intramuscular on 30Dec2020 at first single dose for covid-19 immunization. Medical history included ongoing periodic obstipation (periodic treated), ongoing dementia, ongoing atrial fibrillation, ongoing depression, tibia fracture from 01Nov2020 (treated conservatively). Concomitant medication included apixaban (ELIQUIS) from 09Apr2018 to unknown date for atrial fibrillation, sertraline from 20Jun2018 to unknown date for depression. The patient had not received BNT162B2 before. The patient experienced sudden death on 01Jan2021. There was no immediate illness until the time of vaccination and the nurse described that she "seemed like herself and fresh". The ADRs were by the reporter reported as fatal. Reported cause of death: Unknown caused of death, Sudden death. No treatment due to the death was described. There is no information regarding test results. An autopsy was not performed. Causality. The doctor who issued the death certificate does not suspect that it is the COVID-19 vaccine that is the cause of her death. She slept quietly in, and was old. Due to reporting obligation this case is reported. If the regulatory authority receives supplemental significant information regarding this case the case will be re-submitted.; Reported Cause(s) of Death: Sudden death; Unknown cause of death

 VAERS ID: 934764 (history)
 Vaccinated:
 2020-12-30

 Form:
 Version 2.0
 Onset:
 2020-12-31

 Age:
 Days after
 4

Sex: Male vaccination:

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EJ6797 / UNK - / OT

Administered by: Other Purchased by: ?

Symptoms: Anxiety, C-reactive protein normal, Chronic obstructive pulmonary disease, Condition aggravated, Death, Dyspnoea, Fibrin D dimer normal, Fluid balance assessment, Forced expiratory volume decreased, Hepatic enzyme, Oxygen saturation decreased, PCO2 increased, Respiratory failure, Restlessness SMQs:, Anaphylactic reaction (broad), Asthma/bronchospasm (broad), Anticholinergic syndrome (broad), Shock-associated circulatory or cardiac conditions (excl

SMQs:, Anaphylactic reaction (broad), Asthma/bronchospasm (broad), Anticholinergic syndrome (broad), 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), Dementia (broad), Akathisia (broad), Acute central respiratory depression (narrow), Pulmonary hypertension (broad), Guillain-Barre syndrome (broad), Noninfectious encephalopathy/delirium (broad), Cardiomyopathy (broad), Eosinophilic pneumonia (broad), Hypersensitivity (broad), Respiratory failure (narrow), Hypoglycaemia (broad), Infective pneumonia (broad), Hypokalaemia (broad)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-01-03 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: PREDNISOLON ACTAVIS; IPRAMOL; LYSANTIN; QUETIAPIN ACCORD; VENTOLINE [SALBUTAMOL SULFATE]; PARACETAMOL ORIFARM; QUETIAPIN ARROW; BUPRENORPHINE/NALOXONE MYLAN; XEPLION; TRELEGY ELLIPTA; PHENERGAN [PROMETHAZINE HYDROCHLORIDE]

Current Illness: Alcohol abuse chronic; Anxiety; Chronic obstructive airways disease exacerbated; Dyspnoea; Hallucination; Hypoxic (Hypoxic down to 60 %); Insomnia; Opioid abuse; Pain; Paranoid schizophrenia; Psychosis; Tobacco abuse; Treatment noncompliance

Preexisting Conditions: Medical History/Concurrent Conditions: Amphetamine abuse; Chronic obstructive airways disease exacerbated Allergies:

Diagnostic Lab Data: Test Name: C-reactive protein; Result Unstructured Data: Test Result:normal; Test Date: 20201227; Test Name: C-reactive protein; Result Unstructured Data: Test Result:16; Test Date: 20201231; Test Name: Fibrin D dimer; Result Unstructured Data: Test Result:Normal; Test Date: 20201227; Test Name: Fluid balance assessment; Result Unstructured Data: Test Result:Normal; Test Date: 2018; Test Name: FEV 1; Test Result: 37 %; Test Date: 20201227; Test Name: Hepatic enzyme; Result Unstructured Data: Test Result:Normal; Test Name: Oxygen saturation; Test Result: 64 %; Test Date: 20201220; Test Name: Oxygen saturation; Test Result: 68 %; Test Date: 20201231; Test Name: Oxygen saturation; Test Result: 62 %; Test Date: 20201231; Test Name: Oxygen saturation; Test Result: 35 %; Comments: in the ambulance; Test Date: 20201231; Test Name: Oxygen saturation; Test Result: 100 %; Comments: on oxygen-treatment; Test Date: 20210102; Test Name: Oxygen saturation; Result: 12:47 pm; Test Date: 20210102; Test Name: Oxygen saturation; Test Result: 58 %; Comments: 09:00 am in the ambulance; Test Date: 20210102; Test Name: Oxygen saturation; Test Result: 99 %; Comments: on oxygen-treatment; Test Date: 20210102; Test Name: Oxygen saturation; Test Result: 99 %; Comments: on oxygen-treatment; Test Name: PCO2; Result Unstructured Data: Test Result: Down to 4.8 (Unit not specified); Test Name: PO2; Result Unstructured Data: Test Result:Down to 4.8 (Unit not specified)

CDC Split Type: DKPFIZER INC2021013449

Write-up: Hypoxic respiratory failure; Dyspnea exacerbated; This is a spontaneous report downloaded from the Medicines Agency (MA) WEB DK-DKMA-WBS-0028232. The report was received from a contactable physician via The Medicines Agency (MA). A 45-year-old male patient received BNT162B2 (COMIRNATY) (Lot #: EJ6797, Expiration Date: 30Apr2021), via intramuscular on 30Dec2020 at single dose for Covid-19 vaccination. Medical history included ongoing treatment noncompliance, ongoing alcohol abuse chronic, ongoing psychosis, dyspnoea from 20Dec2020 and ongoing, ongoing hallucination, ongoing tobacco abuse, ongoing paranoid schizophrenia, chronic obstructive airways disease exacerbated from Aug2020 and ongoing, chronic obstructive airways disease exacerbated from Nov2020 to an unknown date (not ongoing), hypoxic down to 60 % from 20Dec2020 and ongoing, Amphetamine abuse (not ongoing), ongoing pain, ongoing opioid abuse, ongoing anxiety, and ongoing insomnia. There is no information regarding past medication. Concomitant medication included prednisolone (PREDNISOLON ACTAVIS) from 20Nov2020 for Chronic obstructive airways disease exacerbated, orphenadrine hydrochloride (LYSANTIN) from 02Dec2019 to 03Jan2021 for Anxiety aggravated, quetiapine fumarate (QUETIAPIN ACCORD) from 16Dec2020 to 03Jan2021 for Psychiatric symptom, salbutamol sulfate (VENTOLINE) from 03Nov2018 for Chronic obstruct airways disease, paracetamol (PARACETAMOL ORIFARM) from 30Nov2020 to 03Jan2021 for Pain, quetiapine fumarate (QUETIAPIN ARROW) from 15Aug2020 to 03Jan2021 for Psychiatric symptom, buprenorphine hydrochloride, naloxone hydrochloride (BUPRENORPHINE/NALOXONE MYLAN) from 29Jun2020 to 03Jan2021 for Opioid abuse, paliperidone palmitate (XEPLION) from 19Dec2019 to 03Jan2021 for Psychiatric disorder prophylaxis, fluticasone furoate, umeclidinium bromide, vilanterol trifenatate (TRELEGY ELLIPTA) from 04Jul2019 to Jul2019 for Chronic obstruct airways disease, promethazine hydrochloride (PHENERGAN) from 24Sep2020 to 03Jan2021 for Insomnia. The patient

patient did not want treatment and that in the given situation there was nothing more to do. Therefore the patient was returned to department with palliative treatment in the form of oxygen, midazolam subcutaneous (S.C.) and morphine S.C. On the 03Jan2021 the patient"s respiration was calm. The patient was unreachable. At 14:00 he was restless and got palliative treatment with midazolam and morphine. The patient underwent lab tests and procedures which included c-reactive protein: normal on an unspecified date, 16 on 27Dec2020, fibrin D dimer: normal on 31Dec2020, fluid balance assessment: normal on 27Dec2020, forced expiratory volume (FEV 1): 37 % on 2018, hepatic enzyme: normal on 27Dec2020, oxygen saturation: 64 % on an unspecified date, 60 % on 20Dec2020, 58 % on 27Dec2020, 62 % on 31Dec2020, 35 % (in the ambulance) on 31Dec2020, 100 % (on oxygen-treatment) on 31Dec2020, 40-60% on 02Jan2021 12:47 pm, 58 % (in the ambulance) on 02Jan2021 09:00 am, 30 % on 02Jan2021 04:24 am, 99 % (on oxygen-treatment) on 02Jan2021, PCO2 up to 12.8 (Unit not specified) on an unspecified date, PO2 Down to 4.8 (Unit not specified) on an unspecified date. The patient died on 03Jan2021. An autopsy was not performed. The outcome of the events was fatal. Causality: The reporter assessed that even though the patient"s symptoms have occurred long before the vaccination, it can not be ruled out that the patient"s dyspnoea and hypoxia due to COPD have been aggravated by the vaccine. If the Medicines Agency receives supplemental significant information regarding this case the case will be re-submitted.; Reported Cause(s) of Death: Dyspnea exacerbated; Hypoxic respiratory failure

**VAERS ID:** 934765 (history) Vaccinated: 2021-01-03 Form: Version 2.0 Onset: 2021-01-04

Days after Age: Sex: Female vaccination:

Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-11

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EJ6797 / UNK

Administered by: Other Purchased by: ? Symptoms: Dyspnoea, Pulmonary oedem

SMQs:, Cardiac failure (narrow), Anaphylactic reaction (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Haemodynamic oedema, effusions and fluid overload (narrow), Cardiomyopathy (broad)

Life Threatening? No

Birth Defect? No Died? Yes Date died: 2021-01-04

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:

Preexisting Conditions: Medical History/Concurrent Conditions: Dementia with Lewy bodies; Hypertension; Osteoporosis

Allergies:

CDC Split Type: DKPFIZER INC2021013357

Write-up: Dyspnoea; suspected pulmonary edema; This is a spontaneous report downloaded from the regulatory authority DK-DKMA-WBS-0028304. Report was received from a contactable physician via from the regulatory authority. An 80-year-old female patient received bnt162b2 (COMIRNATY, lot EJ6797, expiration date 30Apr2021), intramuscularly on 03Jan2021 at single dose for covid-19 immunisation. Medical history included dementia with lewy bodies from an unknown date and unknown if ongoing, osteoporosis from an unknown date and unknown if ongoing, hypertension from an unknown date and unknown if ongoing. No previous drug was given. The patient sconcomitant medications were not reported. On 04Jan2021 around 12, approximately 25 hours after the vaccination the patient developed dyspnoea and pulmonary edema. 4 hours later she died. The patient did not experience any allergic symptoms. Events reported as dyspnoea and suspected pulmonary edema. The ADRs were by the reporter reported as fatal. No treatment due to the ADRs was reported. Reported cause of death was pulmonary edema. Outcome of event dyspnoea also reported as not recovered. There was no information regarding test results. It was not reported if an autopsy was performed.; Reported Cause(s) of Death: Pulmonary edema; Dyspnoea

**VAERS ID:** <u>934781</u> (history) Vaccinated: 2020-12-15 Version 2.0 2020-12-18 Form: Onset:

Days after Age: vaccination: Sex: Female

Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-11

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

Administered by: Other Purchased by: ? Symptoms: Death, Pneumonia, Resuscitation, Sepsis

SMQs:, Eosinophilic pneumonia (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Infective pneumonia (narrow), Sepsis (narrow),

Opportunistic infections (broad)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2020-12-19 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: ; ; ; ; **Current Illness:** 

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021009059

Write-up: Sepsis; Acute bronchopneumonia; This is a spontaneous report received from a contactable physician downloaded from the Regulatory Authority (GB-MHRA-EYC 00236063 and GB-MHRA-ADR 24546059). An 85-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly, on 15Dec2020 as a single dose for COVID-19 vaccination. The patient's medical history was not reported. Concomitant medications included pregabalin (MANUFACTURER UNKNOWN), amitriptyline (MANUFACTURER UNKNOWN), amidepine (MANUFACTURER UNKNOWN), candesartan (MANUFACTURER UNKNOWN), and levothyroxine (MANUFACTURER UNKNOWN). The patient experienced acute bronchopneumonia on 18Dec2020 and sepsis on an unspecified date. The events caused hospitalization and were reported as fatal. The clinical course was reported as follows: The patient was brought to the hospital by ambulance with severe sepsis and bronchopneumonia. She was resuscitated but unfortunately died shortly after arriving. The family reported that the patient received the coronavirus vaccine on 15Dec2020. It was reported that it is unclear from the family history whether she was unwell before she received the vaccine. The clinical outcome of acute bronchopneumonia and sepsis was fatal. The patient died on 19Dec2020. The cause of death was reported as acute bronchopneumonia and sepsis. It was not reported if an autopsy was performed. No follow-up attempts are possible; information on batch number cannot be obtained.; Sender's Comments: The information available in this report is limited and does not allow a medically meaningful assessment of the case. In particular the following relevant information is not available: medical history, autopsy report.; Reported Cause(s) of Death: Sepsis; Acute bronchopneumonia

 VAERS ID: 934782 (history)
 Vaccinated: 2020-12-18

 Form:
 Version 2.0
 Onset:
 0000-00-00

 Age:
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-01-11

Location: Foreign

 Vaccination / Manufacturer
 Lot / Dose
 Site / Route

 COVID19:
 COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH UNKNOWN / UNK
 - / OT

Administered by: Other Purchased by: ?

