Control #	Status	Status Date	.
2015-4481	Withdrawn Closed w/o Charges	06/12/2015	ON-LINE

Recd date:	Due Date	Agency Track	Privacy	Do Not Release
06/08/2015	07/07/2015	Complex	N	N

Requester	Signature
PFIZER	Margaret Sestrom on behalf of Azzura Ravizza

Requester Address	Primary Phone	Email
445 Eastern Point Road, Groton, CT 06320, US	860-441-6224	margaret.m.sestrom@pfizer.com

Bill To	Actual Fees (All Offices)
PFIZER 445 Eastern Point Road, Groton, CT 06320, US, Attn: Margaret Sestrom on behalf of Azzura Ravizza, 860-441-6224, margaret.m.sestrom@pfizer.com	$0.00

Requester Reference	Date Range	Requester Type
	04/01/2014 - 06/30/2014	C

Subject
FAERS REPORTS

Orig. Subject
Safety Reports FAERS database - information is attached to the request.

Entered By	PHS #
KOTLER, SARAH B	

August 3, 2020

In Response Refer to File: ***2020-5641***

Lester Reich
Pfizer
202 Nelson Street
Brooklyn, NY 11231

Dear Requester,

This is in response to your recent electronic Freedom of Information Act submission, in which you requested two adverse event cases associated with the use of Tobramycin (Nebcin). Your request was received in the Center for Drug Evaluation and Research on August 3, 2020.

Please be advised that these are legacy Individual Safety Reports (ISRs) that were migrated into the FAERS database and assigned new case IDs. The title page will reflect their original ISR numbers.

The releasable documents are enclosed. After a thorough review of the responsive records, we have determined that portions of the documents are exempt from disclosure under exemption (b)(6) of the FOIA, 5 U.S.C. § 552, as amended and delineated below:

> Exemption (b)(6) permits the withholding of information which, if released, would constitute a clearly unwarranted invasion of personal privacy. In this case, it was determined that there is no countervailing public interest qualifying under the standard set forth, under exemption (b)(6), to release the personal identifying information of certain third parties.

The following charges may be included in a monthly invoice:

Reproduction: $0.50 Search: $11.50 Review: $11.50 Other: (CD) $0.00 TOTAL: $23.50

The above total may not reflect final charges for this request.

PLEASE DO NOT SEND PAYMENT UNLESS YOU RECEIVE AN INVOICE FOR THE TOTAL MONTHLY FEE.

This concludes the response for the Center for Drug Evaluation and Research. If we can be of further assistance to you, please do not hesitate to contact me at 301-796-3461.

Sincerely,

Eli Landy -S

Digitally signed by Eli Landy -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Eli Landy -S, 0.9.2342.19200300.100.1.1=2000482461
Date: 2020.08.03 16:38:20 -04'00'

Eli Landy
Lead Regulatory Counsel
Division of Information Disclosure Policy
Office of Regulatory Policy
Center for Drug Evaluation and Research

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of this response, to:

Director, Office of the Executive Secretariat
U.S. Food & Drug Administration
5630 Fishers Lane
Room 1050
Rockville, MD 20857
Email: FDAFOIA@fda.hhs.gov

Please clearly mark both the envelope and your letter or email "FDA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Katherine Uhl at 301-796-8975. You may also contact the FDA FOIA Public Liaison for assistance at:

Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov
Fax: 202-741-5769

Enclosure: Tobramycin (Nebcin) MedWatch Reports (5 Pages)

Printer: CDPEDQ5
User: STEPPERH
Date - Time: 03-Aug-2020 03:54 PM
Total Number of Cases (Non-Esub): 2
Total Number of Pages: 4
Print Job Number: 22655

Disclaimers:
Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

Data provided in the Quarterly Data Extract (QDE) or a FAERS FOIA report are a snapshot of FAERS at a given time. There are several reasons that a case captured in this snapshot can be marked as inactive and not show up in subsequent reports. Manufacturers are allowed to electronically delete reports they submitted if they have a valid reason for deletion. FDA may merge cases that are found to describe a single event, marking one of the duplicate reports as inactive. The data marked as inactive are not lost but may not be available under the original case number.

Processed Case Id's for Images:
5181885 5333314

Failed Case Id's for Images:

Total Failed Cases: 0

mcc by FISHER

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

INITIAL SPONTANEOUS 15 DAY ALERT

Eli Lilly and Company

S 300B - 45

FDA Approved 11/30/93

Mfr. report # FR94111177A

UF/Diet report # 1537763

FDA Use Only

A. Patient information

1. Patient Identifier	2. Age at time of event:	3. Sex	4. Weight
UNK	or Date of birth: (b) (6)	☐ female ☒ male	___ lbs or ___ kgs
In confidence			

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☐ death ___ mo/day/yr
- ☐ life-threatening
- ☒ hospitalization - initial or prolonged
- ☐ disability
- ☒ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event (mo/day/yr): UNK

4. Date of this report (mo/day/yr): 11/15/94

5. Describe event or problem

BABY EXPOSED IN UTERO TO NEBCIN.SEE MOTHER DEN REPORT FRP940438. PREMATURE BIRTH AT 35 WEEKS OF AMENORRHEA.WEIGHT 1800 GM;HEIGHT 44.5 CM;CRANIAL PERIMETER 30 CM. MALE. BABY PRESENTS DYSMATURITY HIS RENAL BIOLOGY IS NORMAL;HEARING NORMAL; ONE EPISODE OF SUPRAVENTRICULAR TACHYCARDIA **

DIVISION OF EPIDEMIOLOGY AND SURVEILLANCE
94 NOV 18 AM 11:20

ANOMALY CONGEN

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Race: UNK

C. Suspect medication(s)

1. Name (give labeled strength & mfr./labeler, if known)

#1 NEBCIN

#2

2. Dose, Frequency & route used

#1 UNK

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 --/--/-- --/--/--

#2

4. Diagnosis for use (indication)

#1 UNK

#2

5. Event abated after use stopped or dose reduced

#1 ☐ yes ☐ no ☒ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 ☐ yes ☐ no ☒ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All Manufacturers

1. Contact office - name/address (& mfr'g site for devices)

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana
46285

2. Phone number: (317)276-3714

3. Report source (check all that apply)

- ☒ foreign
- ☐ study
- ☐ literature
- ☐ consumer
- ☒ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other:

4. Date received by manufacturer (mo/day/yr): 11/07/94

5. (A)NDA # 62-008

IND # ___

PLA # ___

pre-1938 ☐ yes

OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)

- ☐ 5-day ☒ 15-day
- ☐ 10-day ☐ periodic
- ☒ initial ☐ follow-up # ___

8. Adverse event term(s)

- PREMATURE BIRTH
- GASTROINTESTINAL DISORDER
- BIRTH WEIGHT SUBNORMAL
- SUPRAVENTRICULAR TACHYCARDIA

9. Mfr. report number: FR94111177A

E. Initial reporter

1. Name, address & phone #

(b) (6)

FRANCE

2. Health professional? ☒ yes ☐ no

3. Occupation: PHYSICIAN

4. Initial reporter also sent report to FDA: ☐ yes ☐ no ☒ unk

FDA FACSIMILE 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Medication
Experience Report
(continued)

Eli Lilly and Company

Mfr report # FR94111177A

UF/Diet report # 1537763

FDA Use Only

FREE TEXT

**CONT:HE HAS A GASTROESOPHAGEAL REFLUX RELATED TO A MALFORMATIN OF THE INFERIOR ESOPHAGEAL SPHINCTER.

VJB

1682400

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Eli Lilly and Company

FOLLOWUP SPONTANEOUS 15 DAY ALERT S 305A - 11

FDA Approved 11/30/95

Mfr. report # GB95113715A

UF/Diet report # 1723867

FDA Use Only

A. Patient information

1. Patient Identifier: UNK (In confidence)
2. Age at time of event: UNK or Date of birth:
3. Sex: [ ] female [X] male
4. Weight: 7 lbs or 3 kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - [ ] death mo/day/yr
   - [ ] life-threatening
   - [ ] hospitalization - initial or prolonged
   - [ ] disability
   - [X] congenital anomaly
   - [ ] required intervention to prevent permanent impairment/damage
   - [ ] other:
3. Date of event (mo/day/yr): UNK
4. Date of this report (mo/day/yr): 12/05/95
5. Describe event or problem:

MULTIPLE VENTRICULAR SEPTAL DEFECTS IN BABY AFTER MOTHER TOOK ABOVE DRUGS DURING PREGNANCY. SEE RELATED CASE UKB9300419.
F/U 27 NOV 95: PHONED REPORTER WHO STATES THAT SHE HAS NO EVIDENCE TO INDICATE THAT THIS DEFECT WAS CAUSED BY THE SINGLE DOSE OF NEBCIN.

DIVISION OF EPIDEMIOLOGY AND SURVEILLANCE
95 DEC 12 AM 4:56

6. Relevant tests/laboratory data, including dates:

APGAR 8 AT 1 MINUTE, 9 AT 5 MINUTES.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Race: UNK
PATIENTS MOTHER HAS CYSTIC FIBROSIS, SMOKES AND DRINKS.

12/12/95

C. Suspect medication(s)

1. Name (give labeled strength & mfr./labeler, if known)
   - #1 NEBCIN
   - #2
2. Dose, Frequency & route used
   - #1 UNK
   - #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   - #1 --/--/-- --/--/--
   - #2
4. Diagnosis for use (indication)
   - #1 UNK
   - #2
5. Event abated after use stopped or dose reduced
   - #1 [ ] yes [ ] no [X] doesn't apply
   - #2 [ ] yes [ ] no [ ] doesn't apply
6. Lot # (if known)
   - #1
   - #2
7. Exp. date (if known)
   - #1
   - #2
8. Event reappeared after reintroduction
   - #1 [ ] yes [ ] no [X] doesn't apply
   - #2 [ ] yes [ ] no [ ] doesn't apply
9. NDC # - for product problems only (if known)
10. Concomitant medical products and therapy dates (exclude treatment of event)

CREON
DATES: --/--/-- --/--/--

(CONTINUED)

G. All Manufacturers

1. Contact office - name/address (& mfring site for devices)

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana
46285

2. Phone number: (317)276-7788
3. Report source (check all that apply)
   - [X] foreign
   - [ ] study
   - [ ] literature
   - [ ] consumer
   - [X] health professional
   - [ ] user facility
   - [ ] company representative
   - [ ] distributor
   - [ ] other:
4. Date received by manufacturer (mo/day/yr): 11/27/95
5. (A)NDA # 62-008
   - IND #
   - PLA #
   - pre-1938 [ ] yes
   - OTC product [ ] yes
6. If IND, protocol #
7. Type of report (check all that apply)
   - [ ] 5-day [X] 15-day
   - [ ] 10-day [ ] periodic
   - [ ] initial [X] follow-up # 1
8. Adverse event term(s)

00/00/00 VENTRICULAR SEPTAL DEF

9. Mfr. report number: GB95113715A

E. Initial reporter

(b) (6)

United Kingdom

2. Health professional? [X] yes [ ] no
3. Occupation: HOSPITAL DOCTOR
4. Initial reporter also sent report to FDA: [ ] yes [ ] no [X] unk

FDA FACSIMILE 5500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

15 DAY PSR REPORT

Medication
Experience Report
(continued)

1723867

Mfr report # GB95113715A

UF/Diet report #

FDA Use Only

Eli Lilly and Company

FREE TEXT

* MOTHER WAS ON OTHER DRUGS. ALSO THIS IS NOT AN UNCOMMON CONGENITAL DEFECT. IN THIS CASE AS THERE IS NO INDICATION OF CAUSALITY WE WILL NOT REPORT. ALSO ADDED PATIENTS SEX.

CONCOM DRUGS AND THERAPY DATES CONTINUED FROM C10	FROM	TO
	--/--/--	--/--/--
CEFTAZIDIME	--/--/--	--/--/--
SALBUTAMOL	--/--/--	--/--/--
ATROVENT		

Control #	Status	Status Date	.
2020-5641	Closed	08/04/2020	ON-LINE

Recd date:	Due Date	Agency Track	Privacy	Do Not Release
08/03/2020	08/31/2020	Simple	N	N

Requester	Signature
PFIZER	lester reich

Requester Address	Primary Phone	Email
202 nelson street, brooklyn, NY 11231, US	718-208-6310	lester.reich@pfizer.com

Bill To	Actual Fees (All Offices)
PFIZER 202 nelson street, brooklyn, NY 11231, US, Attn: lester reich, 718-208-6310, lester.reich@pfizer.com	$23.50

Requester Reference	Date Range	Requester Type
	07/01/1994 - 02/01/1996	C

Subject
2 adverse reaction forms containing narratives SRS FAERS data extract q1 2020 case 1. 01682400-ISR # initial FDA date-12-7-95 suspect drug tobramycin case 2. 01524673 ISR # Initial FDA date 11-18-1994 suspect drug tobramycin

Orig. Subject
2 adverse reaction forms containing narratives SRS FAERS data extract q1 2020 case 1. 01682400-ISR # initial FDA date-12-7-95 suspect drug tobramycin case 2. 01524673 ISR # Initial FDA date 11-18-1994 suspect drug tobramycin

Entered By	PHS #
KOTLER, SARAH B	

Dina B. Tresnan, DVM, PhD
Pfizer Inc.
Eastern Point Rd, MS8260-1188
Groton, CT 06340

Rochelle A. Coleman
Office of the Executive Secretariat
Division of Freedom of Information
U.S. Food and Drug Administration
Tel: 301-796-8982
rochelle.coleman@fda.hhs.gov

Friday, 18 December 2020

RE: Request for reports of VAERS cases 902568, 902794, and 902758

Dear Rochelle,

We received a query to EUA 27034 for COVID-19 vaccine BNT162b2 regarding allergic reaction including anaphylaxis cases mentioning VAERS IDs 902568 and 902794 as well as non-serious events including a case of possible anaphylaxis for VAERS ID 902758. It was indicated that we may request a copy of redacted VAERS report via FOIA. Both anaphylaxis reports and possible anaphylaxis report were associated with Lot EK5730.
This is a request for these VAERS reports to be sent in an expedited manner as soon as possible.

Thank you in advance.

Sincerely,

Dina B. Tresnan

Dina B. Tresnan, DVM, PhD

Dina B. Tresnan, DVM, PhD
Pfizer Inc.
Eastern Point Rd, MS8260-1188
Groton, CT 06340

Rochelle A. Coleman
Office of the Executive Secretariat
Division of Freedom of Information
U.S. Food and Drug Administration
Tel: 301-796-8982
rochelle.coleman@fda.hhs.gov

Wednesday, 30 December 2020

RE: Request for reports of VAERS cases itemized below

Dear Rochelle,

We received a query to EUA 27034 for COVID-19 vaccine BNT162b2 regarding anaphylaxis cases mentioning multiple VAERS IDs (see below email from FDA). It was indicated that we may request a copy of redacted VAERS report via FOIA.
This is a request for the below VAERS reports to be sent in an expedited manner as soon as possible.

From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Sent: Tuesday, December 29, 2020 11:33 AM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Subject: [EXTERNAL] EUA 27034: IR regarding allergic and anaphylactic reactions

Elisa and Carmel,

The review team has the below Information Request (IR) for Pfizer regarding allergic and anaphylactic reactions. Please confirm receipt of this IR and the review team has requested a response within the week.

Reference is made to your EUA 27034 authorized on December 11, 2020.

Allergic and Anaphylactic Reactions. We are aware of at least 21 confirmed cases of anaphylaxis, as well as numerous allergic reactions from the recent post-authorization use of the Pfizer-BioNTech COVID-19 vaccine. Anaphylaxis rarely occurs after vaccination, with an expected incidence of approximately one per million doses (1), and thus is occurring more frequently than expected with use of the Pfizer-BioNTech COVID-19 vaccine. Thus, allergic and anaphylactic reactions are an important identified risk of your product. Please add Allergic and Anaphylactic Reactions to your pharmacovigilance plan (PVP) as an important identified risk. Your revised PVP should include strategies for evaluating and monitoring potential cases of anaphylaxis. In addition, please analyze cases of anaphylaxis as a component of your monthly periodic safety reports.

Please provide your response within one week.

The VAERS IDs for the anaphylaxis cases are listed below. Please note that you may request a copy of redacted VAERS reports via FOIA. Some pertinent clinical information about these cases were obtained through direct communication with providers, and this information may not be reflected in initial reports submitted to VAERS.

902557	903469	904055	906741	907836
902794	903537	904334	906970	
903197	903922	905674	906988	
903243	903945	906002	907019	
903400	904033	906056	907173	

Reference

1. McNeil MM, Weintraub ES, Duffy J, Sukumaran L, Jacobsen SJ, Klein NP, Hambidge SJ, Lee GM, Jackson LA, Irving SA, King JP, Kharbanda EO, Bednarczyk RA, DeStefano F. Risk of anaphylaxis after vaccination in children and adults. J Allergy Clin Immunol. 2016 Mar;137(3):868-78. doi: 10.1016/j.jaci.2015.07.048. Epub 2015 Oct 6. PMID: 26452420; PMCID: PMC4783279.

Regards,

Mike

Mike Smith, Ph.D.
Captain, USPHS

Senior Regulatory Review Officer
Food and Drug Administration
Center for Biologics Evaluation & Research
Office of Vaccines Research & Review
Division of Vaccines and Related Products Applications
Tel: 301-796-2640
michael.smith2@fda.hhs.gov

Thank you in advance.

Sincerely,

Dina B. Tresnan

Dina B. Tresnan, DVM, PhD

U.S. FOOD & DRUG ADMINISTRATION

January 11, 2021

Dr. Dina Tresnan
Pfizer Inc
1 Ascot Lane
Old Lyme Ct. 06371

In reply refer to file: F2021-119

Dear Dr. Tresan,

This is in reply to your Freedom of Information Act (FOIA) request dated December 30, 2020, in which you requested "we received a query to EUA 27034 for Covid-19 vaccine BNT162b2 regarding anaphylaxis cases mentioning multiple VAERS IDs… It was indicated that we may request a copy of redacted VAERS reports via FOIA. This is a request for the below VAERS reports to be sent in an expedited manner as soon as possible." The VAERS IDs listed in your FOIA request were:

902557	903469	904055	906741	907836
902794	903537	904334	906970	
903197	903922	905674	906988	
903243	903945	906002	907019	
903400	904033	906056	907173	

Your request was received in the Center for Biologics Evaluation and Research on January 5, 2021.

Enclosed please find the results of a query of the Vaccine Adverse Event Reporting System (VAERS) using the search parameters listed in your FOIA request. Please note that during a telephone conversation with Catherine Wilusz on January 6, 2021, you stated that medical records would not be considered responsive for this FOIA request.

We have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of this response, to:

Director, Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Katherine Uhl at 301-796-8975.

You may also contact the FDA FOIA Public Liaison for assistance at:

Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

The following may be included in a monthly invoice:

Search	0.5 Hour @ $46.00/hr	$23.00
Review	3 Hour @ $46.00/hr	$138.00
TOTAL		**$161.00**

The above charges may not reflect final charges for this request. Please DO NOT send any payment until you receive an invoice from the Agency's Freedom of Information Staff (HFI-35).

If you have any questions or if we can be of further assistance, please let us know by referencing the above file number. You can contact Catherine Wilusz by phone at 240-402-8184 or by e-mail at Catherine.wilusz@fda.hhs.gov.

Sincerely,

Beth A. Brockner Ryan -S

Digitally signed by Beth A. Brockner Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000524489, cn=Beth A. Brockner Ryan -S
Date: 2021.01.08 14:37:34 -05'00'

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

Next 10 Vaers IDs

VAERS ID: 902557

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 902557 - 1
E-Number: 207125
Doc Number: 1299835
Date Received: 12/15/2020 11:15 PM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (3) (A), (b) (6) (last) (b) (3) (A), (b) (6)
Address (b) (3) (A), (b) (6)
City (b) (3) (A), (b) (6)
State: (b) (3) (A) **ZIP:** (b) (3) (A), (b) (6)
County:
Phone: (b) (3) (A), (b) (6)
Email: (b) (3) (A), (b) (6)

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/15/2020 **Time:** 17:50

5. Date and time adverse event started: 12/15/2020 **Time:** 18:00

6. Age at vaccination: 32 yr.

7. Today's date: 12/15/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Nuvaring

10. Allergies to medications, food, or other products:
None

11. Other illnesses at the time of vaccination and up to one month prior:
none

12. Chronic or long-standing health conditions:
low blood sugar, low blood pressure

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Bartlett Regional Hospital Charlee Gribbon
Relation to Patient: Healthcare professional/staff
Address: 3260 Hospital Dr
City: Juneau
State: AK **ZIP:** 99801
Phone: (907) 796-8413
Email: cgribbon@bartletthospital.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Lindy Jones
Phone: (907) 796-8427 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Bartlett Regional Hospital
Fax:
Facility Address:
3260 Hospital Dr
City: Juneau
State: AK **ZIP:** 99801
Phone: (907) 796-8413

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EK5730	Intramuscular - IM	Right Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
1750- IM injection ot R Deltoid. She was sitting, and felt short of breath without wheeze or tightness in the chest or throat. She stood up, and then felt

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

tunneling. Assisted to chair and floor. Pulse weak, skin flushed, sweating on torso. Face and Neck remained flushed and red. She refused epi at first. So we gave her benedryll 25 mg po with apple juice. She said she just had a big meal 30 min prior, but we checked her blood sugar- it was 85. 10 min after the first SOB feeling, it returned.
BP was recorded as 160/100.

19. Medical tests and laboratory results related to the adverse event(s):
ED visit, blood draw, monitoring - (b) (6)

20. Has the patient recovered from the adverse event(s)?: Unknown

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 902557
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 902557 - 2
E-Number: 207131
Doc Number: 1299846
Date Received: 12/16/2020 4:06 AM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (last)
Address: (b) (3) (A), (b) (6)
City:
State: **ZIP:**
County:
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/15/2020 **Time:** 17:50

5. Date and time adverse event started: 12/15/2020 **Time:** 18:00

6. Age at vaccination: 32 yr.

7. Today's date: 12/16/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Vit D, Women's Multivitamin, Nuvaring

10. Allergies to medications, food, or other products:
None known

11. Other illnesses at the time of vaccination and up to one month prior:
None

12. Chronic or long-standing health conditions:
None

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Noble Anderson, MD
Relation to Patient: Healthcare professional/staff
Address: 3260 Hospital Drive
City: Juneau
State: AK **ZIP:** 99801
Phone: (907) 796-8900
Email: nanderson@bartletthospital.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Noble Anderson
Phone: (907) 796-8473 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Bartlett Regional Hospital
Fax: (907) 796-8478
Facility Address:
3260 Hospital Drive
City: Juneau
State: AK **ZIP:** 99801
Phone: (907) 796-8900

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EK5730	Intramuscular - IM	Right Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Anaphylactic reaction onset 10 minutes after injection. Primary symptoms of diffuse erythematous rash, dyspnea, and dizziness. Patient treated with Diphenhydramine, followed by 0.3mg epinephrine IM w/ improvement of symptoms. Symptoms (b) (6)

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care
* Hospitalization (1 day, Hospital: (b) (6)
* Life threatening illness

recurred/worsened and second dose of epi was given, followed by epinephrine drip. She has recurrence of symptoms with severe dyspnea and diffuse erythema/flushing within 60 seconds of discontinuation of epinephrine. Patient remains on epi drip and is currently admitted to Critical Care Unit for ongoing treatment and observation.

19. Medical tests and laboratory results related to the adverse event(s):
Initial CBC, BMP, CRP, Troponin - remarkable only for mild hypokalemia, and mildly elevated AST/ALT (50/72). TSH mildly elevated at 8.83, but normal FT4.

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 903197
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 903197 - 1
E-Number: 207534
Doc Number: 1300647
Date Received: 12/17/2020 4:58 PM
Severity: Non-Serious
Consolidated: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (3) (A), (b) (6) (last) (b) (3) (A), (b) (6)
Address: (b) (3) (A), (b) (6)
City: (b) (3) (A), (b) (6)
State: (b) (3) (A), **ZIP** (b) (3) (A), (b) (6)
County (b) (3) (A), (b) (6)
Phone:
Email: (b) (3) (A), (b) (6)

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/17/2020 **Time:** AM

5. Date and time adverse event started: 12/17/2020 **Time:** PM

6. Age at vaccination: 33 yr.

7. Today's date: 12/17/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Benadryl 25mg 1hr before vaccine

10. Allergies to medications, food, or other products:
no known

11. Other illnesses at the time of vaccination and up to one month prior:
no

12. Chronic or long-standing health conditions:
no

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Catherine Messenger
Relation to Patient: Healthcare professional/staff
Address: 1650 Cowles St
City: Fairbanks
State: AK **ZIP:** 99701
Phone: (907) 458-4252
Email: catherine.messenger@foundationhealth.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Dr.Blas
Phone: (907) 458-4252 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: FHP Occupational Health
Fax: (907) 458-5094
Facility Address: 1650 Cowles St
City: Fairbanks
State: AK **ZIP:** 99701
Phone: (907) 458-4252

16. Type of facility: Workplace clinic

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EJ1685	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Swollen tongue, scratchy throat, rash, tachycardia, and raspy voice

19. Medical tests and laboratory results related to the adverse event(s):

21. Result or outcome of adverse event(s): (Check all that apply).
* None of the above

none at this time

20. Has the patient recovered from the adverse event(s)?: Unknown

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:** No

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 903197
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 903197 - 2
E-Number: 207935
Doc Number: 1301273
Date Received: 12/18/2020 3:42 PM
Severity: Non-Serious
Consolidated: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (3) (A), (b) (6) (last) (b) (3) (A), (b) (6)
Address: (b) (3) (A), (b) (6)
City: (b) (3) (A), (b) (6)
State: **ZIP:** (b) (3) (A), (b) (6)
County: (b) (3) (A), (b) (6)
Phone: (b) (3) (A), (b) (6)
Email: (b) (3) (A), (b) (6)

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/17/2020 **Time:** 11:45

5. Date and time adverse event started: 12/17/2020 **Time:** 12:05

6. Age at vaccination: 33 yr. 0 mon.

7. Today's date: 12/18/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Benadryl 25mg 1 hr prior to vaccination

10. Allergies to medications, food, or other products:
Mild allergic reaction to scallops, no other shellfish, local reaction to bee sting

11. Other illnesses at the time of vaccination and up to one month prior:
None

12. Chronic or long-standing health conditions:
None

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6)
Relation to Patient: Patient
Address: (b) (6)
City: (b) (6)
State: **ZIP:** (b) (6)
Phone: (b) (6)
Email: (b) (6)
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Dr Owen Hanley
Phone: (907) 450-9151 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Fairbanks memorial hospital
Fax:
Facility Address:
1650 cowles st
City: Fairbanks
State: AK **ZIP:** 99701
Phone: (907) 458-6424

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EJ1685	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Anaphylaxis requiring ER admission and administration of epinephrine x2 doses, steroids,

21. Result or outcome of adverse event(s): (Check all that apply).
* Doctor or other healthcare professional office/clinic visit
* Emergency room/department or urgent care

antihistamines, IV fluid, singular.

19. Medical tests and laboratory results related to the adverse event(s):
Serum tryptase pending

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 903243
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 903243 - 1
E-Number: 207580
Doc Number: 1300694
Date Received: 12/17/2020 6:56 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6) (b) (3) (A)
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/17/2020 **Time:**

5. Date and time adverse event started: 12/17/2020 **Time:** 13:48

6. Age at vaccination: 49 yr.

7. Today's date: 12/17/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Apixaban 5mg BID
Metformin 500mg Daily
Chlorthalidone 12.5mg weekly
Metoprolol 100mg ER BID
Clonidine 0.1mg Q8H
Atorvastatin 20mg QPM
Magnesium Oxide 400mg Daily
Tramadol 50mg Q6H
Diphenhydramine Q6H PRN
Epinephrine 0.3MG Injector PRN serious allergic reaction

10. Allergies to medications, food, or other products:
Iodonated Contrast media

11. Other illnesses at the time of vaccination and up to one month prior:
Strep Pharyngitis 11/29/20; resolved at time of vaccination

12. Chronic or long-standing health conditions:
Essential Hypertension
Protein C Deficiency
Lumbosacral Radiculopathy
Type 2 Diabetes Mellitus
Pulmonary Embolism

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Eric Ritchie, MD
Relation to Patient: Healthcare professional/staff
Address: Highway 191 and Hospital Drive
City: Chinle
State: AZ **ZIP:** 86503
Phone: (928) 674-7001
Email: eric.ritchie@ihs.gov
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Kirk Smith
Phone: (928) 674-7001 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Chinle Comprehensive Healthcare Facility
Fax: (928) 674-7341
Facility Address: Highway 191 and Hospital Drive
City: Chinle
State: AZ **ZIP:** 86503
Phone: (928) 674-7001

16. Type of facility: Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EK5730	Intramuscular - IM	Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Patient developed hives, facial swelling, throat swelling/itching, and nausea approximately 13min after vaccination while in observation. Patient immediately taken to Emergency Department where epinephrine was given IM in the left thigh followed by 125mg IV solumedrol, 50mg IV benadryl, 1000mL NS, and 20mg IV famotidine. Hemodynamically stable throughout ED course.

19. Medical tests and laboratory results related to the adverse event(s):
CRP- 11.0
Glucose- 182
BUN- 29
INR- 1.1
Remained of CMP and CBC are WNL

20. Has the patient recovered from the adverse event(s)?: Yes

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race:

25. Patient's ethnicity: Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 903400
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 903400 - 1
E-Number: 207694
Doc Number: 1300892
Date Received: 12/18/2020 10:18 AM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address:
City:
State: ZIP:
County:
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/17/2020 **Time:** 11:30

5. Date and time adverse event started: 12/17/2020 **Time:** 11:35

6. Age at vaccination: 55 yr.

7. Today's date: 12/18/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Atorvastatin 20 mg once daily

10. Allergies to medications, food, or other products:
Fish
Iodine
Shellfish
Rabies vaccine

11. Other illnesses at the time of vaccination and up to one month prior:
None

12. Chronic or long-standing health conditions:
Severe allergies

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Alla Khaytin
Relation to Patient: Healthcare professional/staff
Address: 3201 Kingshighway
City: Brooklyn
State: NY **ZIP:** 11234
Phone: (646) 330-2362
Email: alla.melamedkhaytin@mountsinai.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Eliezer Parnes
Phone: (718) 338-2283 **Ext:** 205

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Fax:
Facility Address:
3201 Kingshighway
City: Brooklyn
State: NY **ZIP:**
11234
Phone: (646) 330-2362

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EK5730	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
5 minutes after the Pfizer Covid-19 vaccine administration, the patient developed flushing, hives, felt warm and eventually short of breath. She

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care
* Hospitalization (2 days, Hospital: (b) (6) (b) (6)
* Life threatening illness

started to wheeze and was wheeled into ER c/o "I can't breathe while holding throat and thrashing with facial flushness noted. PT took 2 Benadryls and had several Epi shots. She was then discharged from the ER and later on that day, started to feel short of breath again. In the ED today she was audibly gasping for air, however had no wheezing, had a normal saturation and a normal blood pressure. She had taken another dose of her EpiPen IM and diphenhydramine 50 mg by mouth prior to coming. She was then admitted to the hospital for further observation. While on the floor, she started to feel short of breath again (about 9 am on (b) (6) which required an RRT . Patient received another dose of diphenhydramine IV, methylprednisolone 125 mg IV and several doses of IM epinephrine. She also required oxygen. She was then transferred to an ICU for further care.

19. Medical tests and laboratory results related to the adverse event(s):
NA

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: Yes
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):
Rabies vaccine

24. Patient's race: White

25. Patient's ethnicity: Unknown

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 903400
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 903400 - 2
E-Number: 208614
Doc Number: 1301959
Date Received: 12/20/2020 11:43 AM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:**
County:
Phone: (b) (6), (b) (3) (A)
Email: (b) (6), (b) (3) (A)

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/17/2020 **Time:** 11:54

5. Date and time adverse event started: 12/17/2020 **Time:** 12:00

6. Age at vaccination: 55 yr.

7. Today's date: 12/20/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
levothyroxine 100 mcg qd
montelukast 10 mg qd
proair prn
Benadryl 25 mg
decadron 4 mg

10. Allergies to medications, food, or other products:
anaphylaxis to fish 2015 (Although IgE testing was negative as per patient), prohance contrast 2015, Rabies vaccine (Rabies Ig, post cat bite she had resp distress, no intubation)

11. Other illnesses at the time of vaccination and up to one month prior:
none

12. Chronic or long-standing health conditions:
Hypothyroidism, HLD, osteoporosis, GERD, Vertigo, asthma (Diagnosed in 2015, previously on Brio/ rescue inhaler, currently on montelukast and proair)

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Holly Corkill, MD
Relation to Patient: Healthcare professional/staff
Address: 1 Gustave L. Levy place
City: New York
State: NY **ZIP:** 10029
Phone: (212) 241-5111
Email: holly.corkill@mountsinai.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Jennifer Wang
Phone: (212) 241-5111 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Mount Sinai Hospital/Surgical ICU
Fax: (212) 426-0099
Facility Address:
3201 Kings Highway
City: Brooklyn
State: NY **ZIP:** 11234
Phone: (718) 252-3000

16. Type of facility:
Workplace clinic

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	

					Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EK5730	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
On 12/17/2020 she received the COVID 19 vaccine at 11:54 am, patient noted she was premedicated prior to the vaccine with Decadron 4 mg and Benadryl 25 mg. Prior to that patient only had breakfast at 4:00 am which consisted on cheerios, she did not have any thing else additional to eat prior to receiving the vaccine. Almost immediately after having the vaccine the patient began to have a red rash to the chest which progressed to the face, she then began to experience shortness of breath followed by respiratory distress, she self administered Epinephrine, received additional steroids, pepcid, epinenephrine was observed and sent home on benadryl Q6hrly. Around 11:20 pm on that same day she began to experience cough and wheezing, she intially thought it was asthma but noticed additional hives and started to experience respiratory distress. She self injected her epipen and went to the ED at (b) (6) . In the ED she was noted to be in respiratory distress and was complaining of cough, choking sensation, she received an additional dose of Epinephrine, pepcid, steroids and benadryl and was admitted to the medicine floor for observation. While on the floor she began to experience another episode of anaphylaxis described as throat tightening , wheezing with rash developing over chest. This progressed to angioedema/tongue swelling despite appropriate treatment with IM Epi 0.5 mg x 2 and steroids. ENT scoped at bed side with Pertinent Endoscopy Findings: intact septum, boggy nasal turbinates, pale middle meatal mucosa, no lesions within nasopharynx, non-obstructive base of tongue but with mild edema almost touching epiglottis, epiglottis in normal position with no lesions, no edema of false cords, true cords mobile, no edema of arytenoid and post-cricoid mucosa, no pooling in hypopharynx. The remainder of the examination was normal. Post Procedure Diagnosis: mild tongue edema but with widely patent larynx. She was initiated on an Epinephrine Drip and transferred to the ICU. The patient continued on the Epi drip and was weened on (b) (6) around 18:59, with symptoms of tongue swelling improving. Patient was fed and shortly after (pasta with a meat sauce thought to be beef and apple sauce), dietician was contacted at (b) (6) (b) (6) to confirm practices of meal preparation in the hospital kitchen for possible cross contamination with fish. After dinner she began to feel facial flushing especially to the left side of her face with funny sensations leading down he left arm and associated chest pressure, EKG showed normal sinus rhythm, she was placed on oxygen via nasal cannula and Epi drip restarted. Predominantly all symptoms were upper airway with no signs of systemic shock, she did not experience vomiting or diarrhea. Course was also complicated by mild steroid induced hyperglycemia, endocrine was consulted to assist in management. She was transferred to (b) (6) for

21. Result or outcome of adverse event(s): (Check all that apply).
* Hospitalization (3 days, Hospital: (b) (6) transferred to (b) (6))
* Life threatening illness

continued management and remained on upon transfer. She continues on epi 2 mcg/min and remains asymptomatic.