Symptoms: Death, Living in residential institution, Lower respiratory tract infection, Viral test negative

SMQs:, Infective pneumonia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-22 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No ER or Doctor Visit? No

Hospitalized? No Previous Vaccinations:

 $\textbf{Other Medications:}\;;\;;\;\mathsf{SODIUM}\;\mathsf{VALPROATE};\;;\;;\;$ 

**Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Frailty (severely); Vascular dementia

Allergies

Diagnostic Lab Data: Test Name: Body temperature; Result Unstructured Data: Test Result:Settled - before giving vaccine Centigrade; Test Name: COVID-19 virus test; Result Unstructured Data: Test Result:Negative - swab test

CDC Split Type: GBPFIZER INC2021009085

Write-up: Lower respiratory tract infection; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority GB-MHRA-EYC 00236087, Safety Report Unique Identifier: GB-MHRA-ADR 24546153. A 83-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscularly on 18Dec2020 at single dose for covid-19 immunization. Medical history included vascular dementia from an unknown date and unknown if ongoing, severely frail from an unknown date and unknown if ongoing. This patient was severely frail as a result of vascular dementia and was a permanent nursing home resident. Concomitant medication included amoxicillin, doxycycline, sodium valproate, quetiapine, omeprazole, paracetamol. The patient experienced lower respiratory tract infection (LRTI) on an unspecified date. Patient died on 22Dec2020 within 5 days of receiving Covid vaccine, had been on antibiotics for LRTI for 2 days and had appeared to be improving, temperature was settled before vaccine was administered. She had a negative Covid swab at the onset of her symptoms. It would seem more likely that this patient died as a result of an evolving LRTI than as a result of receiving Covid vaccination. She was changed to amoxicillin 2 days before she died. The other outcome for Death was: Died 22Dec2020 but cause of death felt to be due to LRTI not vaccine. It was not reported if an autopsy was performed. No followup attempts are possible, information on batch number cannot be obtained.; Sender's Comments: The underlying predisposing condition (severely frail, lower respiratory tract infection) have been assessed to have played a major role toward the event.; Reported Cause(s) of Death: Lower respiratory tract infection

 VAERS ID: 934826 (history)
 Vaccinated: 2020-12-20

 Form:
 Version 2.0
 Onset: 2020-12-01

 Age:
 Submitted: 0000-00-00

 Sex:
 Male
 Entered: 2021-01-11

Location: Foreign

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

Recovered? No

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-01
Days after onset: 0
Permanent Disability? No

Office Visit? No ER Visit? No ER or Doctor Visit? No Hospitalized? No

Hospitalized? No Previous Vaccinations: Other Medications:

Current Illness: Chronic obstructive pulmonary disease; Depression; Hypertension; Ischaemic heart disease

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021009370

Write-up: Death; This is a spontaneous report from a contactable consumer and a physician downloaded from the Regulatory Authority number GB-MHRA-WEBCOVID-20201222043330 and Safety Report Unique Identifier GB-MHRA-ADR 24545938. A 78-year-old male patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, LOT: EJ0553) via an unspecified route of administration on 20Dec2020 around 15:45 at single dose in left upper arm for COVID-19 vaccination. The patient ongoing medical history included Depression, Hypertension, chronic obstructive pulmonary disease and ischaemic heart disease. Patient is not enrolled in clinical trial. Patient has not been tested/or has had an inconclusive test for COVID-19. Patient has not had symptoms associated with COVID-19. Concomitant medication included citalopram taken for Depression. The patient was taking unspecified concomitant medications for hypertension, chronic obstructive pulmonary disease (COPD) and ischaemic heart disease. The patient experienced death in Dec2020 (reported as in the evening of the 20Dec2020 or morning of 21Dec2020). Specifically, it was reported that the patient had the first dose of the vaccine at around 15:45 on 20Dec2020 and was observed for 15 minutes after with no side effects, the patient then left the site with family member. He was well that evening, he lived alone but spoke on the phone in the evening after twell. On the 21Dec2020, after went to check on him and he was found in his bed passed away. When seeing the body, it was assumed that he had passed away in the evening of the 20Dec2020 or morning of 21Dec2020. Although unlikely, it was less than 24 hours after taking the vaccine. Patient has not tested positive for COVID-19 since having the vaccine. The patient was found dead in his flat the next day on 21Dec2020 by next of kin. He was dropped of home by family after the vaccination, he spoke to his family on the night after having the vaccination and told them he was feeling fine and was going to bed. He did not respond to telephone calls the next day (on Monday 21Dec2020) so the family went over to his flat and found he had passed away. The patient was registered at another surgery. Screening questions were asked, no contra indication found. 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: death

VAERS ID: <u>934881</u> (history) Vaccinated: 0000-00-00 Version 2.0 0000-00-00 Form: Onset: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-01-11

Location: Foreign

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

Purchased by: ? Administered by: Other Symptoms: Death, Palliative care, Pyrexia

SMQs:, Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Malignancy related therapeutic and diagnostic procedures (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: Dementia **Preexisting Conditions:** Allergies: Diagnostic Lab Data:

CDC Split Type: SEPFIZER INC2021009471

Write-up: Fever; This is a spontaneous report from a newsletter, from a contactable consumer (profession unspecified). Regulatory authority report number was not provided. An elderly female patient received bnt162b2 (COMIRNATY, Solution for injection, lot number and expiration date not provided), viá an unspecified route of administration on an unspecified date at single dose for COVID-19 immunization. Medical history included ongoing dementia in a palliative state. The patient"s concomitant medications were not reported. The verbatim narrative was reported as follows: "Status report on suspected side effects from vaccination against covid-19. The report on the second death was received on 05Jan2020. It concerns an elderly female with dementia in a palliative state. The female was vaccinated with Comirnaty, had fever on an unspecified date and passed away three days later. The information in the report is very brief and will seek additional information from the reporter. Currently, has no information on the female"s confirmed cause of death and there is no established causality with the vaccine." The patient died on an unspecified date. It was not reported if an autopsy was performed. The outcome of the event was fatal. No follow-up attempts are possible; information about LOT/batch number cannot be obtained.; Reported Cause(s) of Death: had fever and passed away three days later

VAERS ID: <u>934882 (history)</u> Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-01-11

Location: Foreign

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

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

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: Heart attack

Allergies:

Diagnostic Lab Data:

CDC Split Type: SIPFIZER INC2021009992

Write-up: heart attack; This is a spontaneous report from a non-contactable consumer (discovered on news page and heard in news). An elderly female patient (elderly than 90-year old from home for elderly) received bnt162b2 (COMIRNATY) via unspecified route of administration on unspecified date at single dose for COVID-19 immunization (other details not reported). Medical history included heart attack. Concomitant medications were not reported. patient experienced heart attack six hours after vaccination that obviously occurred after repeated heart attack. It was stated that heart attack was not connected to the vaccination. There was no acute allergic reaction. Case was further investigated (independent committee) and confirmed the vaccination was not reason of death. Patient died from heart attack, it was unknown if autopsy was done. Information on batch number has been request.; Sender's Comments: Fatal heart attack is not related to bnt162b2 use; the advanced old patient had pre-existing medical condition including previous episode of heart attack thus the underlying cardiovascular provided an explanation for the event onset.; Reported Cause(s) of Death: heart attack

https://medalerts.org/vaersdb/findfield.php

VAERS ID: 936170 (history) Vaccinated: 2020-12-31 Version 2.0 Onset: 2020-12-31 Form: Age: Days after

Λ vaccination: Sex: Male

Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-12

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EJ1688 / UNK

Administered by: Other Purchased by: ?

Symptoms: Circulatory collapse, Death, Myocardial infarction

SMQs:, Anaphylactic reaction (narrow), Myocardial infarction (narrow), 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), Hypersensitivity (narrow)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2020-12-31 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: ;; BETNOVATE;;;;;;

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Acute myocardial infarction; Basal cell carcinoma; Cataract; Chronic kidney disease; Colitis ischaemic; Debridement (Arthroscopic debridement of patella); Essential hypertension; Mitral valve incompetence; Myocardial ischaemia; Neoplasm malignant (other/unspecified site); Transurethral bladder resection; Comments: Patient has not had symptoms associated with COVID-19. Patient has not been tested/or has had an inconclusive test for COVID-19. Patient is not enrolled in clinical trial.

Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021012711

Write-up: Myocardial infarct; Circulatory collapse; This is a spontaneous report from a contactable physician from the regulatory authority. The regulatory authority report number is GB-MHRA-ADR 24553112 and GB-MHRA-WEBCOVID-20210104143047. An 82-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; Lot number: EJ1688), via an unspecified route of administration, on 31Dec2020 at a single dose for COVID-19 vaccination. Medical history included mitral valve incompetence from 08May2020, myocardial ischaemia from 07May2020, acute myocardial infarction from 07May2020, cataract from 29Nov2019, chronic kidney disease from 03Oct2013, colitis ischaemic from 23May2013, basal cell carcinoma from 20Apr2012, transurethral bladder resection on 06Sep2005, neoplasm malignant (other/unspecified site) from 16Aug2005, debridement (arthroscopic debridement of patella) on 12Jan2005, and essential hypertension from 2005. The patient had not had symptoms associated with COVID-19. The patient was not been tested/or had an inconclusive test for COVID-19. The patient was not enrolled in clinical trial. Concomitant medications included allopurinol (MANUFACTURER UNKNOWN), atorvastatin (MANUFACTURER UNKNOWN), betamethasone valerate (BETNOVATE), bisoproloi (MANUFACTURER UNKNOWN), furosemide (MANUFACTURER UNKNOWN), glyceryl trinitrate (MANUFACTURER UNKNOWN), loperamide (MANUFACTURER UNKNOWN), omeprazole (MANUFACTURER UNKNOWN), phenoxymethylpenicillin (MANUFACTURER UNKNOWN), and ramipril (MANUFACTURER UNKNOWN). The patient experienced myocardial infarct and circulatory collapse on 31Dec2020. The event, myocardial infarct, was reported as fatal. It was reported that the patient collapsed at home the evening after vaccination. The clinical outcome of myocardial infarct was fatal and of circulatory collapse was not recovered. The patient died on 31Dec2020. The cause of death was reported as myocardial infarct. It was unknown if an autopsy was performed. No followup attempts are possible. No further information is expected.; Reported Cause(s) of Death: Myocardial infarct

VAERS ID: 937724 (history) Vaccinated: 0000-00-00 0000-00-00 Form: Version 2.0 Onset: Age: Submitted: 0000-00-00 Entered: 2021-01-12 Sex: Unknown

Location: Foreign

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

Administered by: Other Purchased by: ?

Symptoms: Autopsy, Death

SMQs:

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:

CDC Split Type: DEPFIZER INC2021006738

Write-up: Death in connection with the vaccination and/or COVID-19 disease/positivity; Death in connection with the vaccination and/or COVID-19 disease/positivity; This is a spontaneous report from a contactable physician. This physician reported similar events for two patients. This is the first of two reports. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration, on an unspecified date at single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On an unspecified date, there was death in connection with the vaccination and/or COVID-19 disease/positivity. It was reported that: two deceased were autopsied, whose death was in connection with the vaccination or COVID-19 disease/positivity. The clinical outcome of death in connection with the vaccination and/or COVID-19 disease/positivity was fatal. The patient died on an unspecified date. The cause of death was reported as: death in connection with the vaccination and/or COVID-19 disease/positivity. An autopsy was performed, and the results were not reported.; Sender's Comments: The association between the event lack of effect (death was in connection with the vaccination or COVID-19 disease positivity) with BNT162b2 can not be fully excluded given the limited information. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.,Linked Report(s): DE-PFIZER INC-2021006905 same reporter, same product, same event, different patient; Reported Cause(s) of Death: Death in connection with the vaccination and/or COVID-19 disease/positivity; Death in connection with the vaccination and/or COVID-19 disease/positivity

VAERS ID: <u>937998</u> (history) 2020-12-17 Vaccinated: Form: Version 2.0 Onset: 2020-12-18

Days after Age: 1 vaccination: Sex: Unknown

Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-12

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

Administered by: Other Purchased by: ?