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: Yes
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):
rabies vaccine 4/30/2018 GSK SW0127AA

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 903469
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 903469 - 1
E-Number: 207745
Doc Number: 1300969
Date Received: 12/18/2020 11:48 AM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6), (b) (3) (A)
Phone: (b) (6), (b) (3) (A)
Email: (b) (6)

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/17/2020 **Time:** 17:30

5. Date and time adverse event started: 12/17/2020 **Time:** 17:40

6. Age at vaccination: 46 yr.

7. Today's date: 12/18/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Levothyroxine
Meloxicam

10. Allergies to medications, food, or other products:
Latex
Pine nuts
Codeine
Hydrocodone

11. Other illnesses at the time of vaccination and up to one month prior:
Hypothyroidism
Osteoarthritis

12. Chronic or long-standing health conditions:
Hypothyroidism
Osteoarthritis

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6)
Relation to Patient: Patient
Address: (b) (6)
City: (b) (6) (b) (6)
State: **ZIP:**
Phone: (b) (6)
Email: (b) (6)
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Tandy Warren RN infection control/ employee healtj
Phone: (405) 756-1404 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Lindsay municipal hospital
Fax:
Facility Address:
1305 west Cherokee
City: Lindsay municipal hospital
State: OK **ZIP:** 73052
Phone: (405) 756-1404

16. Type of facility:
Workplace clinic

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech		Intramuscular - IM	Right Arm	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Initial within 10 minutes, redness and burning pain at site. Ice was applied and this went away, then about 25 minutes, itchy throat, trouble swallowing, mild confusion. Oral benadryl 50mh and solumedrol IM. Once again this dissapated after 30 minutes. 3 hours later, trouble swallowing, felt as if something was in my throat, redness and flushing all over.fluid bolus, epinephrine I'm, iv benadryl, pepcid oral, and claritin oral, fluid bolus. 12 hours after getting the vaccine blurry vision, ringing ears, headache, benadryl, steroid, claritin all oral

19. Medical tests and laboratory results related to the adverse event(s):
None

20. Has the patient recovered from the adverse event(s)?: No

21. Result or outcome of adverse event(s): (Check all that apply).
* Doctor or other healthcare professional office/clinic visit
* Emergency room/department or urgent care

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: Yes
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):
Flu shot 2010, 2011, 2012, 2013, 2017, started with just topical redness at sight and then over the years developed into an itchy throat and rash at site

24. Patient's race: American Indian or Alaska Native, White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site: No

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 903469
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 903469 - 2
E-Number: 207885
Doc Number: 1301222
Date Received: 12/18/2020 2:48 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6), (b) (3) (A)
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/17/2020 **Time:** 19:30

5. Date and time adverse event started: 12/17/2020 **Time:** 19:58

6. Age at vaccination: 46 yr. **7. Today's date:** 12/18/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Levothyroxine
Fioricet
Vitamin C
Elderberry

10. Allergies to medications, food, or other products:
Latex - Anaphylaxis
Hydrocodone - Anaphylaxis
Flu Vaccine/latex stopper in multi-dose vials - Severe
Codeine
Tape

11. Other illnesses at the time of vaccination and up to one month prior:
Recipient marked, "No" on question, "Does the person to be vaccinated have a fever today (>100F orally)?

12. Chronic or long-standing health conditions:
Migraines
Hypothyroidism

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Tandy Warren
Relation to Patient: Healthcare professional/staff
Address: 1305 West Cherokee
City: Lindsay
State: OK **ZIP:** 73052
Phone: (405) 756-1404
Email: twarren@lindsaymunicipalhospital.com
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Tandy N Warren
Phone: (405) 756-1404 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Lindsay Municipal Hospital
Fax: (405) 756-1802
Facility Address:
1305 West Cherokee
City: Lindsay
State: OK **ZIP:** 73052
Phone: (405) 756-1404

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
	Pfizer\BioNTech	EKS730			1

1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Intramuscular - IM	Right Arm

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Recipient voiced arm soreness to observation monitor, localized erythema noted, ice pack provided. Recipient voiced scratchy throat at 17:58, Benadryl 50mg po administered. Provider notified and Solumedrol 125mg IM X1 ordered 1810. 1814 Solumedrol administered. 1825 recipient voiced feeling better and requested to go work. 1835 after 20 minute post IM observation, injection site noted improved with very pale pink discoloration noted to site. Stay with recipient, vitals improved and provider notified at 1855. Recipient stays at hospital to be driven home by son after work. While waiting at 1942 with worsening of symptoms seen at onsite ER. Normal Saline Fluids, Epinephrine 1:1000 0.3mg given IM, Zyrtec 10mg po, Pepcis 20mg po and Zofran 4mg IVP received. Pt improved and discharged home to follow up with PCP. 12/18/2020, recipient contacts DON advising headache and tired, but improved and appt. at Dr. s office 12/18/2020.

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: Yes

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: Yes
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):
Previously to influenza vaccine and advised was not due to vaccine but to latex stopper. Pt has received flu vaccine from single dose syringe since.

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 903537
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 903537 - 1
E-Number: 207803
Doc Number: 1301050
Date Received: 12/18/2020 1:11 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address:
City:
State: ZIP:
County:
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/18/2020 **Time:**

5. Date and time adverse event started: 12/18/2020 **Time:** 11:19

6. Age at vaccination: 41 yr.

7. Today's date: 12/18/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:
Phenergan, Compazine,

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:
SVT

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Geneva Stange RN
Relation to Patient: Healthcare professional/staff
Address:
City:
State: ZIP:
Phone:
Email: geneva.stange@lovelace.com
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Lovelace Westside Hospital
Fax:
Facility Address:
10501 Golf Course Rd
City: Albuquerque
State: NM **ZIP:** 87114
Phone: (505) 727-2000

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EH 9899	Needle and Syringe (not specified further) - SYR	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Metallic taste, chest pain, coughing or throat clearing, bilateral arm numbness

19. Medical tests and laboratory results related to the adverse event(s):

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

20. Has the patient recovered from the adverse event(s)?: Unknown

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race:

25. Patient's ethnicity: **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:** No

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 903922
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 903922 - 1
E-Number: 208150
Doc Number: 1301490
Date Received: 12/18/2020 8:07 PM
Severity: Serious
Received By: Public Site Upload (writable pdf; version: 2.0.08) View PDF
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) [redacted] (last) [redacted]
Address: [redacted]
City: [redacted]
State: [redacted] **ZIP:** [redacted]
County: [redacted]
Phone: [redacted]
Email:

2. Date of birth: [redacted]

3. Sex: Female

4. Date and time of vaccination: 12/18/2020 **Time:** 13:52

5. Date and time adverse event started: 12/18/2020 **Time:** 14:00

6. Age at vaccination: 30 yr.

7. Today's date: 12/18/2020

8. Pregnant at the time of vaccination?: Unknown

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Allegra, Singulair, Pepcid, Vit D

10. Allergies to medications, food, or other products:
Erenumab-aooe, Prednisone, Bees

11. Other illnesses at the time of vaccination and up to one month prior:
None

12. Chronic or long-standing health conditions:
Migraines, allergic rhinitis

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Kristen Cooper
Relation to Patient: Healthcare professional/staff
Address: 801 S. Milwaukee Ave
City: Libertyville
State: IL **ZIP:** 60048
Phone: (847) 362-2900
Email:

14. Best doctor/healthcare professional to contact about the adverse event:
Name: John Piotrowski
Phone: (847) 998-9148 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: AAH Condell Medical Center
Fax:
Facility Address:
801 S. Milwaukee Ave
City: Libertyville
State: IL **ZIP:** 60048
Phone: (847) 362-2900

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EJ1685	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Patient complaint of rash,hives,difficulty breathing and swallowing, wheezing, throat tightness, hoarseness, itching and feeling light headed less than 10 minutes after receiving the vaccine. Patient received Benadryl 50mg IVP, Pepcid 20mg IVP,

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

0.3mg epi IM. EMS arrived and transported patient to ED.
In ED, patient received second dose of 0.3mg epi IM. Patient monitored in ED for approximately 4 hours. Epi drip started and plan to admit patient for observation.

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

PDF UPLOAD DATA

SessionId	File Size	File Name	Created On	Uploader Name	Uploader Email
(b) (6)	3577471 kb	VAERSForm_VS.pdf	12/18/2020	Kristen Cooper	kristen.cooper@aah.org

VAERS ID: 903945
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 903945 - 1
E-Number: 208173
Doc Number: 1301513
Date Received: 12/18/2020 9:00 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County:
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/16/2020 **Time:** 14:50

5. Date and time adverse event started: 12/16/2020 **Time:** 15:00

6. Age at vaccination: 60 yr.

7. Today's date: 12/18/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Allegra, lisinopril, dexilant,Motrin, victoza, insulin

10. Allergies to medications, food, or other products:
Latex, asprin, sulpha
History of allergic reaction to hepatitis andtetnus(40 years ago), anaphylaxis to jellyfish sting
Allergy to eggs, milk

11. Other illnesses at the time of vaccination and up to one month prior:
Diabetes, hypertension, asthma

12. Chronic or long-standing health conditions:
As above

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6)
Relation to Patient: Patient
Address: (b) (6)
City: (b) (6)
State (b) (6) **ZIP** (b) (6)
Phone: (b) (6)
Email: (b) (6)
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Sean Higgins
Phone: (907) 264-1222 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Alaska Regional Hospital
Fax:
Facility Address:
2801 Debarr Road
City: Anchorage
State: AK **ZIP:** 99508
Phone: (907) 276-1131

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EH9899	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Itching started immediately, throat tightness SOB in

21. Result or outcome of adverse event(s): (Check all that apply).
* None of the above

about 10 minutes with hives on chest

19. Medical tests and laboratory results related to the adverse event(s):
(b) (6) -no labs, IV Benadryl, Pepcid and decadron. I2m epinephrine sent home at 9 pm
(b) (6) - took epi pen at home in the morning back to ER given IV decadron, labs, ekg, chest X-ray done discharged home at 6pm

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: Yes
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 903945
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 903945 - 2
E-Number: 208357
Doc Number: 1301697
Date Received: 12/19/2020 1:19 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (last)
Address:
City:
State: **ZIP**
County:
Phone:
Email:

2. Date of birth:

3. Sex: Female

4. Date and time of vaccination: 12/16/2020 **Time:** 14:30

5. Date and time adverse event started: 12/16/2020 **Time:** 14:35

6. Age at vaccination: 60 yr.

7. Today's date: 12/19/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:
States severe allergic reactions to hepatitis vaccine; tetanus booster; sulpha medications - no other information available for other allergies

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:
States medical conditions on vaccine form to include including asthma, high blood pressure, obesity, type 2 diabetes

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to Patient: Healthcare professional/staff
Address:
City:
State: **ZIP:**
Phone:
Email:
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Alaska Regional Hospital
Fax:
Facility Address:
2801 Debarr Rd
City: Anchorage
State: AK **ZIP:** 99508
Phone: (907) 276-1131

16. Type of facility: Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EH9899	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time

21. Result or outcome of adverse event(s): (Check all that apply).

course, etc.)
Patient herself not initially not too concerned, she has had multiple adverse reactions since childhood, she had discussed taking the vaccine with her PCP prior to vaccination, and had her own EPI pens with her. She did not want to take Benadryl because of side effects, and she was supposed to return to work; but had taken Allegra prior to coming to vaccine clinic. Patient reported itching in injection site, then expanding to include both arms, and scalp, with redness on chest and face and hives on skin; reported scratchy throat; pt ambulated self to ER accompanied by ICU RN staff, this writer is unaware of presenting symptoms or treatment received in ER,. She was monitored in ER until 9pm that evening. Pt returned to ER for a second visit on (b) (6) writer unaware of symptoms or treatments at the time.

* Doctor or other healthcare professional office/clinic visit
* Emergency room/department or urgent care

19. Medical tests and laboratory results related to the adverse event(s):
unknown

20. Has the patient recovered from the adverse event(s)?: Unknown

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: Yes
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):
Tetanus booster, hepatitis vaccine

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 904033
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 904033 - 1
E-Number: 208261
Doc Number: 1301601
Date Received: 12/19/2020 8:58 AM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: (b) (6), **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6), (b) (3) (A)
Phone:
Email: (b) (6), (b) (3) (A)

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/18/2020 **Time:** 16:30

5. Date and time adverse event started: 12/18/2020 **Time:** 17:00

6. Age at vaccination: 30 yr.

7. Today's date: 12/19/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Fluoxetine 10mg, prenatals, claratin

10. Allergies to medications, food, or other products:
Seasonal allergies, allergic to dogs and cats (hives and wheezing)

11. Other illnesses at the time of vaccination and up to one month prior:
none

12. Chronic or long-standing health conditions:
anxiety, hx of asthma (over 3 years without symptoms), recurrent miscarriages

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6)
Relation to Patient: Patient
Address: (b) (6)
City: (b) (6)
State: **ZIP:** (b) (6)
Phone (b) (6)
Email: (b) (6)
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Lawrence K Lim, DO
Phone: (773) 665-3086 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
AMITA Health SJH
Fax:
Facility Address:
2900 N Lakeshore Drive
City: Chicago
State: IL **ZIP:** 60614
Phone: (773) 665-3086

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech		Needle and Syringe (not specified further) - SYR	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
lightheadedness, elevated BP, hives, wheezing, hot flashes, pressure on chest

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race:

25. Patient's ethnicity: Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 904033
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 904033 - 2
E-Number: 209921
Doc Number: 1304626
Date Received: 12/22/2020 2:32 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address:
City:
State: ZIP:
County:
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/18/2020 **Time:**

5. Date and time adverse event started: 12/18/2020 **Time:**

6. Age at vaccination: 30 yr.

7. Today's date: 12/22/2020

8. Pregnant at the time of vaccination?:

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Jonathan Stevens, RN
Relation to Patient: Healthcare professional/staff
Address:
City:
State: ZIP:
Phone:
Email: jonathan.stevens@amitahealth.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Fax:
Facility Address:
City:
State: ZIP:
Phone:

16. Type of facility:
Other: hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EJ1685	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Dizziness upon standing, post-vaccine; wheezing, sweating, c/o "chest heaviness"; redness at L arm, red streaks to chest; itching. Taken to ER for further assessment. Follow-up call 12/22/20: patient states she was given IV Benadry and albuterol breathing treatments, with resolution of wheezing and

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

improvement of redness/itching. Itching continues; saw PCP; prescribed Benadryl 50mg Q6hs and Prednisone 50mg Qday, with improvement. Recommended not to take dose #2.

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?:

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race:

25. Patient's ethnicity: **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

Next 1 Vaers IDs

VAERS ID: 904055

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 904055 - 1
E-Number: 208283
Doc Number: 1301623
Date Received: 12/19/2020 10:14 AM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) [redacted] (last) [redacted]
Address: [redacted]
City: [redacted]
State: [redacted] **ZIP:** [redacted]
County: [redacted]
Phone:
Email:

2. Date of birth: [redacted]

3. Sex: Female

4. Date and time of vaccination: 12/18/2020 **Time:** 18:16

5. Date and time adverse event started: 12/19/2020 **Time:** 18:50

6. Age at vaccination: 44 yr. **7. Today's date:** 12/19/2020

8. Pregnant at the time of vaccination?: Unknown

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Per medical record: bimatoprost, desvenlafaxine, levothyroxine, montelukast, phentermine, tretinoin cream, zolpidem

10. Allergies to medications, food, or other products:
Soybean, Corn containing products, Peanut noted in chart. Patient verbally reported anaphylaxis to H1N1 influenza vaccine.

11. Other illnesses at the time of vaccination and up to one month prior:
unknown

12. Chronic or long-standing health conditions:
unknown

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Christopher Martin
Relation to Patient: Healthcare professional/staff
Address: 17384 CABIN HILL LN
City: COLORADO SPRINGS
State: CO **ZIP:** 80908-1463
Phone: (719) 233-6867
Email: christopher.martin@uchealth.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Christopher Martin
Phone: (719) 233-6867 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: UCHealth Memorial Hospital Central - MAC COVID 19 Vaccine Clinic
Fax:
Facility Address: 1400 E Boulder St
City: Colorado Springs
State: CO **ZIP:** 80909
Phone: (719) 365-5000

16. Type of facility:
Other: employee vaccine clinic

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EH9899	Intramuscular - IM	Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Patient received vaccine at 18:16. Approximately 18:50 the patient complained of numbness and tingling around her bottom lip. Lips were noted to be slightly swollen and cyanotic. Speech was observed to be slurred. Diphenhydramine suspension 50 mg PO was administered. At 19:15 patient was noted to have hives on her neck, upper chest and upper arms which continued to become more prominent. 911 was subsequently called and epinephrine administration was advised. Epinephrine 0.3 mg IM was administered at 19:34. Improved coloration and reduction in hives was observed after epinephrine administration. Patient was transported to the (b) (6) ED.

19. Medical tests and laboratory results related to the adverse event(s):
Vital signs:
1900: 147/92; 82; 97% room air
1905: 132/101; 84; 97% room air
1910: 145/104; 84; 97% room air.
1915: 147/104; 81; 97% room air

20. Has the patient recovered from the adverse event(s)?: Unknown

21. Result or outcome of adverse event(s): (Check all that apply).
* None of the above

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: Yes
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):
Patient reported anaphylaxis to H1N1 influenza vaccine

24. Patient's race: White

25. Patient's ethnicity: Unknown

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 904334
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 904334 - 1
E-Number: 208557
Doc Number: 1301902
Date Received: 12/20/2020 12:27 AM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6), (b) (3) (A)
Phone:
Email: (b) (6), (b) (3) (A)

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/19/2020 **Time:** 18:00

5. Date and time adverse event started: 12/19/2020 **Time:** 18:10

6. Age at vaccination: 29 yr.

7. Today's date: 12/20/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
none

10. Allergies to medications, food, or other products:
shrimp and eggs

11. Other illnesses at the time of vaccination and up to one month prior:
none

12. Chronic or long-standing health conditions:
none

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Laurel R Berge MD
Relation to Patient: Healthcare professional/staff
Address: 10800 SE Sunnyside Road
City: Clackamas
State: OR **ZIP:** 97015
Phone: (971) 334-5897
Email: Laurel.r.berge@kp.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Laurel R Berge MD
Phone: (505) 980-1476 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Kaiser Sunnyside Medical Center
Fax:
Facility Address:
10800 SE Sunnyside Road
City: Clackamas
State: OR **ZIP:** 97015
Phone: (971) 334-5897

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EJ1685	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Angioedema, hives, tachycardia, shortness of breath

19. Medical tests and laboratory results related to the adverse event(s):

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care
* Life threatening illness

CBC and BMP - normal

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: Other: Hispanic

25. Patient's ethnicity: Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:** No

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 905674
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 905674 - 1
E-Number: 209257
Doc Number: 1303381
Date Received: 12/21/2020 3:54 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: (b) (6), (b) (3) (A) **ZIP:** (b) (6), (b) (3) (A)
County:
Phone: (b) (6), (b) (3) (A)
Email: (b) (6), (b) (3) (A)

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/21/2020 **Time:** 12:15

5. Date and time adverse event started: 12/21/2020 **Time:** 12:30

6. Age at vaccination: 57 yr.

7. Today's date: 12/21/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:
Penicillins, Azithromycin, Spinach

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) ANDREW T ROSS
Relation to Patient: Healthcare professional/staff
Address: 100 KENYON AVE
City: WAKEFIELD
State: RI **ZIP:** 02879
Phone: (401) 788-1545
Email: AROSS@SOUTHCOUNTYHEALTH.ORG
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: ANDREW T ROSS
Phone: (401) 788-1545 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
South County Health
Fax:
Facility Address:
100 KENYON AVE
City: WAKEFIELD
State: RI **ZIP:** 02879
Phone: (401) 788-1545

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EL0140	Intramuscular - IM		1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Patient pre-medicated with diphenhydramine due to infusion-type reactions in past. Patient with hoarse voice, itchiness to upper back, arms, and face, hives on bilateral arms. Per health system protocol (patient is (b) (6) Patient administered diphenhydramine, famotidine, methylprednisolone succinate, epinephrine. All symptoms resolved by 1440.

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Unknown **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 906002
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 906002 - 1
E-Number: 209507
Doc Number: 1303724
Date Received: 12/21/2020 10:10 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:**
County: (b) (6), (b) (3) (A)
Phone: (b) (6), (b) (3) (A)
Email: (b) (6), (b) (3) (A)

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/21/2020 **Time:** 13:44

5. Date and time adverse event started: 12/21/2020 **Time:** 14:30

6. Age at vaccination: 27 yr.

7. Today's date: 12/21/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
None. Took and oral Pepcid and Zyrtec around noon on 12/21/20 in anticipation of possible symptoms from vaccine.

10. Allergies to medications, food, or other products:
Had syncopal episode with Gardasil vaccine in teens. Food allergy to pineapple. No other known allergies.

11. Other illnesses at the time of vaccination and up to one month prior:
None

12. Chronic or long-standing health conditions:
None

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Dr. Lisa Rabinowitz
Relation to Patient: Healthcare professional/staff
Address: 3600 Providence DR
City: Anchorage
State: AK **ZIP:** 99508
Phone: (907) 212-3111
Email: lisarabinowitz@msn.com
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Lisa Rabinowitz
Phone: (907) 350-9088 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Providence Alaska oncology infusion clinic
Fax:
Facility Address:
3600 Providence DR
City: Anchorage
State: AK **ZIP:** 99508
Phone: (907) 212-3111

16. Type of facility:
Workplace clinic

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	13827	Intramuscular - IM		

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
2 min post injection developed tingling around site, and then urticaria on left upper arm. Then diffuse flushing diffusely and headache. HR=130's, normal

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

BP. Difficulty swallowing during EMS transport. Received EPI sc, Pepcid IV, and Benadryl 50mg IV PTA. HR+140 on arrival post Epi

6 hour obs. NS 1L

D/c home with precautions, epilepsy pen rx, and allergist follow-up

19. Medical tests and laboratory results related to the adverse event(s):
tryptase level pending

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: Unknown

25. Patient's ethnicity: Unknown

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 906056
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 906056 - 1
E-Number: 209538
Doc Number: 1303798
Date Received: 12/22/2020 2:46 AM
Severity: Non-Serious
Consolidated: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6), (b) (3) (A)
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/21/2020 **Time:** 18:00

5. Date and time adverse event started: 12/21/2020 **Time:** 20:30

6. Age at vaccination: 29 yr.

7. Today's date: 12/22/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Tylenol, Albuterol, Airduo, Metformin, Trazodone

10. Allergies to medications, food, or other products:
Mometasone (myalgias)

11. Other illnesses at the time of vaccination and up to one month prior:
none

12. Chronic or long-standing health conditions:
Asthma, Obesity, Pre-diabetes, IBS

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Dirk Becker
Relation to Patient: Healthcare professional/staff
Address: 1500 E Medical Center Dr
City: Ann Arbor
State: MI **ZIP:** 48109
Phone: (734) 936-4000
Email: dirkbe@med.umich.edu
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Dirk Becker
Phone: (734) 936-4000 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Michigan Medicine Emergency Department
Fax:
Facility Address:
1500 E Medical Center Dr
City: Ann Arbor
State: MI **ZIP:** 48109
Phone: (734) 936-4000

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech		Intramuscular - IM	Right Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
(b) (6) notes that she received the COVID vaccine around 1800 today. After receiving the vaccine she notes she had developed a headache.

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

She was otherwise doing fine until around 2000-2100 when she noticed her left arm become numb with paresthesias from her left bicep to her hand with whole arm localization. She felt her hands and wrists were puffy at this time and somewhat swollen. She reports feeling "floaty"/Dizzy at this time, and at least once had to sit down due to this. She started feeling her heart race and some associated SOB, this has since resolved. She notes that she had two loose stools around this time as well.

This progressed to develop into right numbness/paresthesias from her mid right forearm down to her hands. As the evening progressed she developed itchiness of her bilateral arms and torso. She notes that she has had a waxing/waning reddish rash on her arms that has been pruritic. She has since developed intermittent nausea, and still endorses feeling some "skipped beats."

While in the ED from Triage to repeat evaluations her lips began having progressive swelling. She had been given Benadryl 50mg, Zofran 4mg, 1L IVF. Given ongoing tachycardia and lip swelling she was given Prednisone 40mg and Epinephrine for allergic reaction and concern for anaphylaxis.

19. Medical tests and laboratory results related to the adverse event(s):
CBC: 9.6>14.7<312
BMP: Na139, K3.8, Cl105, CO222, BUN 9, Cr 0.57
EKG: Sinus Tachycardia

20. Has the patient recovered from the adverse event(s)?: Unknown

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: Other: Hispanic

25. Patient's ethnicity: Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 906741
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 906741 - 1
E-Number: 209922
Doc Number: 1304627
Date Received: 12/22/2020 2:34 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6) (last) (b) (6), (b)
Address:
City:
State: ZIP:
County:
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Male

4. Date and time of vaccination: 12/22/2020 **Time:** 11:10

5. Date and time adverse event started: 12/22/2020 **Time:** 11:33

6. Age at vaccination: 45 yr. 0 mon.

7. Today's date: 12/22/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
None

10. Allergies to medications, food, or other products:
NKA

11. Other illnesses at the time of vaccination and up to one month prior:
None

12. Chronic or long-standing health conditions:
None

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Joseph Cruz
Relation to Patient: Healthcare professional/staff
Address: 718 Teaneck Rd.
City: Teaneck
State: NJ **ZIP:** 07666
Phone: (201) 833-7015
Email: Joscruz@holyname.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Holy Name Medical Center
Fax:
Facility Address:
718 Teaneck Rd.
City: Teaneck
State: NJ **ZIP:** 07666
Phone: (201) 833-7015

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EJ1685	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Approximately 20 minutes following COVID-19 vaccination the patient suddenly developed hives, itching - Hives around face and upper chest. Throat was red and slightly swollen. Was brought to the Emergency Department within out hospital for

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

assessment and medical care. Acute treatment included methylprednisolone 125 mg IV x 1 dose, diphenhydramine 50 mg IV x 1 dose, epinephrine 0.3 mg IM x 1 dose, and famotidine 20 mg IV x 1 dose. The patient felt better following this treatment Upon reassessment oropharyngeal swelling had improved, the patient no longer had hives and the throat appeared clear. The patient stated he no longer feels itchy but does feel a little short of breath. Lungs were clear with pulse oximetry 97%.

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race:

25. Patient's ethnicity: **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:** No

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 906970
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 906970 - 1
E-Number: 210152
Doc Number: 1304860
Date Received: 12/22/2020 5:52 PM
Severity: Non-Serious
Consolidated: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) [redacted] (last) [redacted]
Address:
City:
State: ZIP:
County:
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/22/2020 **Time:**

5. Date and time adverse event started: 12/22/2020 **Time:**

6. Age at vaccination: 30 yr. **7. Today's date:** 12/22/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:
Anaphylaxis to bee pollens and wasp venom

11. Other illnesses at the time of vaccination and up to one month prior:
None

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Ellen Pappas, DO
Relation to Patient: Healthcare professional/staff
Address:
City:
State: ZIP:
Phone:
Email: ellen.pappas@wellstar.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Wellstar Kennestone
Fax:
Facility Address:
City:
State: ZIP:
Phone:

16. Type of facility: Workplace clinic

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech				

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Pt developed throat tightening, shortness of breath, hives on the anterior chest after receiving COVID-19 Pfizer vaccine. She received vaccine around 9:15 AM and symptoms began at 9:28 AM. Received epi pen by vaccination station staff. Reported to ED. Observed for 3 hours with no further adverse effects. Treated with steroids, Pepcid, Benadryl.

21. Result or outcome of adverse event(s): (Check all that apply).
* Doctor or other healthcare professional office/clinic visit
* Emergency room/department or urgent care

Discharged home with epi pen, medrol dosepak, and allergy/immunology follow up.

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Unknown

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 906970
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 906970 - 2
E-Number: 210373
Doc Number: 1305172
Date Received: 12/23/2020 8:56 AM
Severity: Non-Serious
Consolidated: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County:
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/22/2020 **Time:** 09:13

5. Date and time adverse event started: 12/22/2020 **Time:** 09:15

6. Age at vaccination: 30 yr.

7. Today's date: 12/23/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
No

10. Allergies to medications, food, or other products:
insect sting

11. Other illnesses at the time of vaccination and up to one month prior:
No

12. Chronic or long-standing health conditions:
No

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to Patient: Parent/guardian/caregiver
Address: (b) (6)
City: (b) (6)
State: **ZIP:** (b) (6)
Phone:
Email: (b) (6)
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Wells Star Kennestone Hospital
Fax:
Facility Address:
677 Church Street
City: Marietta
State: GA **ZIP:** 30060
Phone: (770) 793-6000

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech			Left Arm	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
At 9:13am, I got my vaccine. I went to sit in the waiting area, then at 9:18, my throat began to be dry, I try to take Tylenol with some water. I could not swallow the water at all. I began sounding like I was snoring. Doctor saw me and I had hives on my chest and face. They gave me an epi pen within 10 mins of getting vaccine. I received some benadryl

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

and soyum medrall and pepcide. After that, they kept me for about 5 hours in the ER. My vitals were taken: bp 140/90. After released, I woke up with hives on my chest, and my face is flushed. I took my prescribed steroid this morning and a Benadryl. **NOTE: Hospital may have reported this already**

19. Medical tests and laboratory results related to the adverse event(s):
Pregnancy test: not pregnant

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: Yes
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):
Hep B- localized side effect

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 906988
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 906988 - 1
E-Number: 210169
Doc Number: 1304877
Date Received: 12/22/2020 6:08 PM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: (b) (6), (b) **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6), (b) (3) (A)
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/22/2020 **Time:** 15:03

5. Date and time adverse event started: 12/22/2020 **Time:** 15:10

6. Age at vaccination: 52 yr.

7. Today's date: 12/22/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
NONE KNOWN

10. Allergies to medications, food, or other products:
SULFA - ANAPHYLAXIS / EXERBATION OF ASTHMA

11. Other illnesses at the time of vaccination and up to one month prior:
NONE KNOWN

12. Chronic or long-standing health conditions:
ASTHMA

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6) (b) (6)
Relation to Patient: Healthcare professional/staff
Address: (b) (6)
City: (b) (6) (b) (6)
State: **ZIP:** (b) (6)
Phone: (b) (6)
Email:
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: RYAN McMORRIES MD
Phone: (256) 973-2175 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
DECATUR MORGAN HOSPITAL
Fax:
Facility Address:
1201 7TH STREET SE .
City: DECATUR
State: AL **ZIP:** 35601
Phone: (256) 973-2000

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EK5730	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
PT WAS OBSRVED IN HOLDING AREA LEANING FORWARD IN HER CHAIR ABOUT 7 MINUTES AFTER RECIEVING THE VACINE. RN ASSESSED AND

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care
* Life threatening illness

NOTED: AUDIBLE WHEEZE, RESP 40/MIN, LIP SWELLING AND PT COMPLAINED OF NAUSEA.
PT WAS ESCORTED TO ER IN WHEELCHAIR ACCOMPANIED BY 2 RN'S (2 MINUTE WALK)
ONE HOUR LATER - AS REPORTED BY DR (b) (6) (ER)
WORKING DIAGNOSIS - ANAPHYLAXIS / STATUS ASTHMATICUS
MEDS RECIEVED:
SOLUMEDROL 125, DIPHENHYDRAMINE 50MG, FAMOTIDINE 20MG --ALL IV
EPINEPHERINE 0.3MG IM X1 FOLLOWED BY 0.3MG IV X 1 FOLLOWED BY 0.1MG IV X1
PT IS RECIEVING O2 - AND PROGRESSING TO BIPAP

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: Other

25. Patient's ethnicity: Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 907019
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 907019 - 1
E-Number: 210198
Doc Number: 1304916
Date Received: 12/22/2020 6:40 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) [redacted] (last) [redacted]
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6), (b) (3) (A)
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/22/2020 **Time:** 12:25

5. Date and time adverse event started: 12/22/2020 **Time:** 13:19

6. Age at vaccination: 28 yr.

7. Today's date: 12/22/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Larissia 100mg-20mg PO QD

10. Allergies to medications, food, or other products:
Sulfa

11. Other illnesses at the time of vaccination and up to one month prior:
chronic tonsillitis

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Jennifer Radtke
Relation to Patient: Healthcare professional/staff
Address: 1924 Alcoa Highway
City: Knoxville
State: TN **ZIP:** 37922
Phone: (865) 305-9793
Email: Jradtke@utmck.edu
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Dr. Jonathan Koerten
Phone: (865) 305-9402 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: University of Tennessee Medical Center
Fax:
Facility Address:
1924 Alcoa Highway
City: Knoxville
State: TN **ZIP:** 37922
Phone: (865) 305-9793

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EJ1685	Intramuscular - IM	Unknown	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Pt returned to her work area. At 1314 - Team member was taken to the ED. She reported feeling like her tongue was swelling, she attempted to each chips and felt like her throat was sore and needed to be cleared. Pt had a syncopal episode and c/o chest

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

pressure, and difficulty swallowing (able to control secretions). Hives were noted to her face, neck & chest upon arrival to teh ED. At that time - pt reported feeling like her tongue started swelling 15 minutes after the vacciation. Pt was confused and "extremely" anxious. VS: 209/102, HR 125, RR 30 SaO2 96% r/a
1321 -diphenhydramine 25mg IV, pepcid 40mg IV and IV NS started VS: 159/105, HR 118, RR 31, SaO2 100% r/a
1322 - epinephrine 0.3mg SQ, Solumedrol 125mg IV
1332 - Zofran 4mg IV
1351 - Ativan 1mg IV
1359 - 128/91, HR 100, RR 22, SaO2 99%
1411 - pt calm- redness improved. still c/o of feeling something in her throat.
1441 - Calm, asking for a drink - tolerated well. BP 110/72, HR 82, RR 18, SaO2 98%
1635 - d/c orders written.

19. Medical tests and laboratory results related to the adverse event(s):
n/a

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 907173
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 907173 - 1
E-Number: 210330
Doc Number: 1305090
Date Received: 12/23/2020 1:24 AM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6), (b) (3) (A)
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/22/2020 **Time:**

5. Date and time adverse event started: 12/22/2020 **Time:** PM

6. Age at vaccination: 52 yr.

7. Today's date: 12/23/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Advair, Tylenol, Flexeril, Zyrtec, Norco, Singulair, Janumet, Turmeric, vitamin A

10. Allergies to medications, food, or other products:
Metoprolol, Biaxin, Lopressors, Robaxin,

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:
Obesity, asthma

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Cameron G Isaacs
Relation to Patient: Healthcare professional/staff
Address: (b) (6)
City: (b) (6)
State: (b) (6) **ZIP:** (b) (6)
Phone: (704) 657-7438
Email: (b) (6)
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Cameron G Isaacs
Phone: (704) 657-7438 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Alamance Regional Medical Center
Fax:
Facility Address:
1240 Huffman Mill Road
City: Burlington
State: NC **ZIP:** 27215
Phone:

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech		Intramuscular - IM	Left Arm	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Anaphylaxis reaction with hives, stridor/airway edema, wheezing

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date
999 - Vaccine not specified (no brand name)	UNKNOWN MANUFACTURER					

23. Has the patient ever had an adverse event following any previous vaccine?: Unknown
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 907173
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 907173 - 2
E-Number: 210668
Doc Number: 1305800
Date Received: 12/23/2020 2:23 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) [redacted] (last) [redacted]
Address: [redacted]
City: [redacted]
State: [redacted] **ZIP:** [redacted]
County: [redacted]
Phone: [redacted]
Email: [redacted]

2. Date of birth: [redacted]

3. Sex: Female

4. Date and time of vaccination: 12/22/2020 **Time:** 16:15

5. Date and time adverse event started: 12/22/2020 **Time:** 16:30

6. Age at vaccination: 52 yr.

7. Today's date: 12/23/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Singulair, Advair Inhaler, Zyrtec, Tagamet, Albuterol Inhaler, Protonix Magnesium , Potassium, Ibuprofen, Vitamin E Turmeric

10. Allergies to medications, food, or other products:
Reports allergies to Metoprolol, Robaxin, Biaxin, Mangos, Environmental Allergies numerous trees and grasses, dust , mold , dogs and cats

11. Other illnesses at the time of vaccination and up to one month prior:
None

12. Chronic or long-standing health conditions:
Asthma, Reactive Airway Disease, Rheumatoid Arthritis, Diabetes Type 2

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Larry Williams RN
Relation to Patient: Healthcare professional/staff
Address: Alamance Regional Medical Center 1240 Huffman Mill Rd.
City: Burlington
State: NC **ZIP:** 27215
Phone: (336) 807-2531
Email: larry.williams@conehealth.com
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Mary Ruth Hunt MD
Phone: (336) 832-3600 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Alamance Regional Medical Center
Fax: (336) 538-7719
Facility Address:
Alamance Regional Medical Center
1240 Huffman Mill Rd.
City: Burlington
State: NC **ZIP:** 27215
Phone: (336) 807-2531

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EL0140	Intramuscular - IM		1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Vaccine given at 1615. By 1630 became symptomatic shortness of breath, diaphoretic, labored breathing. Teammate seated, given 25mg Benadryl, symptoms worsened, Epi pen administered, and taken by wheelchair to (b) (6) ED.