Symptoms: Condition aggravated, Death, General physical health deterioration, Malaise, Tachycardia, Urinary tract infection

SMQs:, Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Dehydration

(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: MATRIFEN; ; ; ; **Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Chronic kidney disease; Dementia Alzheimer"s type; Frailty; Recurrent urinary tract infection Allergies:

Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021009353

Write-up: Tachycardia; Unwell; This is a spontaneous report from a contactable physician downloaded from the Regulatory Authority-WEB GB-MHRA-EYC 00235994, Safety Report Unique Identifier GB-MHRA-ADR 24545770, received from Regulatory Authority. An 85-years-old patient of an unspecified gender received bnt162b2 (BNT162B2) (batch/lot number unknown), intramuscular on 17Dec2020 at single dose for covid-19 immunisation. Medical history included chronic kidney disease, frailty, recurrent urinary tract infection, dementia alzheimer"s type, all from an unknown date and unknown if ongoing. Concomitant medication included fentanyl (MATRIFEN), folic acid (FOLIC ACID), colecalciferol (COLECALCIFEROL), omeprazole (OMEPRAZOLE), citalopram (CITALOPRAM), paracetamol (PARACETAMOL), all taken from unknown date for unspecified indication. The patient experienced unwell and tachycardia on 18Dec2020. The events were medically significant. The event outcome was unknown. Detail clinical course was provided as patient received vaccine on 17Dec2020, the following day she seemed unwell and tachycardic. No evidence of allergy, fever or coronavirus symptoms. Patient deteriorated over the weekend and passed away 3 days later. Cause of death on certificate was probable urinary tract infection. No follow-up attempts are possible, information on batch number cannot be obtained.; Reported Cause(s) of Death: urinary tract infection

VAERS ID: <u>938038</u> (history) Vaccinated: 2021-01-04 Form: Version 2.0 2021-01-04 Onset: Days after Age: vaccination: Sex: Female

Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-12

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

Administered by: Other Purchased by: ?

Symptoms: <u>Cardiopulmonary failure</u>, <u>Death</u>
SMQs:, Cardiac failure (narrow), Acute central respiratory depression (broad), Respiratory failure (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-04 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: Communication disorder NOS; Frailty; Memory impairment; Mobility decreased

Preexisting Conditions: Medical History/Concurrent Conditions: Vascular dementia

Diagnostic Lab Data: Test Date: 202012; Test Name: COVID-19 virus test; Result Unstructured Data: Test Result:Negative; Test Date: 202012; Test Name: COVID-19 virus test; Result Unstructured Data: Test Result:Negative; Test Date: 20201218; Test Name: COVID-19 virus test; Result Unstructured Data: Test Result:Negative

CDC Split Type: GBPFIZER INC2021012517

Write-up: Acute cardio-respiratory event and died a few hours later; This is a spontaneous report received from a contactable physician by Pfizer from the Regulatory Agency, The regulatory authority report number is GB-MHRA-WEBCOVID-20210107093111. Safety Report Unique Identifier GB-MHRA-ADR 24565959. An 84-yearsold female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) at single dose, on 04Jan2021, for COVID-19 immunisation. Patient was elderly and frail and gradually declining in mobility, communication and memory over the last 12 months. Relevant medical history also included vascular dementia form an unspecified date and unknown if ongoing. Concomitant medications were unknown. Patient was not enrolled in clinical trial. COVID-19 virus test was performed twice on an unspecified date, in Dec2020 and on 18Dec2020 and the results were negative. On 04Jan2021, at 06:00 PM, the patient experienced acute cardio-respiratory event and died a few hours later. It was unknown if autopsy was done. Since the vaccination, the patient has not been tested for COVID-19. Patient did not have symptoms associated with COVID-19. The patient was kept comfortable in the nursing home in these last few hours. There was no way to know whether the vaccine was to blame at all, it was unlikely. No follow-up attempts are possible, information about lot number cannot be obtained.; Reported Cause(s) of Death: Cardiorespiratory failure

VAERS ID: <u>939332</u> (<u>history</u>) 2020-12-30 Vaccinated: Form: Version 2.0 Onset: 2021-01-01

Days after Age: 2 vaccination: Sex: Female

Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-13

| Vaccination / Manufacturer                                     | Lot / Dose   | Site / Route |
|--|--------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EJ1688 / UNK | -/-          |

Administered by: Other Purchased by: ? Symptoms: Death, Malaise, Vomiting

SMQs:, Acute pancreatitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-03 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:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Dementia Alzheimer"s type (Vascular and Alzheimer"s mixed dementia); Fluid intake reduced (patient known to not be eating or drinking); General physical health deterioration (Patient known to be declining); Oral intake reduced (patient known to not be eating or drinking); Vascular dementia (advanced dementia)

Allergies:

Diagnostic Lab Data: Test Date: 20201227; Test Name: COVID-19 virus test; Test Result: Negative

CDC Split Type: GBPFIZER INC2021012468

Write-up: Death; Malaise; Vomiting; This is a spontaneous report received from a contactable physician from the Regulatory Agency (RA). The Regulatory Authority report number is GB-MHRA-WEBCOVID-20210105172532, Safety Report Unique Identifier GB-MHRA-ADR 24558660. An 81-year-old female patient received bnt162b2 (BNT162B2) (lot# EJ1688), via an unspecified route of administration, on 30Dec2020, at single dose, for COVID-19 immunisation. Medical history included vascular dementia (advanced dementia), dementia Alzheimer"s type (vascular and Alzheimer"s mixed dementia), oral intake reduced (patient known to not be eating or drinking), fluid intake reduced, (patient known to not be eating or drinking), general physical health deterioration (patient known to be declining); all from an unknown date and unknown if ongoing. Concomitant medications were not reported. The patient experienced death on 03Jan2021, malaise on 01Jan2021 with fatal outcome, vomiting on 01Jan2021 with fatal outcome. It was reported that 48 hours after vaccination the patient became unwell, vomited and then died on 03Jan2021. The patient underwent lab tests and procedures which included COVID-19 virus test: negative on 27Dec2020. Patient has been not tested positive for COVID-19 since having the vaccine. It was not reported if an autopsy was performed. It was not known whether vaccine caused reaction. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Malaise; Vomiting; Death

VAERS ID: <u>939334</u> (<u>history</u>) Vaccinated: 2020-12-30 Version 2.0 Form: 2021-01-02

Age: Days after 3 vaccination: Male Sex:

Submitted: 0000-00-00 Location: Foreign 2021-01-13 Entered:

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EJ1688 / UNK

Purchased by: ? Administered by: Other

Symptoms: Death, Dyspnoea exertional, SARS-CoV-2 test negative SMQs:, Pulmonary hypertension (broad), COVID-19 (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-02 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:

Preexisting Conditions: Medical History/Concurrent Conditions: Basal cell carcinoma; Bowen's disease; Chronic kidney disease; Essential hypertension

Diagnostic Lab Data: Test Name: COVID-19 virus test; Result Unstructured Data: Test Result:No - Negative COVID-19 test

CDC Split Type: GBPFIZER INC2021012521

Write-up: breathless on exertion; This is a spontaneous report received from a contactable other health professional received from the United Kingdom"s Medicines and Healthcare products Regulatory Agency (UK-MHRA). The regulatory authority report number is GB-MHRA-ADR 24561910, other case identifier number: GB-MHRA-WEBCOVID-20210106094618. An 80-years-old male patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Batch/lot no: EJ1688), via an unspecified route of administration on 30Dec2020 single dose for covid-19 immunisation. Medical history included Bowen's disease, basal cell carcinoma, chronic kidney disease and essential hypertension, all unknown if ongoing. Concomitant medication included alfacalcidol (unknown manufacturer), amlodipine (unknown manufacturer), atorvastatin (unknown manufacturer), clopidogrel (unknown manufacturer), prazosin (unknown manufacturer), sodium bicarbonate (unknown manufacturer), folic acid (unknown manufacturer), furosemide (unknown manufacturer). The patient experienced breathless on exertion on 02Jan2021. The patient died on 02Jan2021 due to the event. The patient underwent lab tests and procedures which included sars-cov-2 test: no - negative covid-19 test on unknown date. It was not reported if an autopsy was performed. No follow-up attempts possible. No further information expected.; Reported Cause(s) of Death: Dyspnoea exertional

VAERS ID: <u>940902</u> (<u>history</u>) Vaccinated: 2021-01-08 Form: Version 2.0 Onset: 2021-01-08

Days after Age: 0 vaccination: Unknown

Sex: 0000-00-00 Submitted: Location: Foreign Entered: 2021-01-13

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EJ6796 / 1 | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-01-08 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:** 

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: DEPFIZER INC2021016328

Write-up: Death 2 hours after vaccination in a retirement home; This is a spontaneous report from a contactable physician. A patient of unspecified age and gender received BNT162B2 (COMIRNATY; PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EJ6796), via an unspecified route of administration on 08Jan2021 as first single dose for covid-19 immunization. The patient"s medical history and concomitant medications were not reported. On 08Jan2021, at 19:24, death 2 hours after vaccination in a retirement home was noted. The patient died on 08Jan2021. It was not reported if an autopsy was performed.; Sender's Comments: The limited information provided in this report does not allow a full assessment of the case. The event "death" is assessed as related to the suspect drug per company guidance. This case will be reassessed when additional information, particularly the clinical course before death, complete medical history and concomitant medication and autopsy report, becomes available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators, as appropriate.; Reported Cause(s) of Death: Death 2 hours after vaccination in a retirement home

VAERS ID: <u>940935</u> (<u>history</u>) Vaccinated: 2021-01-05 Form: Version 2.0 Onset: 2021-01-05 Davs after Age:

Sex: Female vaccination: Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-13

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH BJ1688 / UNK

Administered by: Other Purchased by: ? Symptoms: Death, SARS-CoV-2 test negative, Vomiting

SMQs:, Acute pancreatitis (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), COVID-19 (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-07 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 **Current Illness:** 

Preexisting Conditions: Comments: Patient has not had symptoms associated with COVID-19 Patient is not enrolled in clinical trial

https://medalerts.org/vaersdb/findfield.php

Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Result Unstructured Data: Test Result:no-negative COVID-19 test

CDC Split Type: GBPFIZER INC2021017066

Write-up: Death; Vomiting; This is a spontaneous report from a contactable other health professional from the Regulatory Agency. The regulatory authority report number is GB-MHRA-ADR 24573192. An elderly female patient received the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: BJ1688 and EJ1688; as reported), via an unspecified route of administration on 05Jan2021 at 12:26 at a single dose for COVID-19 immunization. The patient"s medical history and concomitant medications were not reported. The patient had not had symptoms associated with COVID-19; and was not enrolled in the clinical trial. On 05Jan2021 at 12:51, the patient experienced vomiting (non-serious); 25 minutes post vaccine (had further vomiting episodes). On 07Jan2021 at 01:00, the patient experienced death; which caused death, and was medically significant. The patient had not tested positive for COVID-19 since having the vaccine. The patient underwent lab tests and procedures which included COVID-19 virus test: no-negative COVID-19 test on an unspecified date. The clinical outcome of the event, vomiting, was unknown. The clinical outcome of the event, death, was fatal. The patient died on 07Jan2021 at 01:00 due to unknown cause of death. An autopsy was not performed. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Death

VAERS ID: 940940 (history) Vaccinated: 2021-01-03 Form: Version 2.0 Onset: 2021-01-01 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-01-13

Location: Foreign

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EK4175 / 1 | -/-          |

Administered by: Other Purchased by: ?