19. Medical tests and laboratory results related to the adverse event(s):
(b) (6) ED (b) (6) Albuterol Breathing Treatment, Additional Epi doses, Solumedrol IV, Benadryl, Epi breathing treatment

20. Has the patient recovered from the adverse event(s)?: Yes

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: Yes
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):
Flu Vaccine 2008 approx, 40 years old

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

VAERS ID: 907836

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 907836 - 1
E-Number: 210729
Doc Number: 1305886
Date Received: 12/23/2020 3:00 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) [redacted] (last) [redacted]
Address: [redacted]
City: [redacted]
State: [redacted] **ZIP:** [redacted]
County: [redacted]
Phone [redacted]
Email: [redacted]

2. Date of birth: [redacted]

3. Sex: Female

4. Date and time of vaccination: 12/23/2020 **Time:** 12:31

5. Date and time adverse event started: 12/23/2020 **Time:** 12:45

6. Age at vaccination: 40 yr.

7. Today's date: 12/23/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Lipitor
Lexapro
Multivitamin - Flinstones Chewable

10. Allergies to medications, food, or other products:
Sulfa Drugs- skin rash
Keflex- severe systemic reaction
Fentanyl (not really an allergy, just adverse effects)
Influenza Vaccine- anaphylaxis- unknown kind, reaction in 2003 or 2004
Walnuts- anaphylaxis

11. Other illnesses at the time of vaccination and up to one month prior:
none

12. Chronic or long-standing health conditions:
Chronic Pancreatitis

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Rebecca Farren, RN
Relation to Patient: Healthcare professional/staff
Address: 2000 North Avenue
City: Northfield
State: MN **ZIP:** 55044
Phone: (507) 646-1513
Email: farrenr@northfieldhospital.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Jennifer Fischer, MD

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Northfield Hospital and Clinics
Fax: (507) 646-6846
Facility Address: 2000 North Avenue
City: Northfield
State: MN **ZIP:** 55044
Phone: (507) 646-1513

16. Type of facility: Other: Hospital Workforce Occupational Health Clinic

Phone: (612) 245-1426 **Ext:**

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EL0140	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
About 15 minutes I started to get hives, skin reaction and felt chest pressure, I let Dr. (b) (6) know I wasn't feeling well, administered Epinephrine with own EpiPen, noticeable hives and redness across neck and upper chest. Transported to the ED. 2nd dose of Epinephrine at 1:20pm for throat swelling and bronchospasm.

19. Medical tests and laboratory results related to the adverse event(s):
Epinephrine x2,
Benadryl x50mg
Solumedrol
IV fluids,
Oxygen
Tachycardic but normal blood pressure upon admission to the ED

20. Has the patient recovered from the adverse event(s)?: Yes

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: Yes
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):
Anaphylaxis following unknown influenza vaccine in 2003 or 2004

24. Patient's race: White

25. Patient's ethnicity: Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

Dina B. Tresnan, DVM, PhD
Pfizer Inc.
Eastern Point Rd, MS8260-1188
Groton, CT 06340

Rochelle A. Coleman
Office of the Executive Secretariat
Division of Freedom of Information
U.S. Food and Drug Administration
Tel: 301-796-8982
rochelle.coleman@fda.hhs.gov

Sunday, 7 February 2021

RE: Request for reports of VAERS cases itemized below

Dear Rochelle,

We received a query to EUA 27034 for COVID-19 vaccine BNT162b2 regarding reports for delayed onset syncope following immunization with Pfizer-BioNTech COVID-19 Vaccine mentioning multiple VAERS IDs (see below email from FDA). It was indicated that we may request a copy of redacted VAERS report via FOIA.
This is a request for the below VAERS reports to be sent in an expedited manner as soon as possible.

These include 14 cases VAERS IDs 0911694, 0913055, 0931224, 0947528, 0958843, 0951972, 0953072, 0961479, 0962189, 0965551, 0970943,0971535, 0976836, 0929124.

From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Sent: Thursday, February 4, 2021 3:08 PM
To: Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>
Cc: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: [EXTERNAL] IND 19736 – Pfizer-BioNTech COVID-19 Vaccine – CBER comments regarding cases of delayed syncope

Dear Ms. Aghajani Memar,

We have the following comment.

Delayed syncope. FDA identified 27 cases of delayed syncope, occurring one day after vaccination with the Pfizer-BioNTech COVID-19 Vaccine. Two of these were serious reports (VAERS ID 0910202 and 0931224), one of which resulted in patient injury. These VAERS IDs are listed in the table below. Please provide your assessment of delayed syncope, occurring at least one day after vaccination (including any additional cases of which you are aware).

VAERS IDs:

0903014	0908077	0911694	0929124	0958843	0971535
0903510	0908096	0912061	0931224	0961479	0976836
0904158	0908597	0913055	0947528	0962189	
0906119	0908668	0918799	0951972	0965551	

0906822	0910202	0920968	0953072	0970943	

Please submit your response to this request as an amendment to your EUA 27034 by Thursday, February 11, 2021.

Please confirm receipt of this email and let me know if you have any questions or need additional information.

Regards,
Ram

Ramachandra S. Naik, Ph.D.
Biologist (Regulatory) / Primary Reviewer
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-796-2640
ramachandra.naik@fda.hhs.gov

Thank you in advance.

Sincerely,

Dina B. Tresnan

Dina B. Tresnan, DVM, PhD

U.S. FOOD & DRUG ADMINISTRATION

February 19, 2021

Dina Tresnan
Pfizer Inc.
1 Ascot Lane
Old Lyme CT 06731

In reply refer to file: F21-929

Dear Dr. Tresnan,

This is in reply to your Freedom of Information Act (FOIA) request dated February 7, 2021, in which you requested "the below VAERS reports to be sent in an expedited manner as soon as possible. These include 14 cases VAERS IDs 0911694, 0913055, 0931224, 0947528, 0958843, 0951972, 0953072, 0961479, 0962189, 0965551, 0970943,0971535, 0976836, 0929124." Your request was received in the Center for Biologics Evaluation and Research on February 10, 2021.

Enclosed please find the results of a query of the Vaccine Adverse Event Reporting System (VAERS) using the search parameters listed in your FOIA request. Please note that during a telephone conversation with Catherine Wilusz on January 6, 2021, you stated that medical records would not be considered responsive for VAERS FOIA requests.

We have withheld portions of pages under Exemption (b)(3), 5 U.S.C. § 522(b)(3). That exemption prohibits the release of information that is otherwise prohibited from disclosure by another federal statute.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of this response, to:

Director, Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

Please clearly mark both the envelope and your letter “FDA Freedom of Information Act Appeal.”

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Katherine Uhl at 301-796-8975.

You may also contact the FDA FOIA Public Liaison for assistance at:

Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

The following may be included in a monthly invoice:

Search	1 hour @ $46.00/hr	$ 46.00
Review	4 Hours @ $46.00/hr	$184.00
TOTAL		**$230.00**

The above charges may not reflect final charges for this request. Please DO NOT send any payment until you receive an invoice from the Agency's Freedom of Information Staff (HFI-35).

If you have any questions or if we can be of further assistance, please let us know by referencing the above file number. You can contact Catherine Wilusz by phone at 240-402-8184 or by e-mail at Catherine.wilusz@fda.hhs.gov.

Sincerely,

Beth A. Brockner Ryan -S

Digitally signed by Beth A. Brockner Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300052489, cn=Beth A. Brockner Ryan -S
Date: 2021.02.19 09:41:11 -05'00'

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch

VAERS ID: 911694

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 911694 - 1
E-Number: 213572
Doc Number: 1310132
Date Received: 12/29/2020 9:41 AM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:**
County: (b) (6), (b) (3) (A)
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth: (b) (6)

3. Sex: Male

4. Date and time of vaccination: 12/28/2020 **Time:** 14:20

5. Date and time adverse event started: 12/29/2020 **Time:** 02:00

6. Age at vaccination: 46 yr. 0 mon.

7. Today's date: 12/29/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
none

10. Allergies to medications, food, or other products:
Penicillin

11. Other illnesses at the time of vaccination and up to one month prior:
none

12. Chronic or long-standing health conditions:
exercise induced asthma

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6)
Relation to Patient: spouse
Address: (b) (6)
City: (b) (6)
State: **ZIP:** (b) (6)
Phone (b) (6)
Email:
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Dr. Sukipreet Singh
Phone: (734) 981-3200 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Henry Ford Hospital
Fax:
Facility Address: West Grand Blvd
City: Detroit
State: MI **ZIP:** 48202
Phone:

16. Type of facility: Workplace clinic

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EK9231	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
(b) (6) woke up in the night, walked downstairs to get water, walked back upstairs and became nauseous, laid down and became unresponsive. Eyes were open but not focused, breathing was irregular and snoring-like. this lasted less than a minute and he regained consciousness.

19. Medical tests and laboratory results related to the adverse event(s):
none

20. Has the patient recovered from the adverse event(s)?: Yes

21. Result or outcome of adverse event(s): (Check all that apply).
* None of the above

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: Yes
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):
Tdap and Flu vaccine together produced nausea and body aches about ten years ago

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

VAERS ID: 913055

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 913055 - 1
E-Number: 214596
Doc Number: 1311636
Date Received: 12/29/2020 8:21 PM
Severity: Non-Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City (b) (6), (b) (3) (A)
State: (b) (6), (b) **ZIP:** (b) (6), (b) (3) (A)
County
Phone (b) (6), (b) (3) (A)
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/22/2020 **Time:** PM

5. Date and time adverse event started: 12/23/2020 **Time:** AM

6. Age at vaccination: 31 yr. 6 mon. **7. Today's date:** 12/29/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Norethindrone tablets 0.35mg
Sertraline 50 mg
Prenatal mulit+DHA 200mg

10. Allergies to medications, food, or other products:
None

11. Other illnesses at the time of vaccination and up to one month prior:
None

12. Chronic or long-standing health conditions:
Anxiety
Breastfeeding

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6)
Relation to Patient: Patient
Address: (b) (6)
City: (b) (6)
State: (b) (6) **ZIP** (b) (6)
Phone:
Email: (b) (6)
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: **16. Type of facility:**
Fax:
Facility Address:
City:
State: ZIP:
Phone:

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	IR#0659A & 0660A_000078			

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Vasovagal syncopal event

19. Medical tests and laboratory results related to the adverse event(s):
Blood pressure 12/23 after event 79/54

20. Has the patient recovered from the adverse event(s)?: Yes

21. Result or outcome of adverse event(s): (Check all that apply).

* Doctor or other healthcare professional office/clinic visit
* Emergency room/department or urgent care

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

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VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
PCC: N/A
Worldwide ID Number: US-PFIZER INC-2021002951
VAERS Number: 929124 - 1
Doc Number: 1329224
Date Received: 01/08/2021
Severity: Serious
Received by: eVAERS
Manufacturer: Pfizer\Wyeth
Data: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address:
City:
State: ZIP:
County:
Phone:
Email:

(b) (6), (b) (3) (A)

2. Date of birth:

3. Sex: Female

4. Date and time of vaccination: 01/03/2021 Time:

5. Date and time adverse event started: 01/04/2021 Time:

6. Age at vaccination: 26 yr.

7. Today's date: 01/08/2021

8. Pregnant at the time of vaccination?:

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Drug hypersensitivity	23.1	Penicillin allergy	23.1

11. Other illnesses at the time of vaccination and up to one month prior:

This report does not have medical codes at this time

12. Chronic or long-standing health conditions:
Medical History/Concurrent Conditions: COVID-19; Penicillin allergy

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
COVID-19	23.1	COVID-19	23.1

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to Patient: Manufacturer

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Select Specialy Hospital

16. Type of facility:

Address: City: State: ZIP: Phone: Email: 14. Best doctor/healthcare professional to contact about the adverse event: Name: Phone: Ext:	Fax: Facility Address: City: State: ZIP: Phone:	Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Lot Number	Location	Dose number in series	Injection Site Reaction
Pfizer\BioNTech / COVID19 (COVID19 (Pfizer-BioNTech))	EK9231	LA	1	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.) drop in blood pressure resulting in fainting; drop in blood pressure resulting in fainting; Severe headache; fever; This is a spontaneous report from a contactable (b) (6) (b) (6) (patient). A 26-year-old female patient (non-pregnant) received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE, Lot number EK9231), via an unspecified route of administration on 03Jan2021 at single dose at left arm for immunization. Medical history included allergies to Penicillins. The patient's concomitant medications within 2 weeks of vaccination included birth control pill, prenatal vitamin. Patient didn't receive any other vaccines within 4 weeks prior to the COVID vaccine. Prior to vaccination, patient was diagnosed with COVID-19. Since the vaccination, patient has not been tested for COVID-19. The patient experienced severe headache, fever, and drop in

21. Result or outcome of adverse event(s): (Check all that apply).

* Doctor or other healthcare professional office/clinic visit
* OMIC

blood pressure resulting in fainting the morning following receiving the vaccine on 04Jan2021 with outcome of recovering. Patient didn't receive treatment for events. Adverse events resulted in doctor or other healthcare professional office/clinic visit. This report is considered non-serious.

No follow-up attempts are possible. Information about Batch number cannot be obtained. No further information is expected.; Sender's Comments: Based on the close temporal relationship, the association between the event fainting with BNT162b2 can not be completely excluded.

The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Blood pressure decreased	23.1	Drop in blood pressure	23.1
Syncope	23.1	Fainting	23.1
Pyrexia	23.1	Fever	23.1
Headache	23.1	Headache	23.1

19. Medical tests and laboratory results related to the adverse event(s):
Test Date: 20210104; Test Name: Blood pressure; Result Unstructured Data: Test Result:drop

This report does not have medical

codes at this time 20. Has the patient recovered from the adverse event(s)?: No	

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Lot Number	Location	Dose number in series	Date Given

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report number: USPFIZER INC2021002951

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:	28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

OTHER DATA

State (formerly Box 1):	Literature/Study Report:	Manufacturer:	15 day report:
US	No	Pfizer\Wyeth	Yes

Evaluated State: US

Auxiliary Report Identifier:

Date received by mfr./imm. proj. 01/04/2021

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VAERS ID: 931224

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 931224 - 1
E-Number: 229511
Doc Number: 1331384
Date Received: 01/09/2021 11:59 AM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6), (b) (3) (A)
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth (b) (6)

3. Sex: Female

4. Date and time of vaccination: 01/04/2021 **Time:** 20:00

5. Date and time adverse event started: 01/05/2021 **Time:** 08:00

6. Age at vaccination: 39 yr.

7. Today's date: 01/09/2021

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Levothyroxine 200 mcg, Vyvanse 60 mg

10. Allergies to medications, food, or other products:
SHELLFISH, CECLOR

11. Other illnesses at the time of vaccination and up to one month prior:
NONE

12. Chronic or long-standing health conditions:
Hypothyroidism, ADHD

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6)
Relation to Patient: Healthcare professional/staff
Address: (b) (6)
City (b) (6)
State: **ZIP:** (b) (6)
Phone (b) (6)
Email:
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: (b) (6)
Phone **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
CHRISTUS SANTA ROSA
Fax:
Facility Address:
11212 SH 151
Suite 240, Bldg 1
City: San Antonio
State: TX **ZIP:** 78251
Phone: (210) 703-8000

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EJ1686	Intramuscular - IM	Left Arm	2

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Pt experienced extreme fatigue and sleepiness the day following her second vaccination for Covid 19

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care
* Hospitalization (4 days, Hospital: (b) (6)

IR#0659A & 0660A_000084

and was found by her family after collapsing on 1/6/21 at 05:30. Upon arousal, she experienced headache, vomiting, weakness, difficulty speaking and difficulty walking with lower extremity weakness. She was taken to urgent care and subsequently admitted for evaluation at (b) (6) (b) (6) and found to have a normal chemistry, blood count, normal lumbar puncture and normal imaging of her neck and brain. Discharge summary notes 3/5 strength and hyporeflexia throughout. Pt had televisit consult with psychiatry and neurology. She is subsequently to be discharged to a Rehab Facility without explanation for her sudden onset of progressive lower extremity and vocal weakness. She is noted to have a history of shellfish allergy. She experienced mild symptoms after the first vaccination, but no neurologic or vascular symptoms at that time.

(b) (6)

* Disability or permanent damage

19. Medical tests and laboratory results related to the adverse event(s):
(b) (6) Normal BMP, CBC, normal TSH, low B12
Lumbar Puncture: normal cell count and protein, culture pending
Cervical Spine xray: Normal
CT brain (noncontrast): normal

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EJ1685	Intramuscular - IM	Left Arm	1	12/18/2020

23. Has the patient ever had an adverse event following any previous vaccine?: Unknown
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Unknown

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

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VACCINE ADVERSE EVENT REPORTING SYSTEM 24 Hour Toll-free information line: 1-800-822-7967 Fax number: 1-877-721-0366 P.O. Box 1100, Rockville, MD 20849-1100 **PATIENT IDENTITY KEPT CONFIDENTIAL**	***For CDC/FDA Use Only*** **PCC:** N/A **Worldwide ID Number:** US-PFIZER INC-2021014581 **VAERS Number:** 947528 - 1 **Doc Number:** 1349059 **Date Received:** 01/15/2021 **Severity:** Serious **Received by:** eVAERS **Manufacturer:** Pfizer\Wyeth **Data:** This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first [redacted] last [redacted]
   Address:
   City: [redacted]
   State: [redacted] ZIP: [redacted]
   County:
   Phone:
   Email [redacted]

2. Date of birth:

3. Sex: Female

4. Date and time of vaccination: 01/08/2021 Time: 14:30:00

5. Date and time adverse event started: 01/09/2021 Time: 01:30:00

6. Age at vaccination:

7. Today's date: 01/14/2021

8. Pregnant at the time of vaccination?:

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

This report does not have medical codes at this time

11. Other illnesses at the time of vaccination and up to one month prior:

This report does not have medical codes at this time

12. Chronic or long-standing health conditions:
Comments: List of non-encoded Patient Relevant History:
Patient Other Relevant History 1: None

This report does not have medical codes at this time

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM	**INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN**	
13. Form completed by: (name) Relation to Patient: Manufacturer Address: City: State: ZIP:	15. Facility/clinic name: Tufts Medical Center Fax: Facility Address: City: Boston	16. Type of facility: Doctor's office, urgent care, or hospital

14.	Phone: Email: Best doctor/healthcare professional to contact about the adverse event: Name: Phone: Ext:	State: MA ZIP: 02111 Phone:	

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Lot Number	Location	Dose number in series	Injection Site Reaction
Pfizer\BioNTech / COVID19 (COVID19 (Pfizer-BioNTech))	EK9231	LA	1	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Experienced vasovagal syncope after standing, resulting in fall; Experienced vasovagal syncope after standing, resulting in fall; Awoke with severe chills; nausea; body/muscle aches; body/muscle aches; left arm pain; extreme thirst; fatigue; This is a spontaneous report from a contactable consumer. A 44-year-old female patient (non-pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot: EK9231), via an unspecified route of administration on 08Jan2021 14:30 in left arm at single dose for covid-19 immunization. There was no medical history and concomitant medications. Allergies to medications, food, or other products was no. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The most recent COVID-19 vaccine was administered was in hospital. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 09Jan2021 01:30 am, patient woke with severe chills, nausea, body/muscle aches, left

21. Result or outcome of adverse event(s): (Check all that apply).
* OMIC

arm pain, nausea, extreme thirst. Patient experienced vasovagal syncope after standing, resulting in fall. Worst symptoms were lasted about 30 minutes, muscle aches and fatigue continue about 16 hours later. All events were reported as non-serious. No treatment was received for these events. Outcome of all events were recovering.

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Chills	23.1	Chills	23.1
Thirst	23.1	Excessive thirst	23.1
Fall	23.1	Fall	23.1
Fatigue	23.1	Fatigue	23.1
Pain	23.1	Generalized aching	23.1
Myalgia	23.1	Muscle ache	23.1
Nausea	23.1	Nausea	23.1
Pain in extremity	23.1	Painful L arm	23.1
Syncope	23.1	Syncope vasovagal	23.1

19. Medical tests and laboratory results related to the adverse event(s):

This report does not have medical codes at this time

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Lot Number	Location	Dose number in series	Date Given

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino	26. Immuniz. proj. report number: USPFIZER INC2021014581

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:	28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

OTHER DATA

State (formerly Box 1)(b) (6)	Literature/Study Report: No	OMIC Only: Yes	Manufacturer: Pfizer\Wyeth	15 day report: Yes
Evaluated State:(b) (6)				
Auxiliary Report Identifier:			Date received by mfr./imm. proj. 01/09/2021	

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

VACCINE ADVERSE EVENT REPORTING SYSTEM 24 Hour Toll-free information line: 1-800-822-7967 Fax number: 1-877-721-0366 P.O. Box 1100, Rockville, MD 20849-1100 **PATIENT IDENTITY KEPT CONFIDENTIAL**	***For CDC/FDA Use Only*** **PCC:** N/A **Worldwide ID Number:** US-PFIZER INC-2021014461 **VAERS Number:** 951972 - 1 **Doc Number:** 1353641 **Date Received:** 01/18/2021 **Severity:** Serious **Received by:** eVAERS **Manufacturer:** Pfizer\Wyeth **Data:** This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)

Address: (b) (6), (b) (3) (A)

City: (b) (6), (b) (3) (A)

State (b) (6), (b) (3) (A) ZIP: (b) (6), (b) (3) (A)

County:

Phone: (b) (6), (b) (3) (A)

Email:

2. Date of birth:

3. Sex: Female

4. Date and time of vaccination: 01/08/2021 Time: 12:30:00

5. Date and time adverse event started: 01/09/2021 Time: 07:30:00

6. Age at vaccination: 69 yr.

7. Today's date: 01/15/2021

8. Pregnant at the time of vaccination?:

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
;
;
;

10. Allergies to medications, food, or other products:

This report does not have medical codes at this time

11. Other illnesses at the time of vaccination and up to one month prior:

This report does not have medical codes at this time

12. Chronic or long-standing health conditions:
Medical History/Concurrent Conditions: COVID-19; Flu; Migraine with aura; Osteopenia; Reactive attachment disorder of infancy or early childhood (R.A.D.); Syncope vasovagal

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
COVID-19	23.1	COVID-19	23.1
Influenza	23.1	Flu	23.1
Migraine with aura	23.1	Migraine with aura	23.1
Osteopenia	23.1	Osteopenia	23.1
Reactive attachment disorder of infancy or early childhood	23.1	Reactive attachment disorder of infancy or early childhood	23.1
Syncope	23.1	Syncope vasovagal	23.1

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM	INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN	
13. Form completed by: (name) Relation to Patient: Manufacturer Address: City: State: ZIP: Phone: Email: 14. Best doctor/healthcare professional to contact about the adverse event: Name: (b) (6) Phone: Ext:	15. Facility/clinic name: Ed Racine Soccer Complex Fax: Facility Address: City: Tampa State: FL ZIP: Phone:	16. Type of facility: Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Lot Number	Location	Dose number in series	Injection Site Reaction
Pfizer\BioNTech / COVID19 (COVID19 (Pfizer-BioNTech))		LA		

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
I felt quite sick, like I had the flu; became very lightheaded and dizzy; passed out; felt quite sick; This is a spontaneous report from a contactable consumer (patient). A 69-year-old non-pregnant female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), via an unspecified route of administration on 08Jan2021 at 12:30 at single dose in left arm for covid-19 immunization. Medical history included R.A.D., osteopenia, migraine with aura, the patient had previously suffered episodes of vasal vagal syncopy when she got the flu or other severe illnesses, and the patient was diagnosed with COVID-19 prior to vaccination. Concomitant medication included atenolol, atorvastatin, azelastine, and fluticasone. The patient previously took gramicidin, neomycin sulfate, polymyxin b sulfate (NEOSPORIN) and experienced allergies. The morning after receiving the vaccine, she felt

21. Result or outcome of adverse event(s): (Check all that apply).
* OMIC

quite sick, like she had the flu. When she got up from bed and went to the bathroom to urinate, she became very lightheaded and dizzy. She attempted to return to bed, but passed out on the bedroom floor before she could get to the bed, and seized while she was unconscious. Once she came to, she was helped to bed and, after about 90 minutes, felt much better, and got up, and ate food and had coffee. All events occurred at 07:30 AM on 09Jan2021. All events were reported as non-serious by reporter. The patient did not receive treatment for the events. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient has not been tested for COVID-19 since the vaccination. The outcome of the events was resolved in Jan2021.

Information on the lot/batch number has been requested.

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Dizziness	23.1	Dizzy	23.1
Malaise	23.1	Feeling sick	23.1
Influenza like illness	23.1	Flu like symptoms	23.1
Dizziness	23.1	Lightheadedness	23.1
Loss of consciousness	23.1	Passed out	23.1
Seizure	23.1	Seizure	23.1

19. Medical tests and laboratory results related to the adverse event(s):

This report does not have medical codes at this time

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Lot Number	Location	Dose number in series	Date Given

23. Has the patient ever had an adverse event following any previous vaccine?:	
24. Patient's race: White	
25. Patient's ethnicity: Not Hispanic or Latino	26. Immuniz. proj. report number: USPFIZER INC2021014461
COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS	
27. Status at time of vaccination:	28. Vaccinated at Military/DoD site:
PAGE 2 ADDITIONAL INFORMATION	
OTHER DATA	

State (formerly Box 1): (b) (6)	Literature/Study Report: No	OMIC Only: Yes	Manufacturer: Pfizer\Wyeth	15 day report: Yes
Evaluated State: (b) (6)				
Auxiliary Report Identifier:			Date received by mfr./imm. proj. 01/09/2021	

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
PCC: N/A
Worldwide ID Number: US-PFIZER INC-2021014496
VAERS Number: 953072 - 1
Doc Number: 1354785
Date Received: 01/18/2021
Severity: Serious
Received by: eVAERS
Manufacturer: Pfizer\Wyeth
Data: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)

Address: (b) (6), (b) (3) (A)
City (b) (6), (b) (3) (A)
State: (b) (6), (b) (3) ZIP: (b) (6), (b) (3) (A)
County:
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth:

3. Sex: Female

4. Date and time of vaccination: 01/08/2021 Time: 12:15:00

5. Date and time adverse event started: 01/09/2021 Time: 05:00:00

6. Age at vaccination: 29 yr.

7. Today's date: 01/15/2021

8. Pregnant at the time of vaccination?:

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

This report does not have medical codes at this time

11. Other illnesses at the time of vaccination and up to one month prior:

This report does not have medical codes at this time

12. Chronic or long-standing health conditions:

This report does not have medical codes at this time

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)

Relation to Patient: Manufacturer

Address:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Women & Infants Hospital

Fax:

16. Type of facility: Doctor's office, urgent care, or hospital

City: State: ZIP: Phone: Email: 14. Best doctor/healthcare professional to contact about the adverse event: Name: Phone: Ext:	Facility Address: 101 Dudley St City: Providence State: RI ZIP: 02905 Phone:	

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Lot Number	Location	Dose number in series	Injection Site Reaction
Pfizer\BioNTech / COVID19 (COVID19 (Pfizer-BioNTech))	EL1284	RA	2	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Syncopal event; Nausea; Vomiting; This is a spontaneous report from a contactable (b) (6) A 29-year-old female received second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number:EL1284), via an unspecified route of administration on the right arm on 08Jan2021 12:15 at single dose for COVID-19 immunisation. The patient medical history was not reported. Concomitant medication included influenza vaccine (INFLUENZA VACCINE) on 13Dec2020. The patient previously took first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EH9899) on 18Dec2021 12:15. The patient experienced syncopal event, nausea and vomiting on 09Jan2021 05:00. The patient received no treatment. The outcome of the events was recovering.

No follow-up attempts are possible. No further information is expected.; Sender's Comments: Based on the compatible time association, the event syncope is possibly related to suspect drug BNT162B2 administration. The impact of

21. Result or outcome of adverse event(s): (Check all that apply).
* Doctor or other healthcare professional office/clinic visit
* OMIC

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.

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Inappropriate schedule of product administration	23.1	Inappropriate schedule of vaccine administered	23.1
Nausea	23.1	Nausea	23.1
Syncope	23.1	Syncope	23.1
Vomiting	23.1	Vomiting	23.1

19. Medical tests and laboratory results related to the adverse event(s):

This report does not have medical codes at this time

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Lot Number	Location	Dose number in series	Date Given
UNKNOWN MANUFACTURER / Influenza (Seasonal) (no brand name)				12/13/2020

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report number: USPFIZER INC2021014496

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:	28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

OTHER DATA

State (formerly Box 1): (b) (6)	Literature/Study Report:	Manufacturer:	15 day report:
	No	Pfizer\Wyeth	Yes

Evaluated State (b) (6)

Auxiliary Report Identifier: Date received by mfr./imm. proj. 01/09/2021

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VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line:
1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
PCC: N/A
Worldwide ID Number: US-PFIZER INC-2021018854
VAERS Number: 958843 - 1
Doc Number: 1361285
Date Received: 01/20/2021
Severity: Serious
Received by: eVAERS
Manufacturer: Pfizer\Wyeth
Data: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State ZIP (b) (6), (b) (3) (A)
County:
Phone: (b) (6), (b) (3) (A)
Email: (b) (6), (b) (3) (A)

2. Date of birth:

3. Sex: Female

4. Date and time of vaccination: 01/09/2021 Time: 06:00:00

5. Date and time adverse event started: 01/10/2021 Time: 01:00:00

6. Age at vaccination: 58 yr.

7. Today's date: 01/19/2021

8. Pregnant at the time of vaccination?:

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Drug hypersensitivity	23.1	Drug allergy	23.1

11. Other illnesses at the time of vaccination and up to one month prior:

This report does not have medical codes at this time

12. Chronic or long-standing health conditions:
Medical History/Concurrent Conditions: Atrial fibrillation (1 episode)

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Atrial fibrillation	23.1	Atrial fibrillation	23.1

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to Patient: Manufacturer

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Seattle Childrens Hospital

16. Type of facility:

14. Best doctor/healthcare professional to contact about the adverse event: Name: (b) (6) Phone: Ext: Address: City: State: ZIP: Phone: Email:	Fax: Facility Address: 4800 Sand Point Way NE City: Seattle State: WA ZIP: 98108 Phone: +12068535175	Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Lot Number	Location	Dose number in series	Injection Site Reaction
Pfizer\BioNTech / COVID19 (COVID19 (Pfizer-BioNTech))	E1 1283 or F1 1283	OT, LA	2	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
I began to pass out and yelled for my husband, he said when he came in I was sitting on the toilet with my head back, eyes rolling back not responsive.; I had my 2nd vaccine (b) (6) early Sat the 9th and felt increasingly worse all day; I woke up at midnight and felt extreme malaise; I was covered in sweat; vomited; I checked my temp and it was 99.7°F; sore; I think I had either a seizure or a vasovagal response.; This is a spontaneous report from a contactable (b) (6) patient).
This 58-year-old female patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot EJ1685 or FJ1685), intramuscular at single dose in the left arm on 09Jan2021 06:00 for Covid-19 immunisation. Medical history included atrial fibrillation on unknown date (1 episode), allergic to Keflex. There were no concomitant medications. The patient previously received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) (Lot EJ1685 or FJ1685), intramuscular in the left arm on 22Dec2020 for

21. Result or outcome of adverse event(s): (Check all that apply).
* OMIC

Covid-19 immunisation.
On 10Jan2021 01:00 AM, the patient experienced: I began to pass out and yelled for my husband, he said when he came in i was sitting on the toilet with my head back, eyes rolling back not responsive (loss of consciousness) (medically significant), I had my 2nd vaccine (b) (6) early sat the 9th and felt increasingly worse all day (feeling abnormal), Iwoke up at midnight and felt extreme malaise (malaise), I was covered in sweat (hyperhidrosis), vomited (vomiting), I checked my temp and it was 99.7°F (pyrexia), sore (pain), I think I had either a seizure or a vasovagal response (seizure). No treatment required. The outcome of the events was recovered.
The events were described as follows: I am healthy (b) (6) with no active medical problems. I had my 2nd vaccine (b) (6) early Sat the 9th and felt increasingly worse all day, I expected this so was not alarmed and went to bed around 10pm. I woke up at midnight and felt extreme malaise and went to the bathroom in case I might vomit, etc. and I tried to have a BM. I began to pass out and yelled for my husband, he said when he came in I was sitting on the toilet with my head back, eyes rolling back not responsive. He yelled at me for about 10 seconds and I came to, I was covered in sweat. I asked him to walk me back to the bedroom where I again passed out, fell to the floor and hit the bed, then was unresponsive again for about 10 seconds then came to again and vomited. After this I felt completely relieved of my malaise. I checked my temp and it was 99.7°F. After this I was sore but otherwise completely okay, the next day I had a temp of 99.5°F. Today I am back to normal. I think I had either a seizure or a vasovagal response. The vaccine was administered at Hospital Facility. The patient did not receive any other vaccines within 4 weeks prior to the COVID vaccine. The patient was not diagnosed with COVID-19 prior to vaccination. The patient had not been tested for COVID-19 since the vaccination. The patient was not pregnant at the time of vaccination.; Sender's Comments: Based on the close temporal relationship, the

association between the event "began to pass out" 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.

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Eye movement disorder	23.1	Eyes rolling	23.1
Fall	23.1	Fall	23.1
Feeling abnormal	23.1	Feeling bad	23.1
Posture abnormal	23.1	Head posture abnormal	23.1
Malaise	23.1	Malaise	23.1
Pain	23.1	Pain	23.1
Loss of consciousness	23.1	Passed out	23.1
Pyrexia	23.1	Pyrexia	23.1
Hyperhidrosis	23.1	Sweating	23.1
Unresponsive to stimuli	23.1	Unresponsive to stimuli	23.1
Vomiting	23.1	Vomited	23.1

19. Medical tests and laboratory results related to the adverse event(s):
Test Date: 20210110; Test Name: Body temperature; Result Unstructured Data: Test Result:99.7 Fahrenheit; Test Date: 20210111; Test Name: Body temperature; Result Unstructured Data: Test Result:99.5 Fahrenheit; Test Date: 202101; Test Name: Body temperature; Result Unstructured Data: Test Result:back to normal Fahrenheit

This report does not have medical codes at this time 20. Has the patient recovered from the adverse event(s)?: Yes	

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Lot Number	Location	Dose number in series	Date Given

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report number: USPFIZER INC2021018854

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:	28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

OTHER DATA

State (formerly Box 1): (b) (6)
Literature/Study Report: No
OMIC Only: Yes
Manufacturer: Pfizer\Wyeth
15 day report: Yes
Evaluated State (b) (6)

Auxiliary Report Identifier:

Date received by mfr./imm. proj. 01/11/2021

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VACCINE ADVERSE EVENT REPORTING SYSTEM 24 Hour Toll-free information line: 1-800-822-7967 Fax number: 1-877-721-0366 P.O. Box 1100, Rockville, MD 20849-1100 **PATIENT IDENTITY KEPT CONFIDENTIAL**	***For CDC/FDA Use Only*** **PCC:** N/A **Worldwide ID Number:** US-PFIZER INC-2021021731 **VAERS Number:** 961479 - 1 **Doc Number:** 1364059 **Date Received:** 01/21/2021 **Severity:** Serious **Received by:** eVAERS **Manufacturer:** Pfizer\Wyeth **Data:** This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last)

Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: (b) (6), (b) (3) ZIP: (b) (6), (b) (3) (A)
County:
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth:

3. Sex: Female

4. Date and time of vaccination: 01/07/2021 Time: 10:45:00

5. Date and time adverse event started: 01/08/2021 Time: 02:00:00

6. Age at vaccination: 55 yr.

7. Today's date: 01/20/2021

8. Pregnant at the time of vaccination?:

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
VITAMIN D;VITAMIN E

10. Allergies to medications, food, or other products:

This report does not have medical codes at this time

11. Other illnesses at the time of vaccination and up to one month prior:

This report does not have medical codes at this time

12. Chronic or long-standing health conditions:
Medical History/Concurrent Conditions: COVID-19 (covid prior vaccination: Yes)

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
COVID-19	23.1	COVID-19	23.1

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM	INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN	
13. Form completed by: (name) Relation to Patient: Manufacturer	15. Facility/clinic name: St. Anne's	16. Type of facility:

Address: City: State: ZIP: Phone: Email: 14. Best doctor/healthcare professional to contact about the adverse event: Name: (b) (6) Phone: Ext:	Fax: Facility Address: 11855 Quail Roost Drive City: Miami State: ZIP: 33177 Phone:	Other

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Lot Number	Location	Dose number in series	Injection Site Reaction
Pfizer\BioNTech / COVID19 (COVID19 (Pfizer-BioNTech))	EL0140	LA	1	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
several fainting spells because of everything going on; elevated HR in the 130's; Uncontrollable chills; fever of 102.8; pain all over my body; intractable vomiting; This is a spontaneous report from a contactable (b) (6) (patient).
A 55-year-old female patient (not pregnant) received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), lot EL0140, via an unspecified route of administration in left arm on 07Jan2021 10:45 at single dose for covid-19 immunisation. Medical history included covid-19 on an unknown date prior vaccination. There were not known allergies. Covid was not tested post vaccination. Concomitant medication included vitamin D; vitamin E. On 08Jan2021 at 02:00 the patient experienced several fainting spells because of everything going on, uncontrollable chills, fever of 102.8,

21. Result or outcome of adverse event(s): (Check all that apply).
* OMIC

pain all over the body, elevated heart rate in the 130's, and intractable vomiting. The patient was not treated for the events. The outcome of the events was resolved in Jan2021.; Sender's Comments: Based on the time association, all events are reasonably related to suspect BNT162B2 administration. 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.