Symptoms: <u>Cardiac arrest</u>, <u>Cardio-respiratory arrest</u>, <u>Resuscitation</u>
SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (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), Respiratory failure (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-01 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** 

Preexisting Conditions: Medical History/Concurrent Conditions: Cardiac disorder (intended for valve replacement surgery); Diabetes mellitus; Mobility decreased

Diagnostic Lab Data: Test Name: monitor; Result Unstructured Data: Test Result:asystole; Test Name: heart sounds; Result Unstructured Data: Test Result:without heart sounds; Test Name: pupils; Result Unstructured Data: Test Result:pupils do not respond to light

CDC Split Type: ILPFIZER INC2021019507

Write-up: heart pain; cardiac and respiratory arrest; cardiac and respiratory arrest; This is a spontaneous report from a contactable consumer or other non hcp received via regulatory authority. This consumer reported different fatal events for four patients. This is the first of four reports. A 63-year-old male patient received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK4175) via an unspecified route of administration on 03Jan2021 at single dose for covid-19 immunisation. Medical history included Nursing background, cardiac, intended for valve replacement surgery, diabetes mellitus (DM). The patient"s concomitant medications were not reported. The patient was vaccinated on 03Jan2021 with the first dose. From the moment of the vaccine he complained about heart pain. Cardiopulmonary resuscitation (CPR) was performed by the persons on call without an electric shock, emergency services arrived after 5 minutes, resuscitation continued asystole on the monitor, received 4 doses of adrenaline IV, respiration through mask and ambu. After 20 minutes of resuscitation pupils do not respond to light, without heart sounds. The patient died from cardiac and respiratory arrest in Jan2021. It was not reported if an autopsy was performed. The outcome of event heart pain was unknown.; Sender"s Comments: Linked Report(s): IL-PFIZER INC-2021019632 Same reporter, same product, different patient/events.;IL-PFIZER INC-2021019633 Same reporter, same product, different patient/events.;IL-PFIZER INC-2021019634 Same reporter, same product, different patient/events.; Reported Cause(s) of Death: cardiac and respiratory arrest; cardiac and respiratory arrest

**VAERS ID:** 940941 (history) Vaccinated: 2021-01-07 Form: Version 2.0 Onset: 2021-01-08

Davs after Age: Sex: Male vaccination:

Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-13

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EK4238 / 1 | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death, Feeling abnormal

SMQs:, Dementia (broad) Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-08 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** 

Preexisting Conditions: Medical History/Concurrent Conditions: Cancer; Diabetes; Hypercholesterolemia; Osteoarthrosis

Allergies:

Diagnostic Lab Data:

CDC Split Type: ILPFIZER INC2021019634

Write-up: felt bad; This is a spontaneous report from a contactable consumer. This consumer reported different fatal events for four patients. This is the fourth of four reports. A 71-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number EK4238) via an unspecified route of administration on 07Jan2021 at a single dose for COVID-19 immunisation. Medical history included oncological patient, diabetes, hypercholesterolemia, osteoarthrosis. Concomitant medications were not reported. The patient went out for work a day after he received the vaccine, he felt bad on 08Jan2021 and MDA was called, shortly afterwards his death was determined by MDA. The date of death was on 08Jan2021. The cause of death was felt bad. The outcome of event was fatal. It was unknown if an autopsy was performed.; Sender's Comments: Linked Report(s): IL-PFIZER INC-2021019507 Same reporter, same product, different patient/events; Reported Cause(s) of Death: felt bad

 VAERS ID: 941174 (history)
 Vaccinated:
 2020-12-24

 Form:
 Version 2.0
 Onset:
 2020-12-26

Age: Days after Sex: Male vaccination: 2

**Location:** Foreign **Submitted:** 0000-00-00 **Entered:** 2021-01-13

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

Administered by: Other Purchased by: ?

Symptoms: Abdominal pain, Blood pressure decreased, Death, Heart rate increased, Restlessness

**SMQs:**, Anaphylactic reaction (broad), Acute pancreatitis (broad), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Arrhythmia related investigations, signs and symptoms (broad), Retroperitoneal fibrosis (broad), Dementia (broad), Akathisia (broad), Noninfectious encephalopathy/delirium (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Hypoglycaemia (broad), Dehydration (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-29 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: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Dementia; Urinary tract infection

Allergies

Diagnostic Lab Data: Test Date: 20201226; Test Name: blood pressure; Result Unstructured Data: Test Result:decreased; Test Date: 20201226; Test Name: pulse; Result Unstructured Data: Test Result:increased; Test Date: 20201227; Test Name: home doctor examination; Result Unstructured Data: Test Result:stable with persistent sensitivity to pressure of; Comments: stable with persistent sensitivity to pressure of the abdomen

CDC Split Type: CHPFIZER INC2021017201

Write-up: first death case due to Covid-19 vaccination in this country/deterioration in the general condition; stomach was hard and caused pain under pressure; Urethral and abdominal pain; abdominal pain/stomach was hard and caused pain under pressure; restless; his blood pressure dropped; pulse increased; This case was originally submitted under WWID AT-PFIZER INC-2020519756. Upon follow-up, reporter with regulatory authority was considered as primary reporter; as a result of this update case is being resubmitted under new WWID CH-PFIZER INC- 2021017201. As a consequence, this follow-up report will be indicated as an initial report. This is a spontaneous report from six contactable consumers and a contactable other health professional. A 91-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; COMIRNATY), via an unspecified route of administration on 24Dec2020 at single dose for COVID-19 vaccination. Medical history included dementia and urinary tract infection from an unknown date and unknown if ongoing. The patient"s concomitant medications were not reported. The resident had previously reacted negatively to a flu vaccine and therefore no further vaccinations were recommended. The patient experienced urethral and abdominal pain, restless, his blood pressure dropped, pulse increased all on 26Dec2020, deterioration in the general condition and death on 29Dec2020. On Christmas Eve, the residents of a nursing home for dementia were vaccinated with the Pfizer/Biontech vaccine. The affected, otherwise healthy resident, suffered from pain in the urethra and abdomen two days later. The examination by the home doctor revealed a decrease in blood pressure and an increase in the pulse on 26Dec2020. At the last consultation on Sunday evening, 27Dec2020, the patient was stable with persistent sensitivity to pressure of the abdomen. The family doctor in charge examined the patient one last time on Sunday evening, 27Dec2020. He was calm, but his stomach was hard and caused pain under pressure. The following day, the management of the institution did not report back to the home doctor. On the morning of 29Dec2020, the nursing home informed the doctor about a deterioration of the general condition. By the time the doctor was called back the same morning, the patient had already died, vaccinated on Christmas Eve and dead five days later. The patient underwent lab tests and procedures also included home doctor examination: condition was stable with persistent sensitivity to pressure of the abdomen on 27Dec2020. The patient died on 29Dec2020, which was the first death case due to COVID-19 vaccination in this country. It was not reported if an autopsy was performed. The news of the death of a 91-year-old person after he was vaccinated against COVID-19 is circulating on social media channels and information platforms. Investigations by the health authorities have shown that due to the medical history and the course of the disease, a connection between death and the COVID-19 vaccination is unlikely. Neither the medical history nor the acute course of the disease suggest a direct causal connection between the COVID-19 vaccination and death. The comprehensive information available indicates the pre-existing diseases as a natural cause of death. This was also noted on the death certificate. It soon became clear that the home physician, who had implied a connection between vaccination and the death of his elderly patient, was himself. Quoted from the medical record and message spread by email, it was possibly overlooked that patient had symptoms of a urinary tract infection and did not prescribe antibiotics. Event occurred in a country different from that of the reporter. This may be a duplicate report if another reporter from the country where the event occurred has submitted the same information to his/her local agency. Information on the Lot/Batch number has been requested. Follow-up (05Jan2021): New information received from Pfizer Employee, who sent a follow-up from another source included medical history urinary tract infection and cause of death updated. Information on the Lot/Batch number has been requested. Follow-up (08Jan2021): New information received clarified that Reporter with regulatory authority is to be considered as primary reporter. Information on the Lot/Batch number has been requested.; Sender"s Comments: Based on the information available, a possible contributory role of the suspect products cannot be excluded for the reported events due to temporal association. However patient old age of 91 years and other underlying medical conditions could have played a contributory role. Further information including autopsy reports would be helpful for a meaningful medical assessment The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to Regulatory Authorities, Ethics Committees and Investigators as appropriate.; Reported Cause(s) of Death: first death case due to Covid-19 vaccination in this country/deterioration in the general condition

 VAERS ID: 944114 (history)
 Vaccinated:
 2020-12-19

 Form:
 Version 2.0
 Onset:
 2020-12-29

Age: Days after Sex: Male vaccination:

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-14

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EJ0553 / UNK - / -

Administered by: Other Purchased by: ?

Symptoms: Death, Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad) Life Threatening? No

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-29
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: ; LANSOPRAZOL;

**Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Ankle swelling (slight ankle swelling awaiting head ct scan and bloods.); Cerebrovascular accident (previous CVA.); Cholesterol; Memory impairment (Recent memory problems.); Oesophagitis; Waldenstrom"s macroglobulinemia; Comments: Patient has not had symptoms associated with COVID-19 Patient has not been tested/or has had an inconclusive test for COVID-19. Patient is not enrolled in clinical trial

Allergies:

Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021016664

Write-up: Sudden death; This is a spontaneous report from a contactable physician from the regulatory authority. The regulatory authority report number is GB-MHRA-ADR 24556755. An 86-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EJ0553), via an unspecified route of administration on 19Dec2020 as single dose for COVID-19 immunization. Medical history included Waldenstrom's macroglobulinemia for Waldenstrom's macroglobulinaemia, memory impairment, with recent memory problems, cerebrovascular accident, with previous CVA, joint swelling, reported as slight ankle swelling awaiting head CT scan and bloods, oesophagitis, and cholesterol, all from an unknown date and unknown if ongoing. Concomitant medication included acetylsalicylic acid (MANUFACTURER UNKNOWN) for Waldenstrom's macroglobulinaemia, lansoprazol (MANUFACTURER UNKNOWN) for oesophagitis, simvastatin (MANUFACTURER UNKNOWN) for blood cholesterol. The patient had sudden death on 29Dec2020. The patient died on 29Dec2020. It was not reported if an autopsy was performed. The reporter did not think the COVID vaccination caused the patients death; It did not appear to be related. The patient was seen by the physician on the 24th (not otherwise specified), and was fine. The patients son also saw the patient on the 28th (not otherwise specified) and also fine with no side effects from the jab. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the information currently provided, the company considers the patient death is unrelated to the vaccine use; the advance old patient having multiple pre-existing medical conditions including Waldenstrom's macroglobulinaemia and cerebrovascular accident, which more likely led the patient to sudden death.; Reported Cause(s) of Death: Sudden death unexplained

 VAERS ID: 944118 (history)
 Vaccinated: 0000-00-00

 Form:
 Version 2.0
 Onset: 2020-12-27

 Age:
 Submitted: 0000-00-00

 Sex:
 Unknown
 Entered: 2021-01-14

Location: Foreign

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PEIZER-BIONTECH)) / PEIZER/BIONTECH | - / UNK    | -/-          |

Administered by: Other Purchased by: ?

Symptoms: COVID-19, Death, SARS-CoV-2 test positive

SMQs:, Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (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:

Previous Vaccinations:
Other Medications:

Current Illness:

**Preexisting Conditions:** 

Allergies

Diagnostic Lab Data: Test Name: COVID-19 virus test; Result Unstructured Data: Test Result: Yes - Positive COVID-19 test

CDC Split Type: GBPFIZER INC2021016254

Write-up: SARS-CoV-2 infection; SARS-CoV-2 infection; This is a spontaneous report from a contactable physician received by Regulatory Agency . The regulatory authority report number is GB-MHRA-ADR 24558365 & GB-MHRA-WEBCOVID-20210105143744. A patient of unspecified age and gender received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on an unspecified date at a single dose for COVID-19 immunization. The patient is medical history and concomitant medications were not reported. Patient was not enrolled in clinical trial. The patient experienced SARS-coV-2 infection 27Dec2020. The patient underwent lab tests and procedures which included COVID-19 virus test: yes - positive covid-19 test on an unspecified date. The clinical outcome of SARS-coV-2 infection was fatal. The patient died on an unspecified date. An autopsy was not performed. No follow-up attempts are possible; information about batch/lot number cannot be obtained.; Reported Cause(s) of Death: SARS-CoV-2 infection

VAERS ID: <u>944121</u> (<u>history</u>) Vaccinated: 2020-12-23 Form: Version 2.0 Onset: 2020-12-31

Age: Days after vaccination: Sex: Male

Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-14

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

Administered by: Other Purchased by: ?

Symptoms: Cardiac arrest, Death, SARS-CoV-2 test negative

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (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), Respiratory failure (broad), COVID-19 (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-31 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: Dementia

Preexisting Conditions: Medical History/Concurrent Conditions: Cardiac pacemaker insertion; Comments: Patient has not had symptoms associated with COVID-19 Unsure if patient is enrolled in clinical trial

Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Result Unstructured Data: Test Result:No - Negative COVID-19 test

CDC Split Type: GBPFIZER INC2021016800

Write-up: Cardiac arrest; This is a spontaneous report from a contactable physician. This is a report received from the MHRA. Regulatory authority report number GB-MHRA-WEBCOVID-20210105171610, Safety Report Unique Identifier GB-MHRA-ADR 24558665. A male patient of an unspecified age received BNT162B2 (Pfizer-Biontech Covid-19 Vaccine), via an unspecified route of administration on 23Dec2020, at single dose for covid-19 vaccination. Medical history included ongoing dementia, and cardiac pacemaker insertion on an unknown date. Patient has not had symptoms associated with COVID-19. Unsure if patient was enrolled in clinical trial. The patient"s concomitant medications were not reported. The patient experienced cardiac arrest on 31Dec2020. Had spontaneous cardiac arrest 9 days (to be clarified) after vaccination doubtful implicated but new vaccine of course. Patient had not tested positive for COVID-19 since having the vaccine. The patient underwent lab tests and procedures which included COVID-19 virus test: no - negative covid-19 test on an unspecified date. The patient died of cardiac arrest on 31Dec2020. It was not reported if an autopsy was performed. Information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Cardiac arrest

VAERS ID: <u>944154</u> (history) Vaccinated: 2021-01-04 Form: Version 2.0 Onset: 2021-01-01 Submitted: 0000-00-00 Age: Sex: Female Entered: 2021-01-14

Location: Foreign

| Vaccination / Manufacturer                            | Lot / Dose | Site / Route |
|---|------------|--------------|
| COVID19 (COVID19 (PEIZER-BIONTECH)) / PEIZER/BIONTECH | FK4238 / 1 | - / -        |

Administered by: Other Purchased by: ?

Symptoms: Cardiac arrest, Contusion, Death, Fall, Head injury, Resuscitation

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (broad), Haemorrhage terms (excl laboratory terms) (narrow), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Acute central respiratory depression (broad), Accidents and injuries (narrow), Cardiomyopathy (broad), Respiratory failure (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-01 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** 

Preexisting Conditions: Medical History/Concurrent Conditions: Asthma; Dementia; Depression; Gastrointestinal disorder; Heart failure; Living in nursing home

Diagnostic Lab Data: Test Date: 202101; Test Name: heart sounds; Result Unstructured Data: Test Result:asystole without heart sounds

CDC Split Type: ILPFIZER INC2021019632

Write-up: This is a spontaneous report from a contactable consumer. This consumer reported different fatal events for four patients. This is the second of four reports. An 82-year-old female patient in a nursing home received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE lot number: EK4238) via an unspecified route of administration on 04-Jan-2021 at a single dose for COVID-19 immunisation. Medical history included background of asthma, dementia, depression, gastrointestinal and heart failure. Concomitant medications were not reported. 4 Hours after the receipt of the vaccine, she was found in her room on the floor with a bruise on her forehead apparently from a fall, CPR was performed by nursing home staff. Staff performed CPR, asystole without heart sounds, CPR continued for 23 minutes without any change and death was declared. The events occurred in Jan 2021. The date of death was in Jan 2021. The outcome of events was fatal. It was unknown if an autopsy was performed. Sender"s Comments: Linked Report(s): IL-PFIZER INC-2021019507 Same reporter, same product, different patient/events; Reported Cause(s) of Death: was found in her room on the floor with a bruise on her forehead apparently from a fall; was found in her room on the floor with a bruise on her forehead apparently from a fall.

VAERS ID: <u>944155</u> (history) Vaccinated: 2020-12-21 Form: Version 2.0 Onset: 2020-12-24

Age: Days after 3 vaccination: Sex: Male

Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-14

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

Administered by: Other Purchased by: ?

Symptoms: Asthenia, Blood test, Death, Dyspnoea, Haemolytic anaemia, Hypotension, Jaundice, Lymphocytosis, Resuscitation, Tremor

SMQs:, Cholestasis and jaundice of hepatic origin (narrow), Haemolytic disorders (narrow), Anaphylactic reaction (narrow), Acute pancreatitis (broad), Neuroleptic malignant syndrome (broad), Systemic lupus erythematosus (broad), Parkinson-like events (broad), Acute central respiratory depression (broad), Biliary system related investigations, signs and symptoms (narrow), Biliary tract disorders (narrow), Pulmonary hypertension (broad), Guillain-Barre syndrome (broad), Noninfectious encephalopathy/delirium (broad), Cardiomyopathy (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Hypoglycaemia (broad), Dehydration (broad), Hypokalaemia (broad), Immune-mediated/autoimmune disorders (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? Yes, ? days

Extended hospital stay? No

Previous Vaccinations:

Other Medications:

**Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Blood pressure abnormal (treated with nifedipine and TRITACE COMP); Drug hypersensitivity; Hyperlipidemia (treated with statins); Keratitis; Prostate cancer; Prostatectomy

Diagnostic Lab Data: Test Name: blood pressure; Result Unstructured Data: Test Result:low; Test Date: 20201228; Test Name: blood tests; Result Unstructured Data: Test Result:unknown results

CDC Split Type: ILPFIZER INC2021019633

Write-up: hemolytic anemia; reduced air entrance; passed away; low blood pressure; jaundice appeared on the whole body with lymphocytosis; jaundice appeared on the whole body with lymphocytosis; shortness of breath in mild efforts; weakness which expressed by shortness of breath in mild efforts; hands tremor; shortness of breath; This is a spontaneous report from a contactable consumer received via regulatory authority. This consumer reported different fatal events for four patients. This is the third of four reports. A 72-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE; lot number was not specified) via an unspecified route of administration on 21Dec2020 at a single dose for COVID-19 immunisation. Medical history included Kerattis, prostatectomy other, blood pressure problems (treated with nifedipine and hydrochlorothiazide/ramipril (TRITACE COMP)), hyperlipidemia (treated with statins), oncological patient-underwent radical restriction of the prostate, and sensitivity to phenylephrin. Concomitant medications were not reported. Three days after the vaccine (on 24Dec2020) he started to feel shortness of breath, arrived for hospitalization 10 days after vaccination. Five days after vaccination (on 26Dec2020) he experienced weakness which expressed by shortness of breath in mild efforts, hands tremor. 6 days after vaccination (on 27Dec2020) jaundice appeared on the whole body with lymphocytosis. On the day after, he referred to the physician and blood tests were sent. He was hospitalized following diagnosis of hemolytic anemia. He received two blood doses and steroids. Two hours before he passed away, low blood pressure was measured and reduced air entrance, CPR was performed without success and the patient passed away. The date of death was unknown. The cause of death was unknown lt was unknow if an autopsy was performed. The outcome of event unknown cause of death was fatal, and of other events was unknown. Information on the lot/batch number has been requested.; Sender"s Comments: Linked Report(s): IL-PFIZER INC-2021019507 Same reporter, same product, different patient/events; Reported Cause(s) of Death: passed away

**VAERS ID:** <u>945725</u> (history) Vaccinated: 2021-01-08 2021-01-10 Form: Version 2.0 Onset:

Age: Days after vaccination: Sex: Female

Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-15

| Vaccination / Manufacturer                                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (PEIZER-BIONTECH)) / PEIZER/BIONTECH | F.J1688 / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Cardiac failure, Death, Hypotension, Malaise, Mobility decreased, Oxygen saturation decreased, SARS-CoV-2 test negative, Speech disorder SMQs:, Cardiac failure (narrow), Anaphylactic reaction (broad), Neuroleptic malignant syndrome (broad), Dementia (broad), Parkinson-like events (broad), Acute central respiratory depression (broad), Psychosis and psychotic disorders (broad), Guillain-Barre syndrome (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Cardiomyopathy (broad), Respiratory failure (broad), Tendinopathies and ligament disorders (broad), Infective pneumonia (broad), Dehydration (broad), Hypokalaemia (broad), COVID-19 (broad)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-01-11

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:** 

Preexisting Conditions: Comments: The resident had got heart failure. The out of hours GP visited 10/01/2021 and advised she maybe poorly due to having the Covid-19 vaccine. The resident passed away at 7.20am this morning 11/01/2021 Patient has not had symptoms associated with COVID-19 Patient is not enrolled in clinical trial

Allergies:

Diagnostic Lab Data: Test Date: 20210110; Test Name: blood pressure; Result Unstructured Data: Test Result:low; Test Date: 20210110; Test Name: sats; Result Unstructured Data: Test Result:no-negative COVID-19 test CDC Split Type: GBPFIZER INC2021020138

Write-up: heart failure; Death; feeling sick; changes with speech and mobility; changes with speech and mobility; This is a spontaneous report from a contactable consumer received from the regulatory authority. The regulatory authority report number is GB-MHRA-WEBCOVID-20210111094207, Safety Report Unique Identifier: GB-MHRA-ADR 24577774. A 97-year-old female patient received the bnt162b2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot Number: EJ1688), via an unspecified route of administration on 08Jan2021 at a single dose for COVID-19 immunization. The patient's medical history and concomitant medications were not reported. On 10Jan2021, the patient experienced feeling sick (medically significant), changes with speech and mobility (speech disorder) (medically significant). On 11Jan2021, the patient experienced death (death, medically significant). On an unspecified date, the patient experienced heart failure (death, medically significant). The clinical course was reported as follows: "The resident had got heart failure." The patient was feeling sick on 10Jan2021 and was concerned as there were changes with speech and mobility. Emergency was called, and the ambulance arrived. It was stated the sats were low and blood pressure was low. The ambulance crew called for an out of hours general practitioner (GP) to come and see the patient. The out of hours general practitioner (GP) visited on 10Jan2021 and advised "she maybe poorly due to having the Covid-19 vaccine" that was administered on the 08Jan2021. The resident passed away at 07:20 on morning 11Jan2021. The patient had not tested positive for COVID-19 since having the vaccine. The patient had not had symptoms associated with COVID-19. The patient was not enrolled in a clinical trial. The patient underwent lab tests and procedures which included COVID-19 virus test: no-negative COVID-19 test on an unspecified date, oxygen saturation (sats): low on 10Jan2021, blood pressure: low on 10Jan2021. The clinical outcome of the event, death and heart failure. It was unkno

 VAERS ID: 947270 (history)
 Vaccinated:
 2021-01-07

 Form:
 Version 2.0
 Onset:
 2021-01-10

 Age:
 Days after
 2

 Sex:
 Female
 vaccination:

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-15

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

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-01-10 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:

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data:

CDC Split Type: BEPFIZER INC2021027057

Write-up: patient died while there were no other complaints at that time; This is a spontaneous report received from a contactable consumer (Pfizer colleague). A 99-year-old female patient received bnt162b2 (COMIRNATY), via an unspecified route of administration on 07Jan2021 at single dose for covid-19 immunization. The patient"s medical history and concomitant medications were not reported. The patient died 3 days after the vaccination while there were no other complaints at that time on 10Jan2021. The patient died on 10Jan2021. It was not reported if an autopsy was performed. The family assessed there was a causal relationship with the vaccine. Information on the lot/batch number has been requested.; Reported Cause(s) of Death: died 3 days after the vaccination while there were no other complaints

 VAERS ID: 947332 (history)
 Vaccinated:
 2020-12-31

 Form:
 Version 2.0
 Onset:
 2021-01-05

Age: Days after
Sex: Male vaccination:

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-15

| Vaccination / Manufacturer                                     | Lot / Dose    | Site / Route |
|--|---------------|--------------|
| COVID19: COVID19 (COVID19 (PEIZER-BIONTECH)) / PEIZER/BIONTECH | F.J1688 / UNK | -1-          |

5

Administered by: Other Purchased by: ? Symptoms: Death, SARS-CoV-2 test negative

SMQs:, COVID-19 (broad) Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-01-05 Days after onset: 0 Permanent Disability? No Recovered? No Office Visit? No

Office Visit? No ER Visit? No

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations:

 $\textbf{Other Medications:}\ ;;;;;; \texttt{FULTIUM D3};;;;; \texttt{LOTRIDERM};; \texttt{MAROL};;;; \texttt{SENNA} \ [\texttt{SENNA SPP.}]; \texttt{FLUCELVAX TETRA}$ 

Current Illness: Bedridden (Patient bed bound following a craniotomy for an acute subdural haematoma in 2019)

Preexisting Conditions: Medical History/Concurrent Conditions: Acute subdural haematoma; Craniotomy; Comments: Patient has not had symptoms associated with COVID-19 Patient is not enrolled in clinical trial

Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Test Result: Negative CDC Split Type: GBPFIZER INC2021016371

Write-up: Died in sleep; This is a spontaneous report from a contactable physician. This is a report received from the regulatory authority. Regulatory authority report number was GB-MHRA-ADR 24556999 with Safety Report Unique Identifier of GB-MHRA-WEBCOVID-20210105122200. An 85-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EJ1688), via an unspecified route of administration on 31Dec2020 as a single dose for COVID-19 vaccination. Medical history included craniotomy in 2019, acute subdural haematoma in 2019, and ongoing bedridden following a craniotomy for an acute subdural haematoma from 2019. The patient was not enrolled in clinical trial. Concomitant medications included atorvastatin (MANUFACTURER UNKNOWN), cetirizine (MANUFACTURER UNKNOWN), ferrous sulfate (MANUFACTURER UNKNOWN), finasteride (MANUFACTURER UNKNOWN), flucloxacillin (MANUFACTURER UNKNOWN), ielfolds stillate (MANUFACTURER UNKNOWN), introduction (MANUF had tested negative for COVID-19 since having the vaccine on an unknown date. There were no other reactions noted but the patient died in his sleep overnight on 05Jan2021. It was not reported if an autopsy was performed.; Reported Cause(s) of Death: Died in sleep

VAERS ID: <u>947357</u> (<u>history</u>) Vaccinated: 2020-12-19 Form: Version 2.0 Onset: 2021-01-03

Days after Age: 15 vaccination: Sex: Male 0000-00-00 Submitted: Location: Foreign Entered: 2021-01-15

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

Administered by: Other Purchased by: ?

Symptoms: Death, Dyspnoea, Fall, SARS-CoV-2 test positive

SMQs:, Anaphylactic reaction (broad), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Accidents and injuries (narrow),

Cardiomyopathy (broad), Infective pneumonia (broad), Opportunistic infections (broad), COVID-19 (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-03 Days after onset: 0 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: **Current Illness:** 

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: Test Date: 20210103; Test Name: COVID-19 virus test; Test Result: Positive ; Comments: Yes - Positive COVID-19 test CDC Split Type: GBPFIZER INC2021019774

Write-up: tested Covid positive/suspected COVID-19; tested Covid positive/suspected COVID-19; Shortness of breath; Fall; This is a spontaneous report from a contactable physician from the Regulatory Agency. The regulatory authority report number is GB-MHRA-WEBCOVID-20210106123053. An 81-year-old male patient received his first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on 19Dec2020 at single dose for COVID-19 immunisation. Medical history and concomitant medications were not reported. The patient experienced SARS-CoV-2 infection, shortness of breath on 03Jan2021. Reaction to vaccine is none. Patient was admitted with fall and on the floor for 5 hours on 03Jan2021. He was tested COVID positive on admission on 03Jan2021. So he tested positive about two weeks after first dose of Pfizer COVID-19 vaccine. Patient was suspected COVID-19 from 03Jan2021. The patient underwent lab test included COVID-19 virus test: Yes - Positive COVID-19 test (03Jan2021). Outcome of the events was fatal. The patient died on 03Jan2021. It was unknown if an autopsy was performed. Cause of death reported as SARS-CoV-2 infection/suspected COVID-19, shortness of breath and fall. No follow-up attempts possible. Information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: SARS-CoV-2 infection/suspected COVID-19; SARS-CoV-2 infection/suspected COVID-19; shortness of breath; Fall

VAERS ID: <u>947362</u> (history) Vaccinated: 2020-12-30 Form: Version 2.0 Onset: 2020-12-31

Age: Days after vaccination: Female Sex:

Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-15

| Vaccination / Manufacturer                                     | Lot / Dose   | Site / Route |
|--|--------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EJ1688 / UNK | -/-          |

Administered by: Other Purchased by: ? Symptoms: Death, Unresponsive to stimuli

SMQs:, Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Guillain-Barre syndrome (broad), Noninfectious encephalitis (broad), Noninfectious encephalopathy/delirium (broad), Noninfectious meningitis (broad), Hypotonic-hyporesponsive episode (broad), Hypoglycaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-01 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 with Lewy bodies; Frailty; Parkinson's disease

**Preexisting Conditions:** 

Allergies:

Diagnostic Lab Data: Test Date: 20201231; Test Name: examination; Result Unstructured Data: Test Result:no signs of sepsis; Comments: she had no signs of sepsis, she had no fever, her chest was clear and she had no difficulty breathing

CDC Split Type: GBPFIZER INC2021019690

Write-up: Death; Unresponsive to stimuli; This is a spontaneous report received from a contactable physician by Pfizer from the regulatory authority. The regulatory authority report number is GB-MHRA-WEBCOVID-20210106141652 and GB-MHRA-ADR 24563112. A 68-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number EJ1688) via unspecified route of administration on 30Dec2020 at single dose for COVID-19 vaccination. Patient has not had symptoms associated with COVID-19. Patient has not been tested/or has had an inconclusive test for COVID-19. Patient is not enrolled in clinical trial. Medical history included ongoing asthenia, ongoing Parkinson's disease and ongoing dementia with Lewy bodies. The patient experienced unresponsive to stimuli on 31Dec2020, death on 01Jan2021. The reporter described that this lady was extremely frail with a history of Parkinson's and Lewy Body dementia. However, on the day that she received the injection she was not acutely unwell. The reporter visited her the following day (31Dec2020) and found her unresponsive and clearly dying. On examination she had no signs of sepsis, she had no fever, her chest was clear and she had no difficulty breathing. She died the next day 01Jan2021. This could simply be a coincidence of course but this was a sudden change after receiving the vaccine. Patient has not tested positive for COVID-19 since having the vaccine. The patient died on 01Jan2021. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Death; Unresponsive to stimuli

 VAERS ID: 947363 (history)
 Vaccinated:
 2020-12-22

 Form:
 Version 2.0
 Onset:
 2020-12-31

Age: Days after 9
Sex: Male vaccination:

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-15

| Vaccination / Manufacturer                                     | Lot / Dose        | Site / Route |
|--|-------------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EJ0724-L456 / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Acidosis, Acute kidney injury, Blood creatine phosphokinase increased, Circulatory collapse, Death

SMQs:, Rhabdomyolysis/myopathy (broad), Acute renal failure (narrow), Anaphylactic reaction (narrow), Lactic acidosis (broad), Hyperglycaemia/new onset diabetes mellitus (broad), Neuroleptic malignant syndrome (broad), Myocardial infarction (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), Hypoglycaemic and neurogenic shock conditions (narrow), Tumour lysis syndrome (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Dehydration (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-31
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: Chronic kidney disease stage 3; Diabetic (well controlled for 8 years)

Preexisting Conditions: Medical History/Concurrent Conditions: Gout

Allergies

Diagnostic Lab Data: Test Date: 20201231; Test Name: Creatine kinase; Result Unstructured Data: Test Result:significantly raised.; Test Date: 20201231; Test Name: Blood glucose; Result Unstructured Data: Test Result:43

CDC Split Type: GBPFIZER INC2021019684

Write-up: Death; Acidosis; Acute kidney injury; Blood creatine phosphokinase increased; Circulatory collapse; This is a spontaneous report from a contactable physician. This is a report received from the Pfizer from the Regulatory Agency (RA). The regulatory authority report number is GB-MHRA-ADR 24563115. An 89-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot number EJ0724-L456), via an unspecified route of administration on 22Dec2020, as single dose for covid-19 immunization. Medical history included ongoing chronic kidney disease, ongoing diabetes mellitus, well controlled for 8 year and gout from an unknown date. Concomitant medication included allopurinol (MANUFACTURER UNKNOWN) for gout, felodipine (MANUFACTURER UNKNOWN) for hypertension, metformin (MANUFACTURER UNKNOWN) for diabetes mellitus. The patient experienced death on 31Dec2020 (reported as diabetes mellitus inadequate control), acidosis on 31Dec2020, which was medically significant with outcome of not recovered; blood creatine phosphokinase increased on 31Dec2020, which was medically significant with outcome of not recovered; blood creatine phosphokinase increased on 31Dec2020, which was medically significant with outcome of not recovered; circulatory collapse on 31Dec2020, which was medically significant with outcome of not recovered; circulatory collapse were serious as they were medically significant. The patient underwent lab tests and procedures which included creatine kinase, which was significantly raised on 31Dec2020, and blood glucose was 43 on 31Dec2020. Details were as follows: Had vaccine on 22Dec2020. Attended A+E via ambulance after being found on floor 31Dec2020. The patient was found to have extremely high sugars (43) and was acidotic. Acute kidney injury and creatine kinase significantly raised were noted. The patient died on 31Dec2020. It was not reported if an autopsy was performed. Cause of death, was put down as diabetes, but the physician indicated concert as the patients diabetes had been w

 VAERS ID: 947365 (history)
 Vaccinated:
 2020-12-21

 Form:
 Version 2.0
 Onset:
 2020-12-24

 Age:
 Days after
 2

Sex: Male vaccination:

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-15

| Vaccination / Manufacturer                                     | Lot / Dose   | Site / Route |
|--|--------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EJ0553 / UNK | -/-          |

Administered by: Other Purchased by: ? Symptoms: SARS-CoV-2 test, Sudden death

SMQs:, Torsade de pointes/QT prolongation (broad), Arrhythmia related investigations, signs and symptoms (broad), Cardiomyopathy (broad), COVID-19 (broad)

Life Threatening? No

Birth Defect? No Died? Yes

Date died: 2020-12-24 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: ASPIRINE; ; ; ; ZOLADEX LA

**Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Chronic kidney disease; Heart disease, unspecified

Allergies:

Diagnostic Lab Data: Test Name: COVID-19 virus test; Result Unstructured Data: Test Result:No - Negative COVID-19 test

CDC Split Type: GBPFIZER INC2021019671

Write-up: sudden death; This is a spontaneous report received from a contactable physician from the. The regulatory authority report number is GB-MHRA-WEBCOVID-20210106143746. A 90 years old male patient received BNT162B2 (Batch/lot number: EJ0553) on 21Dec2020 at single dose for COVID-19 immunization. Medical history was Chronic kidney disease, heart disease. Concomitant drug was acetylsalicylic acid (ASPIRINE) for Myocardial ischaemia, atorvastatin for Myocardial ischaemia, bisoprolol for Myocardial ischaemia, levothyroxine sodium for Hypothyroidism, ramipril for Hypertension, goserelin acetate (ZOLADEX LA) for Prostate cancer. No reaction noted but sudden death 3 days after vaccination (24Dec2020), although had history of heart disease. Cause of death not reported. Patient has not tested positive for COVID-19 since having the vaccine. Patient has not had symptoms associated with COVID-19. Patient is not enrolled in clinical trial. Outcome of the event was fatal. Unknown whether autopsy done or not. No follow-up attempts possible. No further information expected.; Reported Cause(s) of Death: Sudden death

VAERS ID: <u>947382 (history)</u> Vaccinated: 2020-12-17 Form: Version 2.0 Onset: 2020-12-19

Days after Age: 2 vaccination: Sex: Male

Location: Foreign Submitted: 0000-00-00 Entered: 2021-01-15

| Vaccination / Manufacturer                                     | Lot / Dose         | Site / Route |
|--|--------------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EJ0553/V0001 / UNK | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Cerebrovascular accident, Death, SARS-CoV-2 test negative

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), COVID-19 (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? Yes, ? days Extended hospital stay? No Previous Vaccinations: Other Medications: ;;;;; **Current Illness:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Arteriopathy; IHD

Diagnostic Lab Data: Test Date: 20201221; Test Name: COVID-19 virus test; Result Unstructured Data: Test Result:No - Negative COVID-19 test

CDC Split Type: GBPFIZER INC2021019867

Write-up: stroke; This is a spontaneous report from a contactable physician received by Pfizer from the regulatory authority. The regulatory authority report number is GB-MHRA-ADR 24566618 & GB-MHRA-WEBCOVID-20210107104558. An 84-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EJ0553/V0001), via an unspecified route of administration on 17Dec2020 at a single dose for COVID-19 immunization. Relevant medical history included: ischemic heart disease (IHD) and arteriopathy. Patient has not had symptoms associated with COVID-19 and is not enrolled in clinical trial. Concomitant medications included: clopidogrel (MANUFACTURER UNKNOWN), taken for transient ischaemic attack (TIA) from Jul2012 to an unspecified date, furosemide (MANUFACTURER UNKNOWN) taken from Jul2012 to an unspecified date, lansoprazole (MANUFACTURER UNKNOWN), taken from Nov2012 to an unspecified date, nebivolol (MANUFACTURER UNKNOWN), taken for left ventricular dysfunction from 01Jul2014 to an unspecified date, ramipril (MANUFACTURER UNKNOWN), taken from 2012 to an unspecified date and simvastatin (MANUFACTURER UNKNOWN) taken for hypercholesteremia from Nov2012 to an unspecified date. The patient experienced stroke on 19Dec2020, which caused hospitalization. The patient underwent lab tests and procedures which included COVID-19 virus test: no - negative COVID-19 test on 21Dec2020. The clinical outcome of stroke was fatal. The patient died of the stroke in the hospital on an unspecified date. An autopsy was not performed. Follow-up attempts are completed. No further information is expected.; Reported Cause(s) of Death: Stroke

VAERS ID: <u>947426 (history)</u> Vaccinated: 0000-00-00 2021-01-07 Form: Version 2.0 Onset: Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-01-15

Location: Foreign

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

Administered by: Other Purchased by: ?

Symptoms: Death, Myocardial infarction

SMQs:, Myocardial infarction (narrow), Embolic and thrombotic events, arterial (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-07

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:
Preexisting Conditions: Medical History/Concurrent Conditions: Heart attack (at age 50)

Allergies:

Diagnostic Lab Data:

CDC Split Type: ILPFIZER INC2021026804

Write-up: heart attack; This is a spontaneous report from a contactable consumer (relative). A 67-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration, on an unspecified date as a single dose for COVID-19 immunization. Medical history included heart attack (at age 50) on an unspecified date. The patient"s concomitant medications were not reported. The patient experienced a heart attack on 07Jan2021, which was reported as fatal. The patient died of a heart attack about a week after the vaccine was given. The clinical outcome of heart attack was fatal. The patient died on 07Jan2021. The cause of death was reported as heart attack, it was unknown if an autopsy was performed. No follow-up attempts are possible; information about batch/lot number cannot be obtained.; Reported Cause(s) of Death: heart attack

 VAERS ID: 955204 (history)
 Vaccinated:
 2021-01-04

 Form:
 Version 2.0
 Onset:
 2021-01-10

Age: Days after 6
Sex: Male vaccination: 6

**Location:** Foreign **Submitted:** 0000-00-00 **Entered:** 2021-01-17

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

Administered by: Unknown Purchased by: ?

Symptoms: Asthenia, Death

SMQs:, Guillain-Barre syndrome (broad)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-01-10

Days after onset: 0
Permanent Disability? No
Recovered? No

Office Visit? No ER Visit? No ER or Doctor Visit? No

ER or Doctor Visit? No Hospitalized? No Previous Vaccinations:

Other Medications: calcium channel blocker

**Current Illness:** 

Preexisting Conditions: Psoriasis

Allergies: Diagnostic Lab Data:

CDC Split Type:

Write-up: Our friend passed away 6 days after receiving the first dose of the Pfizer vaccine. He experienced a general weakness on the evening prior to hid death.

 VAERS ID: 952914 (history)
 Vaccinated:
 2020-12-30

 Form:
 Version 2.0
 Onset:
 2020-12-31

 Age:
 Days after vaccination:
 1

Location: Foreign Submitted: 0000-00-00

Entered: 2021-01-18

| Vaccination / Manufacturer                                     | Lot / Dose   | Site / Route |
|--|--------------|--------------|
| COVID19: COVID19 (COVID19 (PEIZER-BIONTECH)) / PEIZER/BIONTECH | EJ6796 / UNK | - / OT       |

Administered by: Other Purchased by: ?

Symptoms: Death, Discoloured vomit

SMQs:, Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-31 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:

Preexisting Conditions: Medical History/Concurrent Conditions: Autoimmune encephalopathy (Especially autoimmune encephalopathy of paraneoplastic origin);

Urothelial carcinoma bladder

Allergies:

Diagnostic Lab Data:

CDC Split Type: DEPFIZER INC2021023705

Write-up: Death (death certificate: uncertain type of death); evening vomiting; This is a spontaneous report from a non-contactable physician the Regulatory Authority. This is a report received from the Regulatory Authority. Regulatory authority report number was DE-PEI-CADRPEI-2021011672. A 79-year-old female patient received BNT162B2 (COMIRNATY; Lot Number: EJ6796), intramuscular on 30Dec2020 as a single dose for COVID-19 immunization. Medical history included especially autoimmune encephalopathy of paraneoplastic origin and suspected urothelial carcinoma of the bladder. The patient"s concomitant medications were not reported. The patient previously received the influenza vaccine (MANUFACTURER UNKNOWN) on 03Dec2020 for immunization and was tolerated. On 31Dec2020 (also reported as 30Dec2020), the patient developed evening vomiting which was dark in color and most likely food related. On 31Dec2020 at 04:35, the patient died. It was not reported if an autopsy was performed. The clinical outcome of vomiting was reported as fatal; however, the cause of death was reported as unknown cause of death. The vomiting and unknown cause of death were reported as medially significant and fatal. No follow-up attempts possible. No further information expected.; Reported Cause(s) of Death: Unknown cause of death

**VAERS ID:** 953012 (history) Vaccinated: 2021-01-05 Form: Version 2.0 2021-01-05 Onset:

Days after Age: vaccination: Sex: Female

Submitted: 0000-00-00 Location: Foreign 2021-01-18 Entered:

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

Purchased by: ? Administered by: Other

Symptoms: Illness, Limb discomfort, Malaise, SARS-CoV-2 test negative, Sudden death, Vomiting

SMQs:, Torsade de pointes/QT prolongation (broad), Acute pancreatitis (broad), Arrhythmia related investigations, signs and symptoms (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (narrow), Cardiomyopathy (broad), COVID-19 (broad)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-01-07 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: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Claudication; Essential hypertension; Living in residential institution; Type 2 diabetes mellitus; Vascular dementia (Vascular dementia with frailty); Comments: Residential care home resident, Vascular dementia with frailty, 2006 Type 2 DM, 2006 Essentia hypertension, 2006 Claudication in legs Patient has not had symptoms associated with COVID-19 Patient is not enrolled in clinical trial Allergies:

Diagnostic Lab Data: Test Date: 20210106; Test Name: COVID-19 virus test; Result Unstructured Data: Test Result:No - Negative COVID-19 test

CDC Split Type: GBPFIZER INC2021022839

Write-up: further sickness; vomited; felt unwell; Sudden death unexplained; slightly sore arm; This is a spontaneous report from a contactable physician received from the regulatory authority. The regulatory authority report number is GB-MHRA-WEBCOVID-20210108094947 & GB-MHRA-ADR 24571609. A 93-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE), via an unspecified route of administration on 05Jan2021 at a single dose for COVID-19 immunization. Medical history included residential care home resident, vascular dementia with frailty, type 2 diabetes mellitus (DM) from 2006 to an unknown date, essential hypertension from 2006 to an unknown date, claudication in legs from 2006 to an unknown date. The patient"s concomitant medications were not reported. The patient had not had symptoms associated with COVID-19 and is not enrolled in a clinical trial. The patient experienced slightly sore arm on 05Jan2021, sudden death unexplained on 07Jan2021 and vomited and felt unwell on 07Jan2021 10:00 PM and further sickness on 07Jan2021 10:15 PM. The patient was entirely well after vaccine apart from a slightly sore arm that resolved. On 07Jan2021, 2 days after the vaccine administration, the patient vomited and felt unwell at 10:00 PM. Observation was stable, then further sickness at 10:15pm. Thereafter slumped to the side and died peacefully. There were no signs of other allergic reaction. The patient underwent lab tests and procedures which included COVID-19 virus test: no - negative covid-19 test on 06Jan2021. The outcome of sudden death unexplained was fatal, of slightly sore arm was recovered in Jan2021 and of vomited, felt unwell and further sickness was unknown. The patient died on 07Jan2021. It was not reported if an autopsy was performed. No follow-up attempts are possible; information about batch/lot number cannot be obtained.; Reported Cause(s) of Death: Sudden death unexplained

VAERS ID: 953036 (history) Vaccinated: 2020-12-29 Form: Version 2.0 Onset: 2021-01-01 Days after

Age: Sex: Male vaccination:

Submitted: 0000-00-00 Location: Foreign Entered: 2021-01-18

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EJ6796 / 1 | -/-          |

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-01-01 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:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Consciousness decreased; Hypermobility syndrome; Pain NOS; Parkinson"s disease

Allergies:

Diagnostic Lab Data:

CDC Split Type: ISPFIZER INC2021004985

Write-up: Death; The initial case was missing the following minimum criteria: reporter with first-hand knowledge. Upon receipt of follow-up information on 14Jan2021 this case now contains all required information to be considered valid. This is a spontaneous report from a contactable physician downloaded from the regulatory authority. This is a report received from the regulatory authority. Regulatory authority report number was IS-IMA-1518. A 75-year-old male patient received the first dose of BNT162B2 (COMIRNATY; Lot Number: EJ6796), via an unspecified route of administration on 29Dec2020 as a single dose for COVID-19 immunization. Medical history included hypermobility syndrome, consciousness decreased, pain, and Parkinson's disease. The patient's concomitant medications were not reported. On 01Jan2021, the patient died. The clinical course was as follows: The patient had impaired consciousness for a few days. On 29Dec2020 the patient was vaccinated with BNT162B2. On 31Dec2020 end-of-life care was initiated. The patient's condition was worsening with hypermobility, dementia and pain (not otherwise specified). The patient had impaired consciousness for the past 6 days. The patient passed away on 01Jan2021. The cause of death was unknown. It was not reported if an autopsy was performed. The physician did not consider that there was a reason to suspect a causal association between the death and the vaccination; however, in the light of the circumstances it was reported.; Sender's Comments: The association between the event death with BNT162b2 can not be fully excluded based on the temporal relationship and the limited information available. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Com

 VAERS ID: 953037 (history)
 Vaccinated:
 2020-12-30

 Form:
 Version 2.0
 Onset:
 2021-01-01

Age: Days after Sex: Female vaccination:

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-18

Vaccination / Manufacturer | Lot / Dose | Site / Route | COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EJ6796 / UNK | - / -

2

Administered by: Other Purchased by: ?

Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-01-01

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: ; VIT D; ; ; RISPERIDON KRKA; ACIDOPHILUS BIFIDUS; ; ; BETMIGA; SOBRIL; ; BETOLVEX [CYANOCOBALAMIN]; ; AMLODIPIN FAMI ODIPINE: VACIETY.

[AMLODIPINE]; VAGIFEM;

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: COPD; Dementia; Pneumonia

Allergies:

Diagnostic Lab Data:

CDC Split Type: ISPFIZER INC2021005061

Write-up: Death; The initial case was missing the following minimum criteria: (no first-hand knowledge). Upon receipt of follow-up information on (14Jan2021), this case now contains all required information to be considered valid. This is a spontaneous report from a contactable physician and healthcare professional. This is a report downloaded from the regulatory authority. The regulatory authority report number IS-IMA-1491. An 88-year-old female patient received BNT162B2 (COMIRNATY; Lot number EJ6796, Expiration date 30Apr2021), via an unspecified route of administration on 30Dec2020 as single dose for covid-19 immunization. Medical history included pneumonia, chronic obstructive pulmonary disease and dementia from an unknown date, and not ongoing. Concomitant medication included vitamin b complex (MANUFACTURER UNKNOWN), ergocalciferol (VIT D), enalapril (MANUFACTURER UNKNOWN), ciprofloxacin (MANUFACTURER UNKNOWN), risperidone (RISPERIDON KRKA), bifidobacterium animalis, lactobacillus acidophillus (ACIDOPHILUS BIFIDUS), escitalopram (MANUFACTURER UNKNOWN), metoprolol (MANUFACTURER UNKNOWN), mirabegron (BETMIGA), oxazepam (SOBRIL), quetiapine (MANUFACTURER UNKNOWN), cyanocobalamin (BETOLVEX [CYANOCOBALAMIN]), folic acid (MANUFACTURER UNKNOWN), amlodipine (AMLODIPIN), estradiol (VAGIFEM), vitamins nos (also reported as Vitaplus), Magical mouthwash, B-kombin, Progastro. The patient experienced worsening of condition on 31Dec2020, which was serious as it was life-threatening and had fatal outcome; the patient experienced death on 01Jan2021. The patient died on 01Jan2021. Details were as follows: patient was vaccinated on 30Dec2020, and on 30Dec2020. The patient condition continued to worsen. On 01Jan2021 the patient passed away. It was not reported if an autopsy was performed. Reporter's comments: There is not an obvious causal association between the death and immunisation with Comirnaty due to worsening of the patients condition prior to immunisation.; Sender's Comments: Based on the close temporal relationship,

 VAERS ID: 953450 (history)
 Vaccinated:
 2020-12-28

 Form:
 Version 2.0
 Onset:
 2020-12-29

 Age:
 Days after
 4

Sex: Male vaccination:

 Location:
 Foreign
 Submitted:
 0000-00-00

 Entered:
 2021-01-18

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

Administered by: Other Purchased by: ? Symptoms: Death, Influenza like illness

SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-29

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: Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Hypertension arterial

Allergies:

Diagnostic Lab Data: CDC Split Type: DEPFIZER INC2021023631

Write-up: Exitus letalis; Influenza like illness; This is a spontaneous report from a non-contactable consumer downloaded from the Medicines Agency (MA) WEB (DE-PEI-CADRPEI-2020011585). A 93-year-old male patient received BNT162B2 (COMIRNATY), intramuscularly, on 28Dec2020 at a single dose for COVID-19 immunization. Medical history included hypertension arterial. The patient"s concomitant medications were not reported. The patient experienced influenza like illness and exitus letalis on 29Dec2020, which were reported as medically significant and fatal. It was reported that two days after vaccination, the patient developed influenza like illness (previously asymptomatic) and then found lifeless the following day (as reported). The clinical outcome of influenza like illness and exitus letalis was fatal. The patient died on 29Dec2020. The cause of death was influenza like illness (reported as unknown cause of death). It was unknown if an autopsy was performed. The causality assessment to both of the events was reported as unclassifiable by Regulatory Authority. No follow-up attempts possible; information about batch number cannot be obtained.; Reporter"s Comments: Previously asymptomatic, then found lifeless the following day.; Reported Cause(s) of Death: Influenza like illness

VAERS ID: <u>953468</u> (history) Vaccinated: 2020-12-17 Form: Version 2.0 Onset: 2020-12-01 Submitted: 0000-00-00 Age: Sex: Male Entered: 2021-01-18

Location: Foreign

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EJ0553 / 1

Administered by: Other Purchased by: ?

Symptoms: Death SMQs:

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-01 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:** 

Preexisting Conditions: Medical History/Concurrent Conditions: Atrial fibrillation; Cataract extraction; Intraocular lens implant; Left inguinal hernia; Osteoarthritis knee (right knee); Polymyalgia rheumatica; Postoperative care (Postop wound management gen secondary care done by practice); Pressure sore; Prostate cancer; Radiofrequency ablation (Radiofrequency ablation of varicose vein of leg); Retention urine; Total hip replacement (Total prosthetic replacement of hip joint using cement - left.); Total knee replacement (Total prosthetic replacement of knee joint using cement - left.); Total knee replacement (Primary total knee replacement NEC); Transurethral prostatectomy (Bladder outlet and prostate operations); Ventricular tachycardia; Wound dressing

Allergies:

Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021022507

Write-up: patient passed away 4 days after receiving vaccination, not known if related but patient was seen 2 days before at the surgery and was fit and well at that time. Death was unexpected.; This is a spontaneous report from a contactable healthcare professional. This is a report received from the Regulatory Authority, RA. Regulatory authority report number was GB-MHRA-ADR 24546873 with Safety Report Unique Identifier of GB-MHRA-EYC 00236252. A 91-year-old male patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EJ0553), intramuscular on 17Dec2020 as 0.3 ml single dose for COVID-19 immunisation. Medical history included cataract operation on 23Oct2020, intraocular lens implant on 23Oct2020, atrial fibrillation from 10May2018 and unknown if ongoing, ventricular tachycardia from 11Sep2003 and unknown if ongoing, polymyalgia rheumatica from 31Mar2008 and unknown if ongoing, total prosthetic replacement of left hip joint using cement on 24Feb2011, total prosthetic replacement of left knee joint using cement on 28Nov2011, osteoarthritis of right knee from 02Jul2012 and unknown if ongoing, prostate cancer from 28Feb2017 and unknown if ongoing, pressure sore from 01Sep2017 and unknown if ongoing, prostoperative care from 10Jan2018 and unknown if ongoing, left inguinal hernia from 07Jun2017 and unknown if ongoing, urine retention from 11Nov2016 to 04Feb2017, transurethral prostatectomy from 17Feb2017 to 13May2017, total knee replacement on 26Oct2018 to 18Jan2019 (as reported), high frequency ablation from 03Jul2019 to 25Sep2019, and wound dressing from 03Jan2019 and unknown if ongoing. Concomitant medications included apixaban (MANUFACTURER UNKNOWN), propatenone (MANUFACTURER UNKNOWN), and zopiclone (MANUFACTURER UNKNOWN). The patient previously took codeine (MANUFACTURER UNKNOWN) from 29Oct2018 to an unknown date for an unknown indication and experienced adverse reaction. In Dec2020 (reported as 4 days after the vaccination), the patient passed away. It was not known if it was related to the vaccine but the patient was seen 2 days before at the surgery and was fit and well at that time. The death was unexpected. An autopsy was performed, and the results were not provided. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: Death unexplained

VAERS ID: 953471 (history) Vaccinated: 2020-12-20 Version 2.0 2020-12-21 Form: Onset:

Age: Days after 1 vaccination: Sex: Female

Submitted: 0000-00-00 Location: Foreign 2021-01-18 Entered:

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

Administered by: Other Purchased by: ?

Symptoms: Death, Hypotension, Livedo reticularis, Loss of consciousness, Peripheral coldness, Respiratory rate increased

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (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 encephalitis (broad), Noninfectious meningitis (broad), Hypotonic-hyporesponsive episode (broad), Generalised convulsive seizures following immunisation (broad), Hypoglycaemia (broad), Dehydration (broad), Hypokalaemia (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-21 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: ASPIRIN [ACETYLSALICYLIC ACID]; ; ; ; ; CO-CODAMOL; ; ; ; ; GLYCERYL TRIACETATE; ; LAXIDO; ; MICRALAX MACROGOL; ; ;

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Abdominal abscess (Chronic); Aortic stenosis; Cervical myelopathy; Chronic kidney disease stage 3; Clammy (Started 2 days prior to vaccine); Dyspnoea (Started 2 days prior to vaccine); Essential hypertension; Feeling cold (Started 2 days prior to vaccine); Fracture of humerus (Closed fracture distal right humerus); Heart failure; Ischaemic foot (Critical left foot ischamia); Ischaemic heart disease; Lethargy (Started 2 days prior to vaccine); Lipodermatosclerosis; Mitral incompetence; Non STEMI (Acute); Peripheral vascular disease; Postmenopausal bleeding (Unidentified cause); Sweaty (Started 2 days prior to vaccine); Unwell (Started 2 days prior to vaccine); Vascular dementia

**Allergies** 

Diagnostic Lab Data: Test Date: 20201221; Test Name: Body temperature; Result Unstructured Data: Test Result:38.1; Test Date: 20201221; Test Name: low blood pressure; Result Unstructured Data: Test Result:high CDC Split Type: GBPFIZER INC2021022784

Write-up: Death within 24 hours of vaccine; Livedo reticularis; Hypotension; Respiratory rate increased; Peripheral coldness; Loss of consciousness; This is a spontaneous report from a contactable physician. This is a report received from the regulatory authority. The regulatory authority report number is GB-MHRA-EYC 00236256. An 82-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE), subcutaneous on 20Dec2020 at first single dose for covid-19 immunization. Medical history included malaise from Dec2020, Started 2 days prior to vaccine; cold sweat from Dec2020, started 2 days prior to vaccine; dyspnoea from Dec2020, started 2 days prior to vaccine; feeling cold from Dec2020, started 2 days prior to vaccine; lethargy from Dec2020, started 2 days prior to vaccine; hyperhidrosis from Dec2020, started 2 days prior to vaccine, peripheral vascular disorder from 1982, peripheral ischaemia from 1982, Critical left foot ischemia; essential hypertension from 2003; myocardial ischaemia from 2005; Chronic kidney disease from 2006; myelopathy from 2007; Acute myocardial infarction in 2012; Mitral valve incompetence in 2012; Cardiac failure in 2013; Post thrombotic syndrome in 2015; Vascular dementia in 2017; Aortic stenosis in 2017; humerus fracture in 2019, Closed fracture distal right humerus; Postmenopausal haemorrhage 2019, unidentified cause; abdominal abscess in Jul2020, chronic, . Concomitant medication included acetylsalicylic acid (ASPIRIN), aforvastatin (MANUFACTURER UNKNOWN), bisoprolol fumarate (MANUFACTURER UNKNOWN), bumetanide (MANUFACTURER UNKNOWN), codeine phosphate, paracetamol (CO-CODAMOL), colecalciferol (MANUFACTURER UNKNOWN), dimeticone (MANUFACTURER UNKNOWN), docusate sodium (MANUFACTURER UNKNOWN), doxycycline hyclate (MANUFACTURER UNKNOWN), glyceryl triacetate (MANUFACTURER UNKNOWN), isosorbide mononitrate (MANUFACTURER UNKNOWN), macrogol 3350, potassium chloride, sodium bloarbonate, sodium chloride (LAXIDO), melatonin (MANUFACTURER UNKNOWN), macrogol (MICRALAX MACROGOL), paracetamol (MANUFACTURER UNKNOWN), senna spp. (SENNA SPP.), tramadol hydrochloride (MANUFACTURER UNKNOWN). The patient previously took trimethoprim, penicillin and ace inhibitors and angiotensin ii receptor blockers and experienced adverse drug reaction, not specified. On 21Dec2020, the patient experienced death within 24 hours of vaccine, livedo reticularis, hypotension, respiratory rate increased, peripheral coldness, loss of consciousness. The events were serious as it lead to death. The patient underwent lab tests and procedures which included body temperature of 38.1 on 21Dec2020. The patient died on 21Dec2020. It was not reported if an autopsy was performed. Details were as follows: Death within 24 hours of first vaccination dose occured. Patient had been unwell two days prior to the vaccination. New onset dyspnoea at rest and lethargy were noted. No fever at that time was noted. Noted to be cold, clammy and sweaty and this persisted for the following two or three days. No doctor notified of these developments. Over the following two days patient remained in a similar condition. She remained cold, clammy and dyspnoeic. Few observations appear to have been taken over this time; I do not know if she was fevered at any point due to lack of data. She was administered her first Covid-19 vaccine dose on 20Dec2020. On the morning of 21Dec2020, she was found unrousable in bed. Paramedics were called. She was noted to be cold and mottled, temperature was 38.1, low blood pressure (BP) and high respiratory rate. She died a couple of hours later. The case was reported to the procurator fiscal (PF) as cause of death was unknown, and death happened within 24 hours of a new vaccine, also with some concerns over patient care after she became unwell, not notifying general practitioner (GP) of deterioration in health. Post mortem was agreed by PF, but date not known. The other outcome for death within 24 hours of first vaccination dose was not known (NK) if death caused by vaccine. The patient was unwell prior to the dose. Cause of death was reported as unknown. The reporter did not know if the Pfizer COVID-19 vaccine caused or accelerated or contributed to this patient"s death. The patient"s deterioration was not informed until after her death. No follow-up attempts are possible; information about lot/batch number cannot be obtained.; Reported Cause(s) of Death: Death

 VAERS ID: 953488 (history)
 Vaccinated:
 2021-01-06

 Form:
 Version 2.0
 Onset:
 2021-01-07

Age: Days after
Sex: Male vaccination:

Location: Foreign Submitted: 0000-00-00
Entered: 2021-01-18

| Vaccination / Manufacturer                                     | Lot / Dose | Site / Route |
|--|------------|--------------|
| COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH | EJ1688 / 2 | -/-          |

1

Administered by: Other Purchased by: ?

Symptoms: Death SMQs: Life Threatening? No

Life Threatening? No Birth Defect? No Died? Yes

Died? Yes
Date died: 2021-01-07
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:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

## CDC Split Type: GBPFIZER INC2021023785

Write-up: Unknown cause of death; This is a spontaneous report from a contactable physician. This is a report received from the Regulatory Authority. Regulatory authority report number was GB-MHRA-ADR 24569457 with Safety Report Unique Identifier of GB-MHRA-WEBCOVID-20210107171332. An 80-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE; Lot Number: EJ1688), via an unspecified route of administration on 06Jan2021 as a single dose for COVID-19 immunisation. Medical history was not reported. It was unknown if the patient had had symptoms associated with COVID-19. The patient was not enrolled in the clinical trial. Concomitant medications included edoxaban (MANUFACTURER UNKNOWN) taken for blood caffeine (as reported) from 06Dec2019 and unknown if ongoing. The patient previously received the first dose of BNT162B2 on an unknown date for COVID-19 immunization and had no known adverse effects. On 07Jan2021, the patient died due to an unknown cause of death. 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: Unknown cause of death

 VAERS ID: 953501 (history)
 Vaccinated:
 2020-12-16

 Form:
 Version 2.0
 Onset:
 2020-12-21

Age: Days after Sex: Female vaccination: 5

**Location:** Foreign **Submitted:** 0000-00-00 **Entered:** 2021-01-18

Vaccination / Manufacturer Lot / Dose Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EJ0553 / UNK -/-

Administered by: Other Purchased by: ?

Symptoms: Cardiac arrest, Death, Fall

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (broad), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Acute central respiratory depression (broad), Accidents and injuries (narrow), Cardiomyopathy (broad), Respiratory failure (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-21 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: ISTIN; ; ; Current Illness: Preexisting Conditions:

Allergies:
Diagnostic Lab Data:

CDC Split Type: GBPFIZER INC2021023371

Write-up: cardiac arrest; suddenly went funny colour, odd noise, and fell back in chair; beath; This is a spontaneous report received from a contactable physician from the Medicines and Healthcare products Regulatory Agency (MHRA). The regulatory authority report number is GB-MHRA-WBCOVID-20210109135858 and GB-MHRA-ADR 24575544. An 88-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 MRNA VACCINE; Lot number: EJ0553), via an unspecified route of administration, on 16Dec2020 at a single dose for COVID-19 vaccination. The patient"s medical history was not reported. Concomitant medications included amlodipine besilate (ISTIN), propranolol (MANUFACTURER UNKNOWN) taken for anxiety from 17Dec2020, levothyroxine (MANUFACTURER UNKNOWN), and ramipril (MANUFACTURER UNKNOWN). The patient previously received the influenza vaccine (reported as flu vaccine; MANUFACTURER UNKNOWN) for immunization on 07Oct2020. The patient suddenly went funny colour, odd noise, and fell back in chair and experienced cardiac arrest on an unspecified date. The patient experienced death on 21Dec2020, which was reported as fatal. The clinical course was reported as follows: The patient was well and suddenly went funny colour, odd noise, and fell back in chair. The emergency services were called and taken in cardiac arrest. The patient died in the emergency department. The patient had not had symptoms associated with COVID-19. The patient was not enrolled in a clinical trial. The clinical outcome of suddenly went funny colour, odd noise, and fell back in chair was unknown and of cardiac arrest and death was fatal. The patient died on 21Dec2020. The cause of death was reported as cardiac arrest. It was unknown if an autopsy was performed. It was also reported that since the vaccination, the patient had not been tested for COVID-19. No follow-up attempts are possible. No further information is expected.; Reported Cause(s) of Death: cardiac arrest

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