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Chills	23.1	Chills	23.1
Syncope	23.1	Fainting	23.1
Pyrexia	23.1	Fever	23.1
Pain	23.1	General body pain	23.1
Heart rate increased	23.1	Heart rate increased	23.1
Vomiting	23.1	Vomiting	23.1

19. Medical tests and laboratory results related to the adverse event(s):
Test Date: 20210108; Test Name: fever; Result Unstructured Data: Test Result:102.8; Test Date: 20210108; Test Name: Heart rate; Test Result: 130 s; Comments: elevated

This report does not have medical codes at this time

20. Has the patient recovered from the

adverse event(s)?: Yes	

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Lot Number	Location	Dose number in series	Date Given

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: Unknown

25. Patient's ethnicity: Hispanic or Latino

26. Immuniz. proj. report number: USPFIZER INC2021021731

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:	28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

OTHER DATA

State (formerly Box 1)(b) (6)	Literature/Study Report: No	OMIC Only: Yes	Manufacturer: Pfizer\Wyeth	15 day report: Yes
Evaluated State(b) (6)				
Auxiliary Report Identifier:			Date received by mfr./imm. proj. 01/12/2021	

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VACCINE ADVERSE EVENT REPORTING SYSTEM 24 Hour Toll-free information line: 1-800-822-7967 Fax number: 1-877-721-0366 P.O. Box 1100, Rockville, MD 20849-1100 **PATIENT IDENTITY KEPT CONFIDENTIAL**	***For CDC/FDA Use Only*** **PCC:** N/A **Worldwide ID Number:** US-PFIZER INC-2021023579 **VAERS Number:** 962189 - 1 **Doc Number:** 1364900 **Date Received:** 01/21/2021 **Severity:** Serious **Received by:** eVAERS **Manufacturer:** Pfizer\Wyeth **Data:** This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)

Address: (b) (6), (b) (3) (A)

City: (b) (6), (b) (3) (A)

State: (b) (6), (b) (3) (A) ZIP: (b) (6), (b) (3) (A)

County:

Phone: (b) (6), (b) (3) (A)

Email:

2. Date of birth:

3. Sex: Female

4. Date and time of vaccination: 01/12/2021 Time: 12:15:00

5. Date and time adverse event started: 01/12/2021 Time:

6. Age at vaccination: 25 yr.

7. Today's date: 01/20/2021

8. Pregnant at the time of vaccination?:

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

This report does not have medical codes at this time

11. Other illnesses at the time of vaccination and up to one month prior:

This report does not have medical codes at this time

12. Chronic or long-standing health conditions:
Medical History/Concurrent Conditions: Asthma

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Asthma	23.1	Asthma	23.1

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)

Relation to Patient: Manufacturer

Address:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Barnes Jewish Hospital

Fax:

16. Type of facility:

City: State: ZIP: Phone: Email: 14. Best doctor/healthcare professional to contact about the adverse event: Name: (b) (6) Phone Ext:	Facility Address: City: State: ZIP: Phone:	Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Lot Number	Location	Dose number in series	Injection Site Reaction
Pfizer\BioNTech / COVID19 (COVID19 (Pfizer-BioNTech))	EK4176	OT, RA	2	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Loss of consciousness; Muscle aches; Headache; Nausea; Vomiting; Dose1 26Dec2020, dose 2 12Jan2021; Dose1 26Dec2020, dose 2 12Jan2021; This is a spontaneous report from a contactable (b) (6) A 25-year-old female patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on the right arm second dose on 12Jan2021 12:15 at a single dose (lot number: EK4176) and intramuscular on the right arm first dose on 26Dec2020 10:15 at a single dose (lot number: EL1284) for COVID-19 immunisation. Medical history included asthma. Concomitant medication included Women's multivitamin within two weeks of vaccination. The patient had no allergies to medications, food, or other products; was not diagnosed with COVID-19 prior to vaccination, did not receive any other vaccines within four weeks prior to the COVID vaccine and was not pregnant at the time of vaccination. The most recent COVID-19 vaccine was administered at a hospital facility. On 13Jan2021 03:30, the patient experienced muscle aches, headache, nausea, vomiting and loss of consciousness.

21. Result or outcome of adverse event(s): (Check all that apply).
* OMIC

Treatment was not received for the events. Since the vaccination, the patient has not been tested for COVID-19. Outcome of the events was recovering.

Information on the lot/batch number has been requested.

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Headache	23.1	Headache	23.1
Loss of consciousness	23.1	Loss of consciousness	23.1
Myalgia	23.1	Muscle ache	23.1
Nausea	23.1	Nausea	23.1
Vomiting	23.1	Vomiting	23.1

19. Medical tests and laboratory results related to the adverse event(s):

This report does not have medical codes at this time

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Lot Number	Location	Dose number in series	Date Given
Pfizer\BioNTech / COVID19 (COVID19 (Pfizer-BioNTech))	EL1284	RA	1	12/26/2020

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report number: USPFIZER INC2021023579

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:	28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

OTHER DATA				
State (formerly Box 1): (b) (6) Evaluated State (b) (6)	Literature/Study Report: No	OMIC Only: Yes	Manufacturer: Pfizer\Wyeth	15 day report: Yes
Auxiliary Report Identifier:			Date received by mfr./imm. proj. 01/13/2021	

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VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
PCC: N/A
Worldwide ID Number: US-PFIZER INC-2021021441
VAERS Number: 965551 - 1
Doc Number: 1368596
Date Received: 01/22/2021
Severity: Serious
Received by: eVAERS
Manufacturer: Pfizer\Wyeth
Data: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address:
City:
State: ZIP:
County:
Phone:
Email:

2. Date of birth:

3. Sex: Female

4. Date and time of vaccination: 01/11/2021 Time: 14:00:00

5. Date and time adverse event started: 01/12/2021 Time: 05:45:00

6. Age at vaccination: 22 yr.

7. Today's date: 01/22/2021

8. Pregnant at the time of vaccination?:

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
VITAMIN D [COLECALCIFEROL]

10. Allergies to medications, food, or other products:

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Drug hypersensitivity	23.1	Penicillin allergy	23.1

11. Other illnesses at the time of vaccination and up to one month prior:

This report does not have medical codes at this time

12. Chronic or long-standing health conditions:
Medical History/Concurrent Conditions: Penicillin allergy; Situational anxiety

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Anxiety	23.1	Situational anxiety	23.1

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to Patient: Manufacturer

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: North Memorial

16. Type of facility:

	Address: City: State: ZIP: Phone: Email:	Fax: Facility Address: City: Robbinsdale State: MN ZIP: Phone:	Doctor's office, urgent care, or hospital
14.	Best doctor/healthcare professional to contact about the adverse event: Name: Sheila McIntire Phone: +17636848300 Ext:		

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Lot Number	Location	Dose number in series	Injection Site Reaction
Pfizer\BioNTech / COVID19 (COVID19 (Pfizer-BioNTech))		OT	1	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
dizziness then syncope; dizziness then syncope; This is a spontaneous report from a contactable Other HCP. A 22-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), intramuscular on 11Jan2021 14:00 at single dose for COVID-19 immunisation. Medical history included situational anxiety, known allergies_penicillin. Concomitant medication included colecalciferol (VITAMIN D [COLECALCIFEROL]). The patient previously took amoxicillin;clavulanic acid (AUGMENTIN) and moxifloxacin and experienced allergies. The patient experienced dizziness then syncope on 12Jan2021 05:45. The patient underwent lab tests and procedures which included electrocardiogram: unknown results, laboratory test: unknown results. Therapeutic measures were taken as a result of dizziness then syncope. The outcome of the events was resolving.

Information on batch/lot number was requested.; Sender's Comments: Based on the time association, the event syncope is possibly

21. Result or outcome of adverse event(s): (Check all that apply).
* Doctor or other healthcare professional office/clinic visit
* OMIC

related to suspect BNT162B2 administration. 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.

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Dizziness	23.1	Dizziness	23.1
Syncope	23.1	Syncope	23.1

19. Medical tests and laboratory results related to the adverse event(s):
Test Name: ECG; Result Unstructured Data: Test Result:Unknown results; Test Name: Lab test; Result Unstructured Data: Test Result:Unknown results

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Electrocardiogram	23.1	ECG	23.1
Laboratory test	23.1	Lab test	23.1

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Lot Number	Location	Dose number in series	Date Given

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report number: USPFIZER INC2021021441

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION			
OTHER DATA			
State (formerly Box 1): (b) (6)	Literature/Study Report: No	Manufacturer: Pfizer\Wyeth	15 day report: Yes
Evaluated State: (b) (6)			
Auxiliary Report Identifier:		Date received by mfr./imm. proj. 01/12/2021	

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VAERS ID: 970943

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 970943 - 1
E-Number: 261263
Doc Number: 1374205
Date Received: 01/25/2021 12:03 PM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6), (b) (3) (A)
Phone:
Email: (b) (6), (b) (3) (A)

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 01/22/2021 **Time:** 14:00

5. Date and time adverse event started: 01/23/2021 **Time:** 13:00

6. Age at vaccination: 22 yr.

7. Today's date: 01/25/2021

8. Pregnant at the time of vaccination?: Unknown

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Unknown ? ? Midodrine

10. Allergies to medications, food, or other products:
unknown

11. Other illnesses at the time of vaccination and up to one month prior:
Traumatic Brain Injury ? 2019
Syncope ? 2019

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Patricia Higazi
Relation to Patient: Healthcare professional/staff
Address: 601 Children's Lane
City: Norfolk
State: VA **ZIP:** 23507
Phone: (757) 668-7491
Email: patricia.higazi@chkd.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: CHKD Occupational health
Fax: (757) 668-8775
Facility Address: 601 Children's Lane
City: Norfolk
State: VA **ZIP:** 23507
Phone: (757) 668-7491

16. Type of facility: Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EL1284	Intramuscular - IM	Left Arm	2

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Syncopal episodes X 4 on 1/23 - transferred to ed - admitted
Fever chills aches on 1/22/21 pm

19. Medical tests and laboratory results related to the adverse event(s):
unknow

20. Has the patient recovered from the adverse event(s)?: No

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care
* Hospitalization - (3 days, Hospital: (b) (6)

(b) (6)

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: Unknown
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: Unknown

25. Patient's ethnicity: Unknown

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line:
1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
PCC: N/A
Worldwide ID Number: US-PFIZER INC-2021027344
VAERS Number: 971535 - 1
Doc Number: 1374855
Date Received: 01/25/2021
Severity: Serious
Received by: eVAERS
Manufacturer: Pfizer\Wyeth
Combination Product: No
Combination Product Type: 15 Day See View Image
Data: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) [redacted] (last) [redacted]
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: [redacted] ZIP: [redacted]
County:
Phone: (b) (6), (b) (3) (A)
Email: [redacted]

2. Date of birth:

3. Sex: Female

4. Date and time of vaccination: 01/13/2021 Time: 13:30:00

5. Date and time adverse event started: 01/14/2021 Time: 04:00:00

6. Age at vaccination: 37 yr.

7. Today's date: 01/25/2021

8. Pregnant at the time of vaccination?:

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
VITAMIN B-12; IRON; VITAMIN D [VITAMIN D NOS]

10. Allergies to medications, food, or other products:

This report does not have medical codes at this time

11. Other illnesses at the time of vaccination and up to one month prior:

This report does not have medical codes at this time

12. Chronic or long-standing health conditions:
Medical History/Concurrent Conditions: Chronic fatigue syndrome

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Chronic fatigue syndrome	23.1	Chronic fatigue syndrome	23.1

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

13. Form completed by: (name)
Relation to Patient: Manufacturer
Address:
City:
State: ZIP:
Phone:
Email:

14. Best doctor/healthcare professional to contact about the adverse event:
Name (b) (6)
Phone Ext:

15. Facility/clinic name: Eastern Michigan University Convocation Center
Fax:
Facility Address:
399 Hewitt Rd
City: Ypsilanti
State: MI ZIP: 48197
Phone:

16. Type of facility:
School or student health clinic

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Lot Number	Location	Dose number in series	Injection Site Reaction
Pfizer\BioNTech / COVID19 (COVID19 (Pfizer-BioNTech))	EL3249	LA	1	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
lost consciousness; Severe cramping; diarrhea; This is a spontaneous report from a contactable (b) (6) (patient). A 37-year-old female patient received the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) Solution for injection (lot number: EL3249, expiry date unknown), via an unspecified route of administration on the left arm on 13Jan2021 13:30 at single dose for COVID-19 immunization. The patient's medical history included chronic fatigue syndrome from an unknown date and unknown if ongoing. The patient has no known allergies. Patient is not pregnant at the time of vaccination. Concomitant medications included cyanocobalamin (VITAMIN B-12), Iron, and Vitamin D (VITAMIN D NOS); patient received these medications within 2 weeks of vaccination. The patient did not receive any other vaccines within 4 weeks prior to

21. Result or outcome of adverse event(s): (Check all that apply).
* OMIC

BNT162B2. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient had not been tested for COVID-19. On 14Jan2021 04:00 AM, the patient experienced severe cramping, followed by episode of diarrhea. During the cramping, she lost consciousness for an unknown amount of time. No therapeutic measures were taken in response to the events. Outcome of the events at the time of last observation was recovering. The events were reported as non-serious.; Sender's Comments: A possible contribution role of the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) to the onset of lost consciousness cannot be excluded due to temporal relationship. 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.

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version
Muscle spasms	23.1	Cramps	23.1
Diarrhoea	23.1	Diarrhea	23.1
Loss of consciousness	23.1	Lost consciousness	23.1

19. Medical tests and laboratory results related to the adverse event(s):

This report does not have medical codes at this time

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Lot Number	Location	Dose number in series	Date Given

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report number: USPFIZER INC2021027344

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:	28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

OTHER DATA

State (formerly Box 1): (b) (6)
Literature/Study Report: No
OMIC Only: Yes
Manufacturer: Pfizer\Wyeth
15 day report: Yes
Evaluated State: (b) (6)

Auxiliary Report Identifier:

Date received by mfr./imm. proj. 01/14/2021

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
PCC: N/A
Worldwide ID Number: US-PFIZER INC-2021033566
VAERS Number: 976836 - 1
Doc Number: 1380551
Date Received: 01/27/2021
Severity: Serious
Received by: eVAERS
Manufacturer: Pfizer\Wyeth
Combination Product: No
Combination Product Type: 15 Day See View Image
Data: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first (b) (6), (b) (3) (A) last) (b) (6), (b) (3) (A)

Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State (b) (6), (b) (3) (A) ZIP: (b) (6), (b) (3) (A)
County:
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth:

3. Sex: Female

4. Date and time of vaccination: 01/14/2021 Time: 08:30:00

5. Date and time adverse event started: 01/15/2021 Time: 03:00:00

6. Age at vaccination: 41 yr.

7. Today's date: 01/26/2021

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
AMPHETAMINE SALTS

10. Allergies to medications, food, or other products:

This report does not have medical codes at this time

11. Other illnesses at the time of vaccination and up to one month prior:

This report does not have medical codes at this time

12. Chronic or long-standing health conditions:
Comments: List of non-encoded Patient Relevant History:
Patient Other Relevant History 1: None

This report does not have medical codes at this time

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM	**INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN**	
13. Form completed by: (name)	15.	16. Type of facility:

Relation to Patient: Manufacturer Address: City: State: ZIP: Phone: Email: 14. Best doctor/healthcare professional to contact about the adverse event: Name (b) (6) Phone Ext:	Facility/clinic name: Wchd Fax: Facility Address: 3303 Van Born road City: Wayne State: MI ZIP: Phone:	Public health clinic

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Lot Number	Location	Dose number in series	Injection Site Reaction
Pfizer\BioNTech / COVID19 (COVID19 (Pfizer-BioNTech))	EK9231	LA	1	

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
seeing gray spots room started spinning felt nauseous collapsed on the table; loss of vision; loss of hearing; seeing gray spots room started spinning felt nauseous collapsed on the table; seeing gray spots room started spinning felt nauseous collapsed on the table; seeing gray spots room started spinning felt nauseous collapsed on the table; loss of the onion ability to stand up or walk; loss of the onion ability to stand up or walk; This is a spontaneous report from a contactable (b) (6) (patient), a 41-year-old female patient received first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, lot number: EK9231) at left arm on 14Jan2021 08:30 AM at single dose for covid-19 immunization in a public health facility. Medical history was none. Allergies to medications, food, or other products was No. Patient was not pregnant at the time

21. Result or outcome of adverse event(s): (Check all that apply).
* Doctor or other healthcare professional office/clinic visit
* OMIC

of vaccination. the patient was not received any other vaccines within 4 weeks prior to the COVID vaccine. the patient received within 2 weeks of vaccination included amphetamine salts 15 mg. Patient woke up in the middle of the night got out of bed walk down a set of stairs started seeing gray spots room started spinning felt nauseous collapsed on the table. Had to call her husband to carry her back up the stairs. she had loss of vision loss of hearing and the onion ability to stand up or walk. He laid her back in bed to pick up his phone and call emergency services within five minutes everything had gone back to normal. adverse event start date was 15Jan2021 03:00 AM. the adverse event result in doctor or other healthcare professional office/clinic visit. Prior to vaccination, the patient was not diagnosed with COVID-19. Since the vaccination, the patient has not been tested for COVID-19. The final outcome of the events was unknown (if patient recovered: Unknown). It was reported as non-serious. Seriousness criteria Results in death, Life threatening, caused/prolonged hospitalization, Disabling/Incapacitating and Congenital anomaly/birth defect were all no.; Sender's Comments: A causal association between BNT162B2 and the reported events cannot be excluded based on a compatible temporal relation.
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.

MedDRA PT Name	PT Version	MedDRA LLT Name	LLT Version

Dysstasia	23.1	Difficulty in standing	23.1
Gait disturbance	23.1	Difficulty in walking	23.1
Deafness	23.1	Hearing loss	23.1
Blindness	23.1	Loss of vision	23.1
Nausea	23.1	Nauseous	23.1
Syncope	23.1	Orthostatic collapse	23.1
Vertigo	23.1	Spinning sensation	23.1
Visual impairment	23.1	Spots before eyes	23.1

19. Medical tests and laboratory results related to the adverse event(s):

This report does not have medical codes at this time

20. Has the patient recovered from the adverse event(s)?: Unknown

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Lot Number	Location	Dose number in series	Date Given

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: White

25. Patient's ethnicity: Hispanic or Latino

26. Immuniz. proj. report number: USPFIZER INC2021033566

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:	28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

OTHER DATA

State (formerly Box 1):	Literature/Study Report:	Manufacturer:	15 day report:
(b) (6)	No	Pfizer\Wyeth	Yes
Evaluated State: (b) (6)			
Auxiliary Report Identifier:		Date received by mfr./imm. proj. 01/15/2021	

U.S. FOOD & DRUG ADMINISTRATION

February 2, 2021

Dina Tresnan
Pfizer Inc.
1 Ascot Lane
Old Lyme CT 06731

In reply refer to file: F21-513

Dear Dr. Tresnan,

This is in reply to your Freedom of Information Act (FOIA) request dated January 21, 2021, in which you requested "a copy of redacted VAERS reports via FOIA. This is a request for the below VAERS reports to be sent in an expedited manner as soon as possible. These include six serious cases of ITP for VAERS IDs 905345, 906910, 908869, 920719, 930153, and 939654." Your request was received in the Center for Biologics Evaluation and Research on January 25, 2021.

Enclosed please find the results of a query of the Vaccine Adverse Event Reporting System (VAERS) using the search parameters listed in your FOIA request. Please note that during a telephone conversation with Catherine Wilusz on January 6, 2021, you stated that medical records would not be considered responsive for this FOIA request. In addition, per a telephone conversation with Catherine Wilusz on February 2, 2021, it was agreed that a Pfizer submitted VAERS report (906910-3) would not be included in the response.

We have withheld portions of pages under Exemption (b)(3), 5 U.S.C. § 522(b)(3). That exemption prohibits the release of information that is otherwise prohibited from disclosure by another federal statute.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of this response, to:

Director, Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Katherine Uhl at 301-796-8975.

You may also contact the FDA FOIA Public Liaison for assistance at:

Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

The following may be included in a monthly invoice:

Search	1/2 Hour @ $46.00/hr	$23.00
Review	2 Hours @ $46.00/hr	$92.00
TOTAL		**$115.00**

The above charges may not reflect final charges for this request. Please DO NOT send any payment until you receive an invoice from the Agency's Freedom of Information Staff (HFI-35).

If you have any questions or if we can be of further assistance, please let us know by referencing the above file number. You can contact Catherine Wilusz by phone at 240-402-8184 or by e-mail at Catherine.wilusz@fda.hhs.gov.

Sincerely,

Beth A. Brockner Ryan -S

Digitally signed by Beth A. Brockner Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300052489, cn=Beth A. Brockner Ryan -S
Date: 2021.02.02 14:42:15 -05'00'

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

VAERS ID: 905345

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 905345 - 1
E-Number: 209068
Doc Number: 1302975
Date Received: 12/21/2020 1:08 PM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6) (last) (b) (6), (b)
Address:
City:
State: ZIP:
County:
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Male

4. Date and time of vaccination: 12/17/2020 **Time:**

5. Date and time adverse event started: 12/20/2020 **Time:**

6. Age at vaccination: 22 yr.

7. Today's date: 12/21/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
None reported by patient

10. Allergies to medications, food, or other products:
No known allergies

11. Other illnesses at the time of vaccination and up to one month prior:
No known past medical history

12. Chronic or long-standing health conditions:
None

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Ryan
Relation to Patient: Healthcare professional/staff
Address:
City:
State: ZIP:
Phone:
Email: ryan.servais@aah.org
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Aurora St. Luke's Medical Center
Fax:
Facility Address:
2900 W Oklahoma Ave
City: Milwaukee
State: WI **ZIP:**
Phone:

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech		Intramuscular - IM		1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Patient received Pfizer COVID 19 vaccine last Thursday 12/17. Admitted (b) (6)(b) (6) with bleeding and low platelet count - working up for ITP, TTP. Given recency of vaccination and no known contributory allergy or medical history, physician thought potentially associated with vaccination.

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care
* Hospitalization

19. Medical tests and laboratory results related to the adverse event(s):
COVID (-)
Platelets 2000 cells/mcL

20. Has the patient recovered from the adverse event(s)?:

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: Unknown

25. Patient's ethnicity: Unknown

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 905345
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 905345 - 2
E-Number: 209075
Doc Number: 1303057
Date Received: 12/21/2020 1:15 PM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:**
County: (b) (6), (b) (3) (A)
Phone (b) (6), (b) (3) (A)
Email:

2. Date of birth: (b) (6)

3. Sex: Male

4. Date and time of vaccination: 12/17/2020 **Time:** 07:14

5. Date and time adverse event started: 12/20/2020 **Time:** 07:00

6. Age at vaccination: 22 yr. 0 mon.

7. Today's date: 12/21/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
NONE

10. Allergies to medications, food, or other products:
NONE

11. Other illnesses at the time of vaccination and up to one month prior:
NONE

12. Chronic or long-standing health conditions:
NONE

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) JANET KLAPATAUSKAS
Relation to Patient: Healthcare professional/staff
Address: 950 N 12TH ST
City: MILWAUKEE
State: WI **ZIP:** 53233
Phone: (414) 219-5105
Email: JANET.KLAPATAUSKAS@AAH.ORG
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: MIHAIL ANDREEV
Phone: (414) 219-7813 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: AURORA ST LUKES MEDICAL CENTER
Fax: (414) 649-5113
Facility Address: 2900 W. OKLAHOMA
City: MILWAUKEE
State: WI **ZIP:** 53215
Phone: (414) 649-6322

16. Type of facility: Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EK5730	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Recieved the COVID 19 vaccine 12/17/2020. Rash to chest started 12/20/2020, spread to back, body throughout day. By evening bleeding sores in mouth.

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care
* Hospitalization (Hospital: (b) (6) (b) (6)

19. Medical tests and laboratory results related to the adverse event(s):
Diagnosed with Thrombocytopenia and admitted
(b) (6)

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: Unknown

25. Patient's ethnicity: Unknown

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

VAERS ID: 906910

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 906910 - 1
E-Number: 210092
Doc Number: 1304800
Date Received: 12/22/2020 4:37 PM
Severity: Death
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient N (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County:
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth: (b) (6)

3. Sex: Male

4. Date and time of vaccination: 12/18/2020 **Time:**

5. Date and time adverse event started: 12/21/2020 **Time:** PM

6. Age at vaccination: 56 yr.

7. Today's date: 12/22/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
No home medications at the time of vaccination or hospital admission

10. Allergies to medications, food, or other products:
No known allergies of any type

11. Other illnesses at the time of vaccination and up to one month prior:
No pertinent past medical history prior to vaccination

12. Chronic or long-standing health conditions:
No pertinent past medical history prior to vaccination

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to Patient: Healthcare professional/staff
Address: 4300 Alton Road
City: Miami Beach
State: FL **ZIP:** 33140
Phone: (305) 674-2314
Email: Julieth.formosa@msmc.com
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Julieth Formosa
Phone: (305) 674-2314 **Ext:** 3056742314

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Mount Sinai Medical Center
Fax: (305) 535-1832
Facility Address:
4300 Alton Road
Suite 2020
City: Miami Beach
State: FL **ZIP:** 33140
Phone: (305) 674-2314

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EH9899	Intramuscular - IM	Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
HPI: 56 y.o. male with no pmhx c/o generalized bruising for 2 days, noticed small blood tinged spots generalized. Gradual onset, severe on severity, no alleviating or aggravating factors. Patient denies

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care
* Hospitalization (1 day, Hospital: (b) (6)
(b) (6)

fevers, chills, N/V/D, abdominal pain. In ER: Platelet <1. Platelet transfusion in ER. Admitted for Thrombocytopenia/ITP

19. Medical tests and laboratory results related to the adverse event(s):
BP: 159/106 (b) (6) Platelets 0 (b) (6) , monocytes 12.1% (b) (6) BUN 22.3 (b) (6) BILI 1.50 (b) (6) calculated osmolality 297 (b) (6) . All other labs are w

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: Unknown

25. Patient's ethnicity: Unknown

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

VAERS ID: 906910
EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 906910 - 2
E-Number: 211492
Doc Number: 1306922
Date Received: 12/24/2020 2:14 PM
Severity: Non-Serious
Consolidated: Death
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: (b) (6), (b) (3) (A) **ZIP:**
County: (b) (6), (b) (3) (A)
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth: (b) (6)

3. Sex: Male

4. Date and time of vaccination: 12/18/2020 **Time:** 10:20

5. Date and time adverse event started: 12/21/2020 **Time:** 08:00

6. Age at vaccination: 56 yr.

7. Today's date: 12/24/2020

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
nothing

10. Allergies to medications, food, or other products:
no

11. Other illnesses at the time of vaccination and up to one month prior:
no

12. Chronic or long-standing health conditions:
no

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to Patient: Healthcare professional/staff
Address: 4302 alton road
City: miami beach
State: FL **ZIP:** 33140
Phone: (305) 968-2601
Email: (b) (6)
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: mount sinai medical center
Fax:
Facility Address:
4300 alton road
City: miami beach
State: FL **ZIP:** 33140
Phone: (305) 968-2601

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech		Intramuscular - IM	Right Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
got shot Friday
developed platelet count of 0 3 days later!
had cbc normal 6 months prior

21. Result or outcome of adverse event(s): (Check all that apply).
* Doctor or other healthcare professional office/clinic visit

19. Medical tests and laboratory results related to the adverse event(s):
cbc shows plt 0 on(b) (6)

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

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VAERS ID: 908869

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 908869 - 1
E-Number: 211539
Doc Number: 1307032
Date Received: 12/24/2020 3:10 PM
Severity: Serious
Received By: Public Site Upload (writable pdf; version: 2.0.09) View PDF
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State (b) (6), (b) (3) (A) **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6), (b) (3) (A)
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Male

4. Date and time of vaccination: 12/18/2020 **Time:** 10:13

5. Date and time adverse event started: 12/19/2020 **Time:** 09:00

6. Age at vaccination: 73 yr.

7. Today's date: 12/23/2020 (b) (6)

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Comprehensive list displayed in additional information below.

10. Allergies to medications, food, or other products:
NKDA

11. Other illnesses at the time of vaccination and up to one month prior:
Vague symptoms (anorexia, fatigue)

12. Chronic or long-standing health conditions:
HTN, Type II Diabetes

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) Aubrey Jones
Relation to Patient: Healthcare professional/staff
Address: 1000 N. Lee Ave
City: Oklahoma City
State: OK **ZIP:** 73102
Phone: (405) 272-6796
Email: aubrey.jones@ssmhealth.com

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Darin Smith
Phone: (405) 815-5073 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: SSM Health - St. Anthony Hospital
Fax:
Facility Address: 1000 N. Lee Ave
City: Oklahoma City
State: OK **ZIP:** 73102
Phone: (405) 815-5073

16. Type of facility: Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EH9899	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
12/18/2020: COVID19 vaccine received.
12/19/2020: Patient noticed petechiae/bruising on

21. Result or outcome of adverse event(s): (Check all that apply).
* Doctor or other healthcare professional office/clinic visit
* Hospitalization (2 days, Hospital: (b) (6)

arms, legs and face. Worsened over next 48 hours. 12/21/2020: Patient had blood drawn (CMP, PT/INR, CBC) at (b) (6)
12/22/2020: Labs resulted; CMP and PT/INR WNL (exceptions: SCr 1.24, TBil 1.7); CBC with platelet count of 1,000 resulting in patient admission to (b) (6) (b) (6) At admission he received 80 mg of prednisone, 40 g of IV Ig and a unit of platelets.
(b) (6) Continued hospitalization. Patient's platelets improved to 20,000 and he received another 35g of IV Ig.
(b) (6) Patient discharged with platelets of 38,000.

(b) (6)
* Life threatening illness

19. Medical tests and laboratory results related to the adverse event(s):
12/21/2020 CBC: platelets of 1,000

20. Has the patient recovered from the adverse event(s)?: Yes

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date
1199 - Influenza (Seasonal) (Fluzone High-Dose Quadrivalent)	Sanofi Pasteur	U35UAB	Intramuscular - IM	Left Arm	1	11/25/2020

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:
Additional information for Item 9: ascorbic acid daily, atorvastatin 40mg daily, cholecalciferol daily, docusate 100mg daily, levothyroxine 100mcg daily, losartan 100mg daily, zinc 50mg daily

Additional information for Item 11: Received high-dose influenza vaccination on 11/25/2020 at (b) (6) employee health department. On 11/29/2020 patient began having generalized fatigue, anorexia, and occasional chills. Presented to (b) (6) Urgent care on (b) (6) and reported same symptoms for past 5 days with 10-12 lb weight loss and worsening fatigue. Pfizer rapid PCR COVID test negative. Patient's symptoms improved and he returned to normal activities of daily living until 12/19/2020, 1 day after COVID19 vaccination.

PDF UPLOAD DATA

SessionId	File Size	File Name	Created On	Uploader Name	Uploader Email
(b) (6)	3873198 kb	VAERSForm(b) (6)df	12/24/2020	Aubrey Jones	aubrey.jones@ssmhealth.com

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VAERS ID: 920719

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 920719 - 1
E-Number: 221033
Doc Number: 1319996
Date Received: 01/05/2021 11:58 AM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County (b) (6), (b) (3) (A)
Phone
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 12/23/2020 **Time:** 16:32

5. Date and time adverse event started: 12/28/2020 **Time:** 07:30

6. Age at vaccination: 36 yr.

7. Today's date: 01/05/2021

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
none

10. Allergies to medications, food, or other products:
none

11. Other illnesses at the time of vaccination and up to one month prior:
none

12. Chronic or long-standing health conditions:
none

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6) (b) (6)
Relation to Patient: Patient
Address: (b) (6)
City (b) (6) (b) (6)
State: (b) (6) **ZIP:**
Phone: (b) (6)
Email:
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Dr. Jacqueline Mackey
Phone: (215) 385-1561 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Abington Jefferson Health
Fax:
Facility Address:
1200 Old York Road
City: Abington
State: PA **ZIP:** 19001
Phone: (215) 481-2000

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	EL0140	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
starting to feel lethargic and weak. Had menses with increased blessed. Called physician to have blood work done to see if I was experiencing anemia. Blood work complete on 12/31/2020. On (b) (6) I

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care
* Hospitalization (2 days, Hospital (b) (6) (b) (6)

woke up with blood blisters all over the inside of my mouth and petechia on my trunk and bilateral upper and lower extremities. I called my primary physician to report the symptoms. He suggested to go to the ER if my symptoms worsened. Later that evening I started with a nose bleed and did go to the ER. Upon arrival to the ER, my platelet count was 9. I was admitted to the hospital and diagnosed with ITP.

19. Medical tests and laboratory results related to the adverse event(s):
blood work

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

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VAERS ID: 930153

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 930153 - 1
E-Number: 228476
Doc Number: 1330305
Date Received: 01/08/2021 4:34 PM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:**
County:
Phone: (b) (6), (b) (3) (A)
Email:

2. Date of birth: (b) (6)

3. Sex: Male

4. Date and time of vaccination: 01/05/2021 **Time:**

5. Date and time adverse event started: 01/07/2021 **Time:** 08:00

6. Age at vaccination: 41 yr.

7. Today's date: 01/08/2021

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Atorvastain 10mg
Levothyroxine 112mcg
Prilosec 20mg
Insulin

10. Allergies to medications, food, or other products:
PCN

11. Other illnesses at the time of vaccination and up to one month prior:
NA

12. Chronic or long-standing health conditions:
Insulin dependent Diabetes
HX of ITP 2014, in remession

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6)
Relation to Patient: Healthcare professional/staff
Address: (b) (6)
City: (b) (6)
State: **ZIP:** (b) (6)
Phone
Email: (b) (6)
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: (b) (6)

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Charlevoix Health Department
Fax: (231) 547-6238
Facility Address:
220 W. Garfield Ave
City: Charlevoix
State: MI **ZIP:** 49720
Phone: (800) 432-4121

16. Type of facility:
Public health clinic

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech		Intramuscular - IM	Right Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)

21. Result or outcome of adverse event(s): (Check all that apply).
* Hospitalization (1 day, Hospital: (b) (6)

ITP Plt 2

(b) (6)

* Life threatening illness

19. Medical tests and laboratory results related to the adverse event(s):
Plt 2

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: White

25. Patient's ethnicity:

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site: No

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

01/18/2021 12:03 EST (b) (6) Re: Acknowledgement w/ Missing Data

003/ 1364485 930153 - 1 01/18/2021 - Serious Page 1

Subject **Re: Acknowledgement w/ Missing Data**
From (b) (6)
To info@vaers.org <info@vaers.org>
Date 2021-01-15 07:49

(b) (6)
(b) (6)
Email

Lot number EL0140

Get Outlook for iOS

From: info@vaers.org <info@vaers.org>
Sent: Thursday, January 14, 2021 3:20:10 PM
To: (b) (6)
Subject: Acknowledgement w/ Missing Data

****WARNING:** This email originated from outside of (b) (6)
DO NOT CLICK on any links or open any attachments unless you recognize the sender and are expecting the message.
NEVER provide your login or password

VAERS
Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Report Confirmation + Information Request

VAERS
JAN 18 2021
Rockville, MD

Dear (b) (6)

Thank you for submitting a report to the Vaccine Adverse Event Reporting System (VAERS). Your report helps the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) monitor the safety of vaccines and protect America's health.

We Need Additional Information About Your Report

Please complete the form below and return electronically (using auto upload), by fax, or by mail.

To protect patient privacy, please do not send confidential information (such as patient name or date of birth) by email.

Your VAERS Report ID
and how to contact us

VAERS ID: 939654

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 939654 - 1
E-Number: 236305
Doc Number: 1340477
Date Received: 01/13/2021 7:21 AM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: (b) (6), (b) **ZIP:** (b) (6), (b) (3) (A)
County
Phone (b) (6), (b) (3) (A)
Email:

2. Date of birth (b) (6)

3. Sex: Male

4. Date and time of vaccination: 12/23/2020 **Time:** 13:00

5. Date and time adverse event started: 01/07/2021 **Time:** 10:00

6. Age at vaccination: 53 yr.

7. Today's date: 01/13/2021

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
Allpurinol 100mg/day, amLopidine-olmesartan 4-40mg, atorvastatin 40mg

10. Allergies to medications, food, or other products:
seasonal allegeries

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:
fatty liver

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6)
Relation to Patient: Patient
Address: (b) (6)
City: (b) (6)
State: **ZIP:** (b) (6)
Phone:
Email: (b) (6)
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name: Rachna Raman
Phone: (804) 287-7804 **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: Bon Secours Mercy Health - St Mary's
Fax:
Facility Address:
5801 Bremo Rd
City: Richmond
State: VA **ZIP:** 23226
Phone: (804) 393-9805

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	eh9899	Intramuscular - IM	Left Arm	1

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Vaccine was given on 12/23/20 on (b) (6) went to get a routine physical and received an emergency call that my pallet blood count was around 10K instead of 150k. Was instructed to go to the ER asap. However didn't received the message until the next morning at 6:30am. Was checked into the E.R. , given sterioids, pallets, hemogolibin. Stayed overnight in the hospital was able to leaved the next day around 1pm with pallets at 47k.

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: Unknown

21. Result or outcome of adverse event(s): (Check all that apply).

* Doctor or other healthcare professional office/clinic visit
* Emergency room/department or urgent care
* Hospitalization (1 day, Hospital: (b) (6) - (b) (6)

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech	eh9899	Intramuscular - IM	Left Arm	1	12/23/2020

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: Black or African American

25. Patient's ethnicity:

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: Other: Veteran

28. Vaccinated at Military/DoD site: No

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information: