From: "Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR)" <[redacted]>
To: "Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)" <[redacted]>, "Weintraub, Eric (CDC/DDID/NCEZID/DHQP)" <[redacted]>
Subject: FW: RE ACIP PowerPoint Presentation
Date: Tue, 1 Aug 2023 20:23:19 +0000
Importance: Normal
Attachments: PAL_Request_Form.pdf; ACIP_PPP-Feb_24,_2023-23-00835-FOIA.pdf
Inline-Images: image001.jpg

Greetings!

See below and advise. Thanks.

Elnetta Mitchell, MBA
Goldbelt C6, LLC
DHQP/NCEZID/CDC
Centers for Disease Control and Prevention
Email: [redacted]
Phone: [redacted]

From: Diaz, Irma S. (CDC/OCOO/OD) <[redacted]>
Sent: Tuesday, August 1, 2023 4:14 PM
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP) <[redacted]>; Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR) <[redacted]>
Subject: RE ACIP PowerPoint Presentation

Hi PerStephanie and Elnetta:

I need a big favor. Could you please check with your SME about the attached PPP? Can we release in full to Mr. Stieber?

Please call me if you have any questions.

Thank you.

Best.

Irma S. Diaz, DrPH.
Government Information Specialist (Appeals & Litigations)
CDC/ATSDR Freedom of Information Act Office
Direct [redacted]
Main:
Email: [redacted]

From: Kristin Goddard
Sent: Fri, 24 Feb 2023 15:12:42 +0000
To: Weintraub, Eric (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: NICOLA P KLEIN; Ned Lewis
Subject: RE: Poss error in slides 30 and 31 from today
Attachments: 02_COVID_Shimabukuro_2023_02_24_posting_nck.pptx

Corrected version attached.

Kristin

From: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Friday, February 24, 2023 6:50 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Kristin Goddard <[redacted]>
Cc: NICOLA P KLEIN <Nicola.Klein@kp.org>; Ned Lewis <[redacted]>
Subject: Re: Poss error in slides 30 and 31 from today

Yea. Looks like somewhere down the line the Moderna results are copies of Pfizer for primary and first booster.
Slide just needs to be updated with the results from Kristins paper. (I'm thinking I made the edits but then the slides we're saved properly) Strange for sure.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Friday, February 24, 2023 9:27:06 AM
To: Kristin Goddard <[redacted]>
Cc: Weintraub, Eric (CDC/DDID/NCEZID/DHQP) <[redacted]>; NICOLA P KLEIN <[redacted]>; Ned Lewis <[redacted]>
Subject: FW: Poss error in slides 30 and 31 from today

Kristin – Can you look at slides 29 and 30 on the attached presentation (slides 30 and 31 that Jamie is referring to). I see what he is talking about with the case counts being the same for both vaccines. If it is a cut/copy and paste error it could have been me that made the error when I was reformatting things in the tables. Thanks.
Tom

From: Jamie Loehr <[redacted]>
Sent: Friday, February 24, 2023 9:19 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; [redacted]
Subject: Poss error in slides 30 and 31 from today

Hi Tom,

I just wanted to share a possible error in your slides 30 and 31 from today, at least in the printed version.

Slide 30 is the VSD incidence rates of verified myocaridits... Pfizer
Slide 31 is the VSD incidence rates of verified myocarditis... Moderna

On the printed version in our handouts, the data in 18-29 years and 30-39 years for Dose 2 primary series and 1st monovalent booster dose columns is the same in both slides
For example, even though slide 30 says Pfizer and slide 31 says Moderna, both say 27 cases in males, 2 cases in females and both have the 1st booster column for 30-39 males of 197,554.

The Bivalent Booster Dose column is different (50,687 bivalent booster doses in 18-29 year males for Pfizer vs 18,499 for Moderna)

I suspect it was a cut and paste error but wanted to let you know.

Jamie Loehr
ACIP member

National Center for Emerging and Zoonotic Infectious Diseases

COVID-19 mRNA bivalent booster vaccine safety

Advisory Committee on Immunization Practices (ACIP) meeting

February 24, 2023

Tom T. Shimabukuro, MD, MPH, MBA
Director, Immunization Safety Office
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention (CDC)

Topics

- Describe CDC's Vaccine Safety Datalink (VSD) Rapid Cycle Analysis (RCA) monitoring methods and assessment processes for statistical signals
- Describe VSD RCA signal detection and signal assessment for ischemic stroke after Pfizer-BioNTech COVID-19 mRNA bivalent booster dose vaccination in the age group 65 years and older
- Describe rates of myocarditis/pericarditis following COVID-19 mRNA vaccination

Background: COVID-19 mRNA bivalent booster vaccination in the United States

- Bivalent COVID-19 mRNA booster vaccinations first became available in the United States in September 2022
- As of February 8, 2023, 52.5 million COVID-19 mRNA bivalent booster doses administered in people ages 5 years and older in the United States*
  - Includes 22.3 million doses in people ages 65 years and older*
- CDC and partners monitor the safety of licensed and authorized U.S. vaccines using multiple complementary systems (Vaccine Information and Safety Studies | Vaccine Safety | CDC)
- Safety data support CDC recommendations that everyone eligible for a COVID-19 mRNA bivalent booster get vaccinated

* CDC COVID Data Tracker: Vaccinations in the US

VSD COVID-19 Rapid Cycle Analysis: Preliminary Analyses of Ischemic Stroke after Pfizer-BioNTech Bivalent Booster Dose

Prepared by:
Kaiser Permanente Northern California Vaccine Study Center

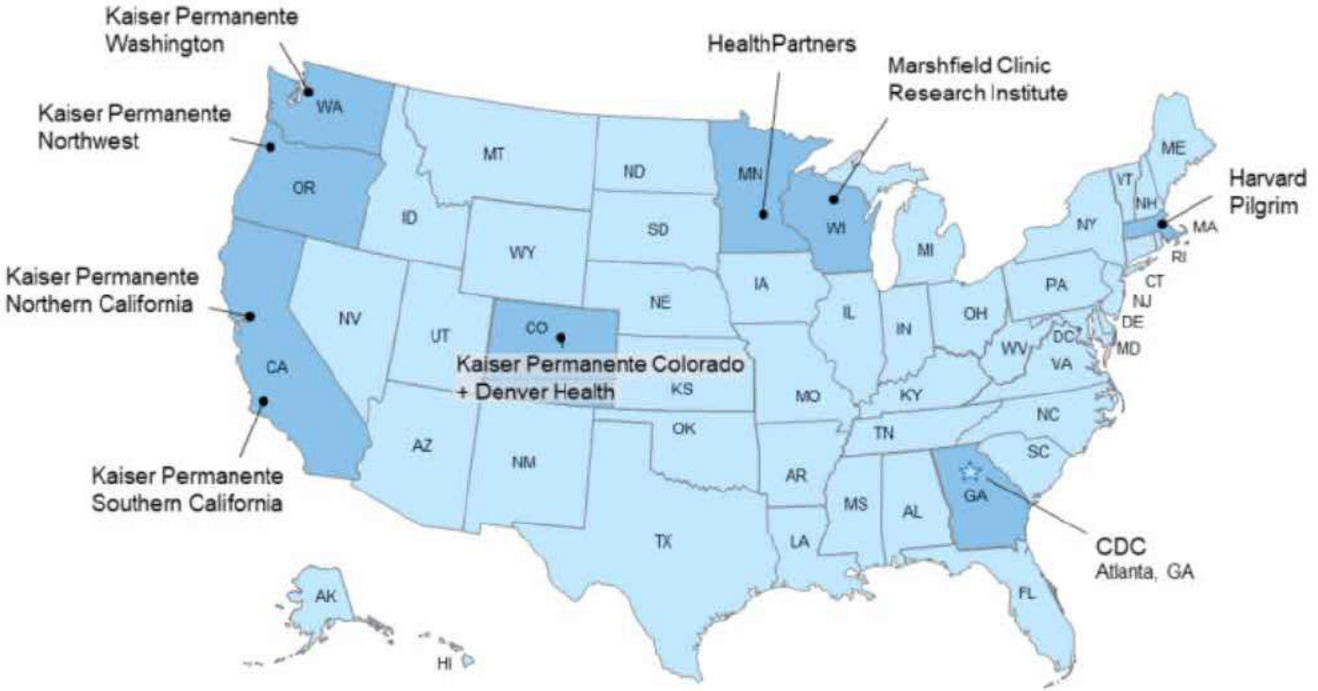
Presented by Tom Shimabukuro, MD, MPH, MBA
Centers for Disease Control and Prevention

KAISER PERMANENTE VACCINE STUDY CENTER

CDC

Marshfield Clinic Research Institute

Vaccine Safety Datalink (VSD)



- Established in 1990
- Collaborative project between CDC and 9 integrated healthcare organizations
- Includes electronic health record data on ~12.5 million individuals

Strengths of VSD Rapid Cycle Analysis (RCA)

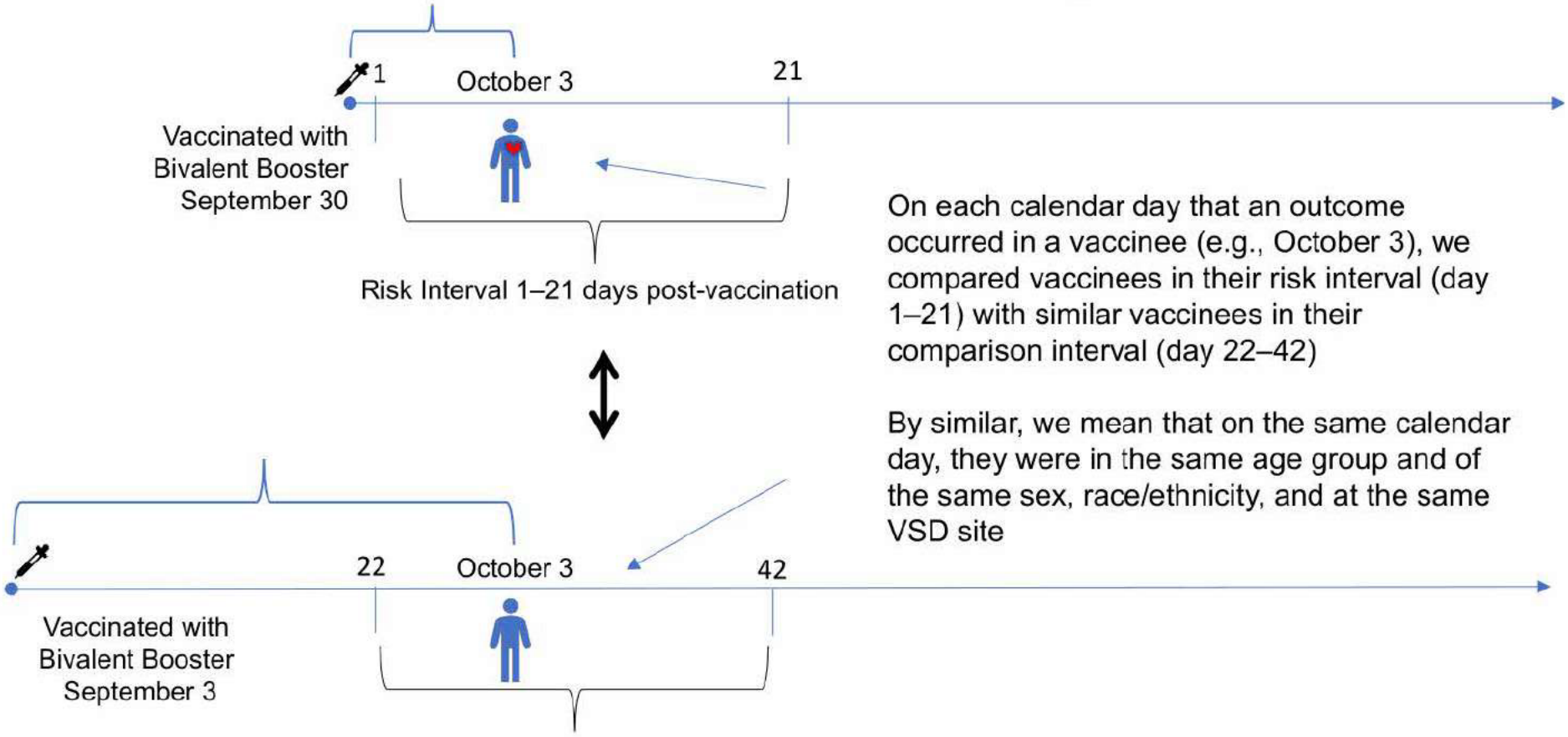
- **Population**
  - ~12.5 million people (equal to ~4% of the U.S. population) across VSD data sites are geographically and racially/ethnically diverse
- **Data**
  - Near real-time data, with analyses updated weekly
  - Access to comprehensive medical records, including exposures (vaccination) and outcomes, allowing rapid chart reviews to obtain additional clinical information as needed
- **Innovative Methods**
  - *Vaccinated concurrent comparators:* Recent vaccinees as comparators are expected to be more similar to current vaccinees than unvaccinated individuals with the following advantages
    - Careful adjustment for potential biases associated with calendar time, site, and demographic factors
    - Analyses can begin sooner than alternative methods
  - *Supplemental analyses conducted weekly:* Unvaccinated/un-boosted comparators would also be available to provide context in real time
  - Using vaccinated concurrent comparators with supplemental analyses offers substantial benefits compared with either unvaccinated or historical comparators

VSD RCA for bivalent boosters

- Pre-specified outcomes were assessed during weekly sequential monitoring after COVID-19 bivalent booster vaccination*
  - Risk of pre-specified outcomes 1–21 days following a bivalent vaccination compared with bivalent vaccinated individuals who were 22–42 days following the bivalent dose
  - All analyses adjusted for age, sex, race/ethnicity, VSD site, calendar time (days) and seasonality (time)
  - Signal if p-value <0.01 (1-sided)

* Rapid Cycle Analysis (RCA) to monitor the safety of COVID-19 vaccines in near real-time within the Vaccine Safety Datalink. Available at: Rapid Cycle Analysis (RCA) to monitor the safety of COVID-19 vaccines in near real-time within the Vaccine Safety Datalink | CDC

Vaccinee with outcome in the risk interval and a concurrent comparator "bivalent vaccinated individuals only"



On each calendar day that an outcome occurred in a vaccinee (e.g., October 3), we compared vaccinees in their risk interval (day 1–21) with similar vaccinees in their comparison interval (day 22–42)

By similar, we mean that on the same calendar day, they were in the same age group and of the same sex, race/ethnicity, and at the same VSD site

VSD COVID-19 vaccine RCA prespecified surveillance outcomes

- In COVID-19 bivalent booster vaccine monitoring, VSD RCA detected a statistical signal for ischemic stroke after Pfizer-BioNTech bivalent booster vaccination in the age group 65 years and older
- No other VSD RCA pre-specified surveillance outcomes have signaled in any age groups for either of the mRNA COVID-19 bivalent booster vaccines or when data for the two mRNA vaccine types are combined/pooled

Prespecified outcomes	Settings
Acute disseminated encephalomyelitis	Emergency dept, Inpatient
Acute myocardial infarction	Emergency dept, Inpatient
Acute respiratory distress syndrome	Emergency dept, Inpatient
Anaphylaxis*	Emergency dept, Inpatient
Appendicitis	Emergency dept, Inpatient
Bell's palsy	Emergency dept, Inpatient, Outpatient
Cerebral venous sinus thrombosis	Emergency dept, Inpatient
Disseminated intravascular coagulation	Emergency dept, Inpatient
Encephalitis / myelitis / encephalomyelitis	Emergency dept, Inpatient
Guillain-Barré syndrome	Emergency dept, Inpatient
Immune thrombocytopenia	Emergency dept, Inpatient, Outpatient
Kawasaki disease	Emergency dept, Inpatient
Multisystem inflammatory syndrome in children/adults (MIS-C/MIS-A)	Emergency dept, Inpatient
Myocarditis / pericarditis*	Emergency dept, Inpatient
Narcolepsy / cataplexy	Emergency dept, Inpatient, Outpatient
Pulmonary embolism	Emergency dept, Inpatient
Seizures/Convulsions (including 0-7 days for youngest ages)	Emergency dept, Inpatient
Stroke, hemorrhagic	Emergency dept, Inpatient
Stroke, ischemic	Emergency dept, Inpatient
Thrombosis with thrombocytopenia syndrome	Emergency dept, Inpatient
Thrombotic thrombocytopenic purpura	Emergency dept, Inpatient
Transverse myelitis	Emergency dept, Inpatient
Venous thromboembolism	Emergency dept, Inpatient, Outpatient

*All outcomes are first ever in the ICD-10 era, except anaphylaxis which is first in 7 days, and myocarditis/pericarditis which is first in 60 days

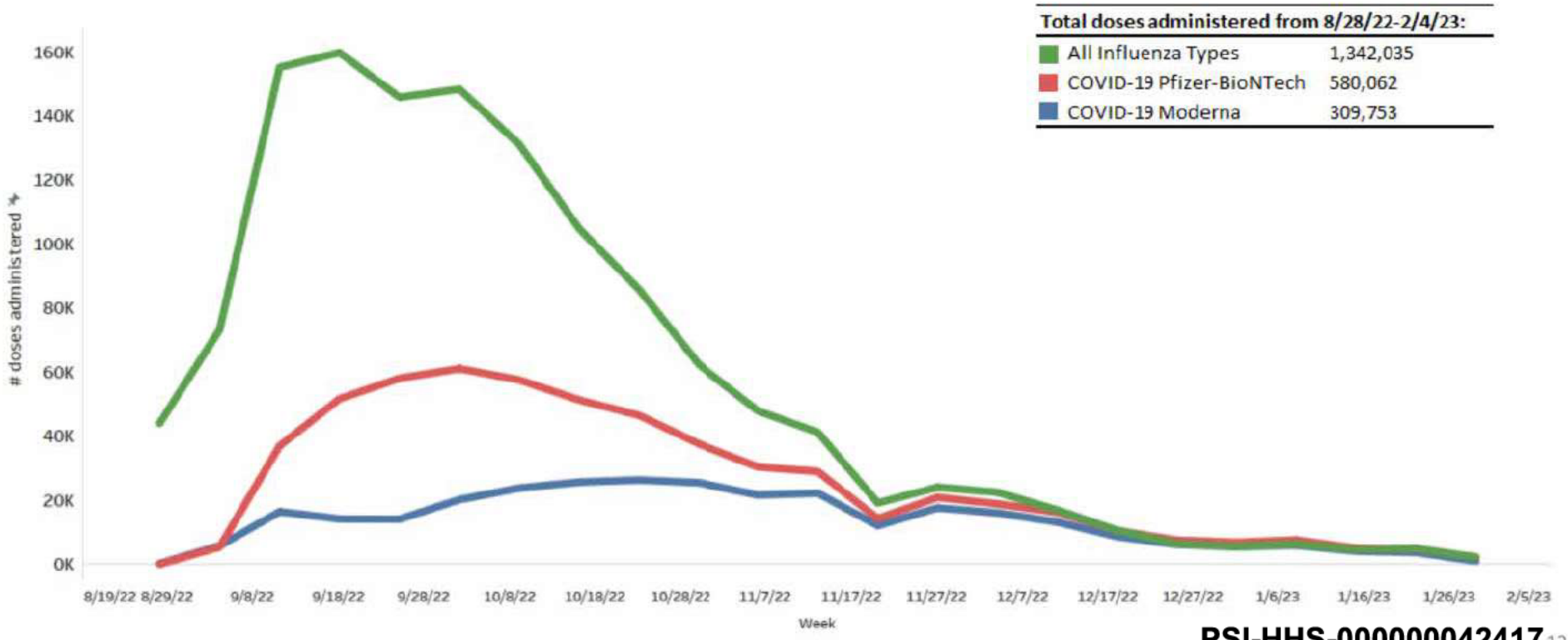
VSD investigations of an RCA signal to assess whether it reflects a real effect of vaccination on an outcome

- Data quality assessment for errors, anomalies, or missing/late-arriving data
- Analyses using different comparators than primary concurrent (e.g., un-boosted, unvaccinated or "historical" comparators) to supplement our primary analyses
- Additional investigations to provide context (e.g., background rates, etc.)
- Graphic displays of outcome incidence day by day after vaccination, using temporal scan statistics to assess apparent clustering
  - Examine the temporal clustering of outcome events in subgroups defined by demographics, site or simultaneous exposure (e.g., flu vaccine)
- If the signal is driven by a strong association in one subgroup or VSD site, further analyses by site or subgroup as appropriate
- Chart review to confirm cases and collect additional data (e.g., date of symptom onset).
- Consider epidemiologic studies to further investigate surveillance findings

Rapid Cycle Analysis (RCA) to monitor the safety of COVID-19 vaccines in near real-time within the Vaccine Safety Datalink. Available at: Rapid Cycle Analysis (RCA) to monitor the safety of COVID-19 vaccines in near real-time within the Vaccine Safety Datalink (education)

VSD COVID-19 RCA preliminary analyses: Ischemic stroke after Pfizer-BioNTech bivalent booster among people ≥65 years of age

Number of COVID-19 bivalent booster doses and influenza vaccine doses administered over time among persons aged ≥65 years, by vaccine type in VSD



VSD RCA Ischemic Stroke Definition

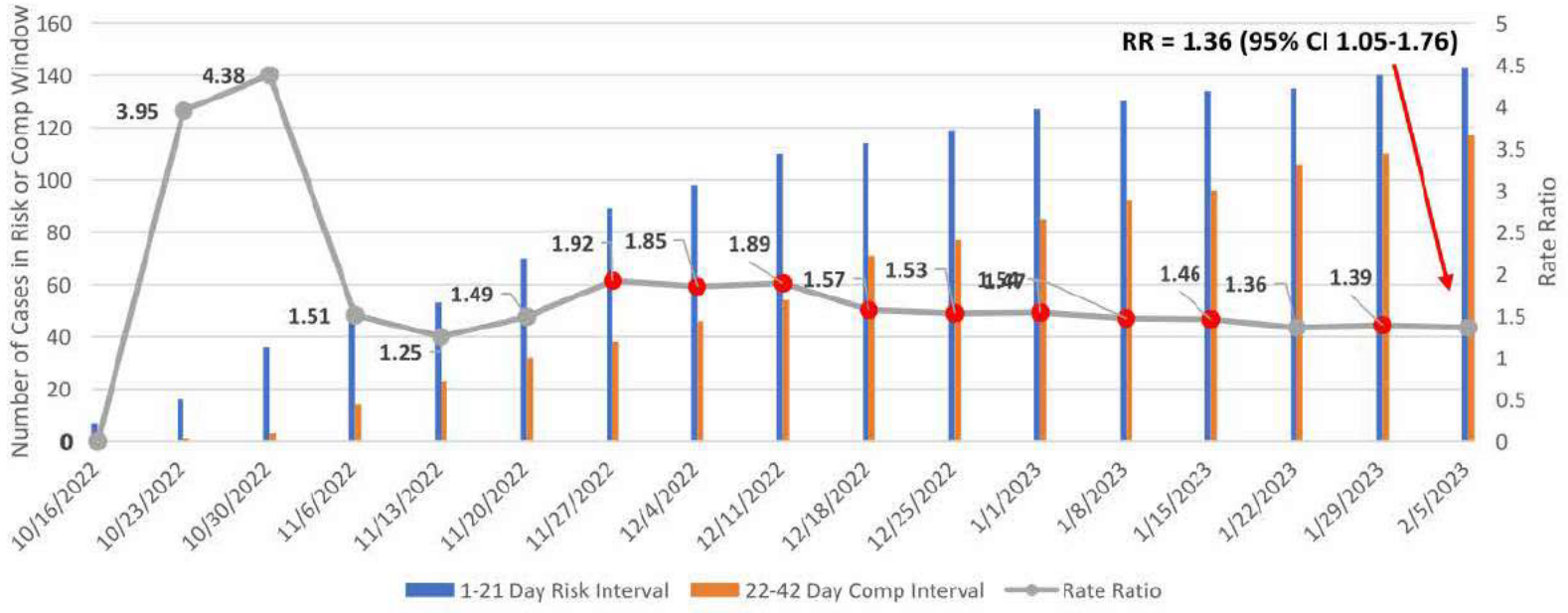
ICD-10 CODES TO FIND INCIDENT CASES	ICD-10 CODES FOR LOOKBACK TO ADJUST ONSET DATE (in all settings)	ICD-10 CODES - TO DETECT PREVALENCE (history of, in all settings)	ICD-10 CODES - OTHER CAUSE EXCLUSIONS (in all settings)
Stroke, ischemic (settings = Emergency, Inpatient)	Codes to adjust Stroke, ischemic onset (if seen within 1 day before case)	Stroke, ischemic - Review for Prevalence - 1ST EVER	Other possible causes of Stroke, ischemic
G45.8 Other transient cerebral ischemic attacks and related syndromes G45.9 Transient cerebral ischemic attack, unspecified I63.* Cerebral infarction	**Adjust onset date if occurs in the 1 day prior to incident case:** Z92.82 Status post administration of tPA (rtPA) in a different facility within the last 24 hours prior to admission to current facility R51.* Headache R47.* Speech disturbances, not elsewhere classified R29.810 Facial weakness R53.1 Weakness R42.* Dizziness and giddiness R41.82 Altered mental status, unspecified R40.4 Transient alternation of awareness G81.9* Hemiplegia, unspecified H53.9 Unspecified visual disturbance H53.13* Sudden visual loss	**Exclude if occurs EVER prior to incident case:** Z86.73 Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits I69.* Sequelae of cerebrovascular disease	**Exclude if COVID-19 in the last 30 days prior to incident case (not including same day):** COVID-19 DIAGNOSIS **OR** COVID-19 POSITIVE LAB TEST **Exclude if occurs in the time period noted prior to incident case (not including same day):** I48.* Atrial fibrillation and flutter (if seen EVER prior to incident case) I21.* Acute myocardial infarction (if seen within 28 days prior to incident case) S15.* Injury of blood vessels at neck level (if seen within 1 day prior to incident case) I74.* Arterial embolism and thrombosis (if seen within 1 day prior to incident case) D57.* Sickle-cell disorders (if seen EVER prior to incident case) D68.5* Primary thrombophilia (if seen EVER prior to incident case)

Bivalent RCA concurrent comparator analyses of ischemic strokes during a 1–21-day Risk Interval versus a 22–42-day Comparison Interval*

				Nominal analysis		Sequential analysis	
Age group (years)	Vaccine	Risk events (N)	Comp events (N)	Adjusted Rate Ratio	95% Confidence Interval	1-sided p-value	Signal? 1-sided p <0.01
18–64	Pfizer	39	38	1.09	0.68 – 1.75	0.398	No
	Moderna	14	26	0.49	0.24 – 0.95	0.990	No
65+	**Pfizer**	**143**	**117**	**1.36**	**1.05 – 1.76**	**0.011**	**No**
	Moderna	68	63	1.17	0.82 – 1.67	0.224	No

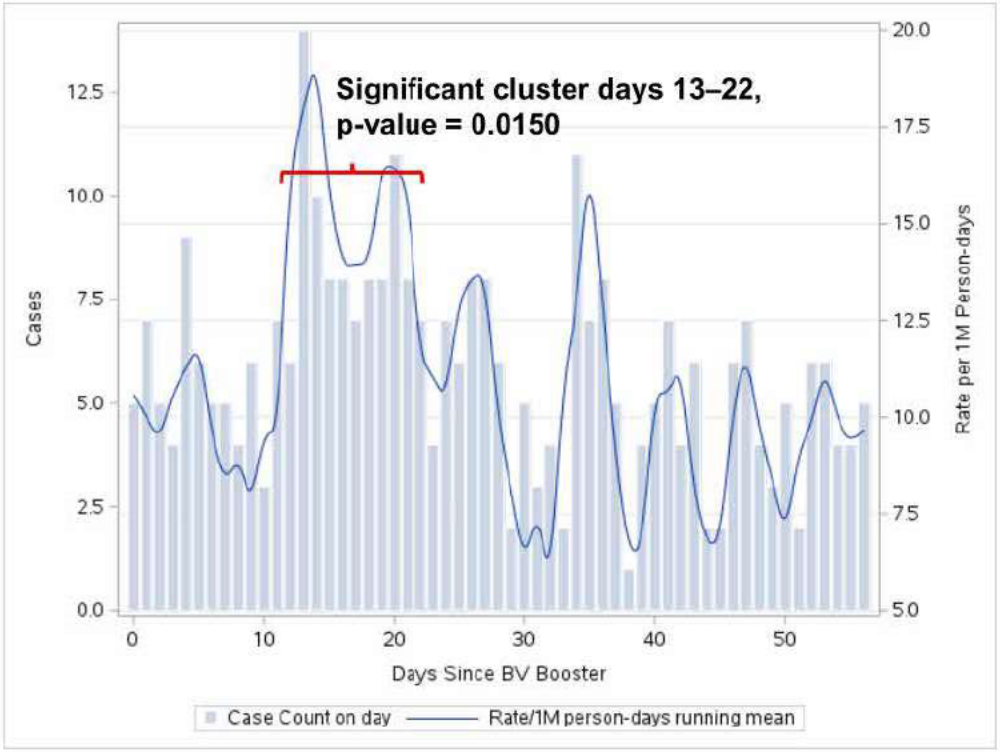
* Data through Feb 4, 2023

Ischemic stroke after Pfizer-BioNTech bivalent booster, age ≥65 years, counts and adjusted rate ratios (Oct 16, 2022 – Feb 4, 2023)



- Red dot represents sequential signal: p-value <0.01 (1-sided)

Ischemic stroke by day after Pfizer-BioNTech bivalent boosters, people ages ≥65 Years*



* Data cutoff 3 weeks prior

Ischemic stroke *preliminary* chart review: Cases ≥65 years old during days 11–21 post-Pfizer-BioNTech bivalent booster vaccination

- Review of a subset of cases at one site (N=24); 22 of 24 were incident stroke/TIA (pos. pred. value 92%)
  - None had any history of stroke or transient ischemic attack (TIA)
  - Median age of verified cases was 77.5 years
  - Symptom onset date rarely shifted from electronic date
  - 5 (23%) with known history of SARS-CoV-2 infection, only 1 within last 6 months
  - 0 with mention of recent exposure to SARS-CoV-2 in chart notes
  - 14 (64%) had simultaneous flu vaccination on the same day (13 high-dose flu vaccines and 1 adjuvanted flu vaccine)
- Outcomes
  - 13 of 22 (59%) discharged home
  - 4 of 22 (18%) discharged home with home health
  - 2 of 22 (9%) discharged to a skilled nursing facility
  - 3 of 22 (14%) died
    - One death in a 75–79-year-old male ~1 month after stroke; death was likely related to the stroke
    - One stroke in a 65–69-year-old female noted after craniotomy, though relationship with surgery unclear; death due to cardiac arrest ~2.5 months later
    - One stroke in a 70–74-year-old male during hospitalization for metastatic cancer, with subsequent death due to cancer-related complications during hospitalization
- Currently reviewing a random sample of risk and comparison interval cases across VSD sites

Supplemental analyses: Ischemic strokes during the *1–21*-day interval comparing *bivalent boosted vs. un-boosted* concurrent comparators (but eligible for bivalent booster)*

Age group (years)	Interval (days)	Comparators	Vaccine	Risk events (N)	Comp events (N)	Adjusted Rate Ratio	95% Confidence Interval	P-value (2-sided)
65+	1–21	Not bivalent boosted	Pfizer	134	1510	1.07	0.89–1.28	0.483

* Analyses only included outcomes through December 10, 2022.

Supplemental analyses: Ischemic strokes during the 1–21 and 22–42-day interval comparing *bivalent boosted vs. un-boosted* concurrent comparators (but eligible for bivalent booster)*

Age group (years)	Interval (days)	Comparators	Vaccine	Risk events (N)	Comp events (N)	Adjusted Rate Ratio	95% Confidence Interval	P-value (2-sided)
65+	1–21	Not bivalent boosted	Pfizer	134	1510	1.07	0.89–1.28	0.483
	22–42	Not bivalent boosted	Pfizer	83	1081	**0.76**	0.60–0.95	**0.018**

* Analyses only included outcomes through December 10, 2022.

- **Findings suggest reduced rate of stroke in comparison interval**

Post-signal analyses:
Simultaneous high-dose or adjuvanted influenza vaccines

Post-signal analyses*: Ischemic stroke incidence during days 1–21 compared with days 22–42, among ≥65 years with and without simultaneous influenza vaccination

Analytic population	Cases in 1–21-day Risk Interval (N=139)	Cases in 22–42-day Comparison Interval (N=108)	Adjusted Rate Ratio** (95% CI)	P-value
Bivalent Pfizer + same-day high-dose or adjuvanted flu vaccine	43	26	**1.65 (1.02 – 2.72)**	**0.04**
Bivalent Pfizer + same day standard dose flu vaccine	8	8	1.00 (0.36 – 2.76)	1.00
Bivalent Pfizer without any same day flu vaccine	88	74	1.19 (0.87 – 1.62)	0.27

* Analyses only include vaccination data through December 3, 2022, and stroke outcome data through January 14, 2023
** Adjusted by 5-year age groups

Post-signal analyses*:

Expected cases after bivalent booster + high-dose or adjuvanted flu vaccine, based on ischemic stroke incidence in un-boosted people eligible for a booster

Age at vaccination	Expected cases in a 3-week interval (Risk or Comparison)	Observed cases in a 1–21-day Risk Interval (N)	Observed cases in 22–42-day Comparison Interval (N)
65–69 years	7.3	8	6
70–74 years	8.5	8	7
75–79 years	9.8	11	6
80–84 years	6.3	8	3
85–89 years	4.2	5	4
90+ years	2.5	3	0
Total	**38.7**	**43**	**26**

* Analyses only include vaccination data through December 3, 2022, and stroke outcome data through January 14, 2023

- **Findings also suggest reduced rate of stroke in comparison interval**

Ischemic stroke following bivalent Pfizer-BioNTech COVID-19 mRNA booster vaccination in people ages 65+ years

- **Statistical signal persistent for 8 weeks**
  - Rate ratio has slowly attenuated from 1.92 to 1.36 and intermittently met signaling criteria
- **Additional signal investigation analyses**
  - Temporal clustering evaluation found a significant cluster 13–22 days after vaccination
  - Supplemental analyses using un-boosted concurrent comparators showed a rate ratio RR=1.07 (95% CI 0.89–1.28)
  - Of small subset of charts reviewed, most confirmed cases had simultaneous high-dose or adjuvanted flu vaccine
  - Analyses evaluating simultaneous high-dose or adjuvanted flu vaccine showed a rate ratio RR=1.65 (95% CI 1.02–2.72; p-value 0.04)
    - Separate analyses did not detect an elevated RR for stroke after flu vaccine alone (data not shown)
  - Supplemental analyses suggest comparison interval (22–42 days) rates were lower than expected

Additional considerations

- **Small numbers of strokes and imprecise rate ratios limit some analyses**
  - Reduced follow-up time after Moderna booster due to distribution delays
  - Simultaneous flu vaccine analyses limited by small numbers
- **Difficult to interpret temporal clustering during risk and comparison intervals**
- **Possible unmeasured confounding**
  - Results may be influenced by confounders that vary over time
  - Do early adopters of bivalent booster vaccine have greater risk of near-term cardiovascular events?
    - Same trend has not been observed for acute myocardial infarctions
    - Potential impact of differential vaccine availability after EUA (Pfizer-BioNTech > Moderna)
- **Possible role of SARS-CoV-2 infection before booster?**
  - Background incidence of SARS-CoV-2 infection was rapidly changing during bivalent booster uptake
    - Analysis excluded cases with COVID-19 diagnosis or positive test in prior 30 days, although asymptomatic infections and home antigen tests are not consistently documented in EHR; however, KPNC chart reviews did not find recent SARS-CoV-2 infection or exposure

Further evaluation and key next steps

Further evaluation

- Continue to monitor weekly and explore potential data-related explanations for the statistical signal in VSD
- In the process of chart reviewing a random sample of 100 cases across VSD sites
- Consult with other surveillance systems to better understand:
  - Possible role of simultaneous high-dose or adjuvanted flu vaccination with COVID-19 vaccination
  - Possible decreased rate of stroke in the 3–6 weeks following vaccination

Key next steps

- CDC continues to recommend that everyone eligible for a COVID-19 mRNA bivalent booster or a flu vaccine get vaccinated
- CDC and FDA are engaged in epidemiologic analyses regarding simultaneous of COVID-19 mRNA bivalent booster and flu vaccines

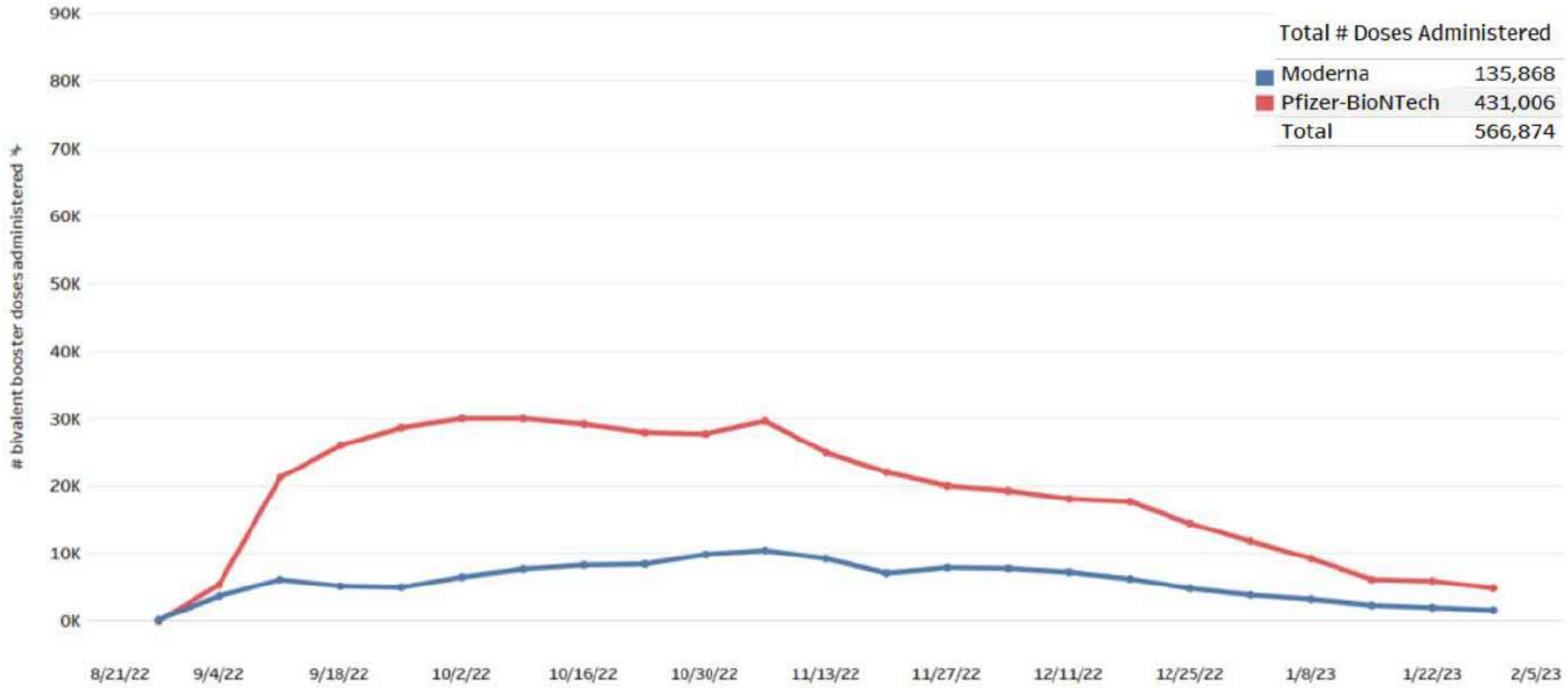
COVID-19 mRNA bivalent booster vaccination safety – data from other monitoring systems and programs*

- No unusual or unexpected reporting patterns observed, and no evidence of a safety concern detected for ischemic stroke with either COVID-19 mRNA bivalent boosters in Vaccine Adverse Event Reporting System (VAERS) monitoring (see supplemental slides)
- FDA monitoring in the CMS data and Department of Veterans Affairs monitoring in the VA system have not detected any safety signals for ischemic stroke following COVID-19 mRNA bivalent boosters using historical comparator designs
- Surveillance conducted by international regulatory and public health partners has not detected a safety concern for ischemic stroke following bivalent COVID-19 mRNA booster vaccination
- No evidence of a safety signal for ischemic stroke in Pfizer's global monitoring of bivalent COVID-19 mRNA booster vaccination
- No safety signals were detected for ischemic stroke for ***primary series*** or ***monovalent boosters*** for Pfizer-BioNTech or Moderna COVID-19 vaccines in U.S. and global monitoring

* These surveillance activities did not include analyses to evaluate the effect of simultaneous flu vaccination; different formulations of COVID-19 mRNA bivalent booster vaccinations were used globally

Myocarditis/pericarditis following COVID-19 mRNA vaccination in VSD

Number of COVID-19 bivalent booster doses administered over time among persons aged 12-39 years, by vaccine type in VSD



* Bivalent booster data through January 29, 2023

VSD incidence rates of verified myocarditis or pericarditis in the 0–7 days after Pfizer-BioNTech vaccination in people ages 12–39 years*

	Dose 2 primary series Pfizer-BioNTech			1st monovalent booster dose Pfizer-BioNTech			Bivalent booster dose Pfizer-BioNTech		
Age/sex	Cases	Dose 2 total	Incidence rate/ million doses (95% CI)	Cases	1st booster total	Incidence rate/ million doses (95% CI)	Cases	Bivalent booster total	Incidence rate/ million doses (95% CI)
12–17 years									
Males	45	308,046	146.1 (106.6–195.5)	14	129,487	108.1 (59.1–181.4)	0	48,066	0.0 (0.0–62.3)
Females	6	311,247	19.3 (7.1–42.0)	2	139,118	14.4 (1.7–51.9)	0	49,725	0.0 (0.0–60.2)
18–29 years									
Males	27	331,889	81.4 (53.6–118.4)	7	166,973	41.9 (16.9–86.4)	1	50,687	19.7 (0.5–53.1)
Females	2	400,321	5.0 (0.6–18.0)	1	240,226	4.2 (0.1–23.2)	0	80,211	0.0 (0.0–37.3)
30–39 years									
Males	5	341,527	14.6 (4.8–34.2)	3	197,554	15.2 (3.1–44.4)	0	82,191	0.0 (0.0–36.4)
Females	3	410,713	7.3 (1.5–21.3)	1	268,412	3.7 (0.1–20.8)	0	115,014	0.0 (0.0–26.0)

* Primary series and 1st monovalent booster data through August 20, 2022, bivalent booster data through January 29, 2023; Source: Goddard K, et al. Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States. Ann Intern Med. 2022;175:1169-1771.

VSD incidence rates of verified myocarditis or pericarditis in the 0–7 days after Moderna vaccination in people ages 18–39 years*

	Dose 2 primary series Moderna			1st monovalent booster dose Moderna			Bivalent booster dose Moderna		
Age/sex	Cases	Dose 2 total	Incidence rate/ million doses (95% CI)	Cases	1st booster total	Incidence rate/ million doses (95% CI)	Cases	Bivalent booster total	Incidence rate/ million doses (95% CI)
18–29 years									
Males	19	195,809	97.0 (58.4 – 151.5)	7	109,337	64.0 (25.7 – 131.9)	0	18,499	0.0 (0.0–161.9)
Females	0	243,560	0.0 (0.0 – 12.3)	1	156,707	6.4 (0.2 – 35.6)	0	29,561	0.0 (0.0–101.3)
30–39 years									
Males	8	216,583	36.9 (15.9 – 72.8)	1	149,468	6.7 (0.2 – 37.3)	0	35,318	0.0 (0.0–84.8)
Females	1	259,780	3.9 (0.1 – 21.4)	2	191,765	10.4 (1.3 – 37.7)	0	47,620	0.0 (0.0–62.9)

* Primary series and 1st monovalent booster data through August 20, 2022, bivalent booster data through January 29, 2023; source: Goddard K, et al. Incidence of Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination Among Children and Younger Adults in the United States. Ann Intern Med. 2022;175:1169-1771.

Acknowledgements

- CDC Immunization Safety Office
  - VAERS Team
  - V-safe Team
  - Clinical Immunization Safety Assessment (CISA) Project
  - Vaccine Safety Datalink (VSD) Team
- COVID-19 Vaccine Task Force Data Monitoring and Reporting Group
- Kaiser Permanente Northern California (VSD)
- Marshfield Clinic Research Institute (VSD)
- VSD sites
  - HealthPartners Institute, Minneapolis, MN
  - Kaiser Permanente Colorado, Denver, CO
  - Kaiser Permanente Northwest, Portland, OR
  - Kaiser Permanente Southern California, Los Angeles, CA
  - Kaiser Permanente Washington, Seattle, WA
  - Denver Health, Denver, CO

Disclaimer/disclosures

- The findings and conclusions in this presentation are those of the presenters and do not necessarily represent the official position of the CDC
- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC
- Dr. Nicola Klein reports research support from Pfizer for COVID-19 vaccine clinical trials and from Pfizer, GlaxoSmithKline, Merck and Sanofi Pasteur for unrelated studies

Photo credit: James Gathany (https://phil.cdc.gov/Details.aspx?pid=8876)

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

VAERS and v-safe supplemental slides

VAERS is the nation's early warning system for vaccine safety

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

U.S. reports to VAERS following bivalent booster COVID-19 mRNA vaccination among ages ≥5 years* (as of February 6, 2023) (N=23,395)

Manufacturer	Median Age (IQR), years	Male† N (%)	Female† N (%)	Non-serious N (%)	Serious N (%)	Doses admin‡
Pfizer-BioNTech	54 (33–69)	5,450 (38)	8,750 (61)	13,496 (93)	944 (7)	33,676,379
Moderna	61 (44–71)	3,378 (38)	5,457 (61)	8,460 (94)	495 (6)	19,076,635
Total	**58 (37–70)**	**8,828 (38)**	**14,207 (61)**	**21,956 (94)**	**1,439 (6)**	**52,753,014**

- **Distribution by age, sex, and serious status similar regardless of manufacturer**
  - Most reports (94%) were non-serious
  - Race, ethnicity distribution comparable to monovalent COVID-19 mRNA vaccines (49% race and/or ethnicity unknown; 39% non-Hispanic white)

* Includes reports after Moderna bivalent booster among ages ≥6 years; † Excludes 360 (2%) reports where sex was not reported

‡ Doses administered among children ages 5–11 years vaccinated during October 18, 2022–February 8, 2023

Most frequent MedDRA Preferred Terms* to VAERS following *Pfizer-BioNTech* bivalent booster vaccination among people ages ≥5 years (as of February 6, 2023)

Non-serious reports (N=13,496)†

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	COVID-19	1,785 (13)
2	Fatigue	1,091 (8)
3	Headache	1,067 (8)
4	Pyrexia/fever	1,016 (8)
5	SARS-CoV-2 test positive	974 (7)
6	Pain	969 (7)
7	Cough	779 (5)
8	Chills	677 (5)
9	Dizziness	571 (4)
10	Pain in extremity	554 (4)

Serious reports (N=944)

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	COVID-19	274 (29)
2	SARS-CoV-2 test positive	238 (25)
3	Dyspoena	138 (15)
4	Asthenia	109 (12)
5	Condition aggravated	93 (10)
6	Pyrexia/fever	87 (9)
7	Death‡	83 (9)
8	Cerebrovascular accident	72 (8)
9	Cough	71 (8)
10	Fatigue	69 (7)

* Medical Dictionary for Regulatory Activities Preferred Terms (https://www.meddra.org/how-to-use/basics/hierarchy)
† Clinical outcomes only, as determined by subject matter expert consensus
‡ Median age 80 years (IQR: 72–88)

Most frequent MedDRA Preferred Terms* to VAERS following *Moderna* bivalent booster vaccination among people ages ≥6 years (as of February 6, 2023)

Non-serious reports (N=8,460)†

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	COVID-19	877 (10)
2	Headache	863 (10)
3	Pyrexia/fever	858 (10)
4	Fatigue	837 (10)
5	SARS-CoV-2 test positive	792 (9)
6	Pain	751 (9)
7	Cough	604 (7)
8	Chills	536 (6)
9	Pain in extremity	440 (5)
10	Oropharyngeal pain	404 (5)

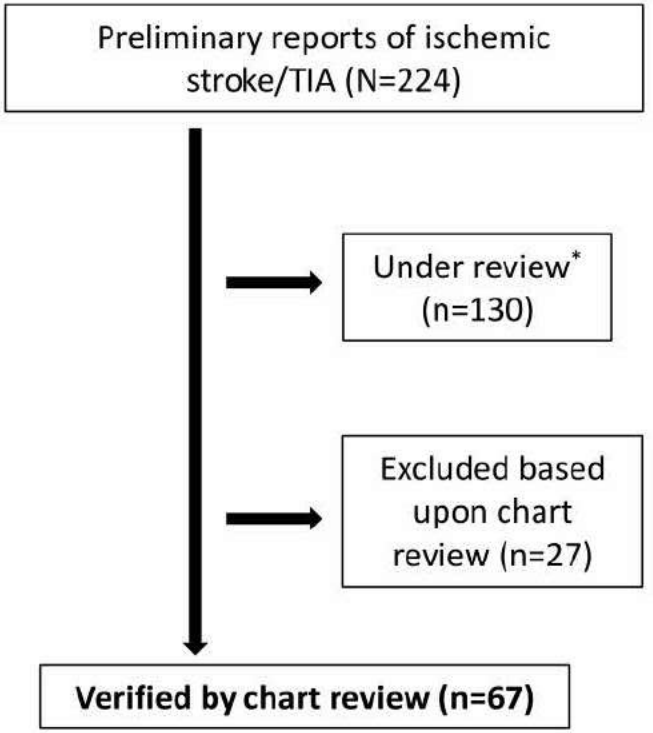
Serious reports (N=495)

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	COVID-19	146 (30)
2	SARS-CoV-2 test positive	134 (27)
3	Dyspnoea	86 (17)
4	Condition aggravated	50 (10)
5	Death‡	47 (9)
6	Asthenia	46 (9)
7	Pyrexia/fever	45 (9)
8	Cough	44 (9)
9	Anticoagulant therapy	42 (8)
10	Dizziness	38 (8)

* Medical Dictionary for Regulatory Activities Preferred Terms (https://www.meddra.org/how-to-use/basics/hierarchy)
† Clinical outcomes only, as determined by subject matter expert consensus
‡ Median age 75 years (IQR: 66–84)

Reports to VAERS of ischemic stroke/transient ischemic attack (TIA) after bivalent COVID-19 mRNA vaccination (as of February 6, 2023)

- 67 verified reports of ischemic stroke/TIA
  - Median age: 73 years (IQR: 67–79 years)
  - Median time to onset: 8 days (IQR: 3–24 days)
  - 28 males, 39 females
  - 47 after Pfizer-BioNTech bivalent
  - 20 after Moderna bivalent



* Awaiting medical records and/or healthcare provider interview; some still processing

Reporting rate to VAERS of ischemic stroke/transient ischemic attack after bivalent COVID-19 mRNA vaccine in people ages ≥65 years
(as of February 6, 2023)

	Chart-verified reports			Chart-verified reports + reports under review		
Manufacturer	Reports	Doses administered*	Reporting rate (per million doses administered)	Reports	Doses administered*	Reporting rate (per million doses administered)
Pfizer-BioNTech	47	13,217,119	**2.9**	139	13,217,119	**8.4**
Moderna	20	9,268,318	**1.9**	58	9,268,318	**4.8**

- Incidence of ischemic stroke among people ages ≥65 years = 670–970 per 100,000 person years†

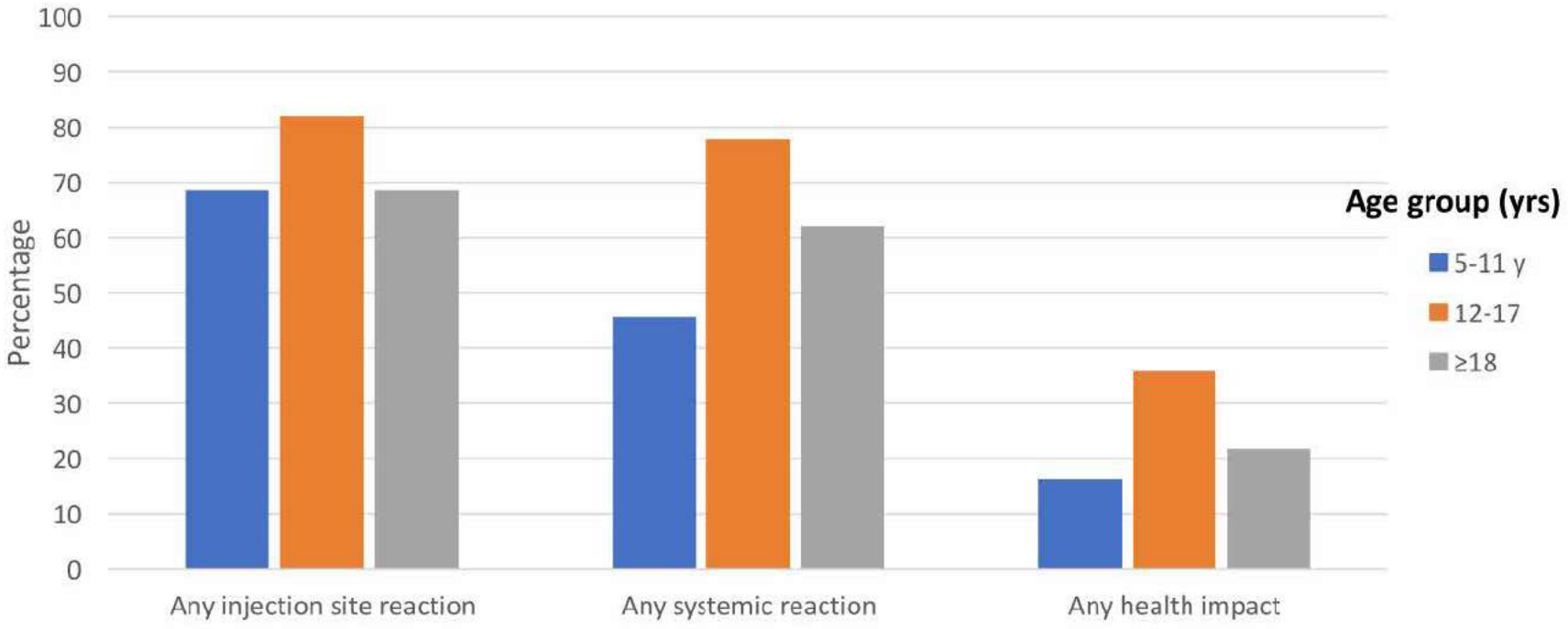
* Doses administered as of Feb 9, 2023; † Roger et al. Heart disease and stroke statistics—2011 update: a report from the American Heart Association [illegible]

V-safe: Smartphone-based active safety monitoring

v-safe℠
after vaccination
health checker

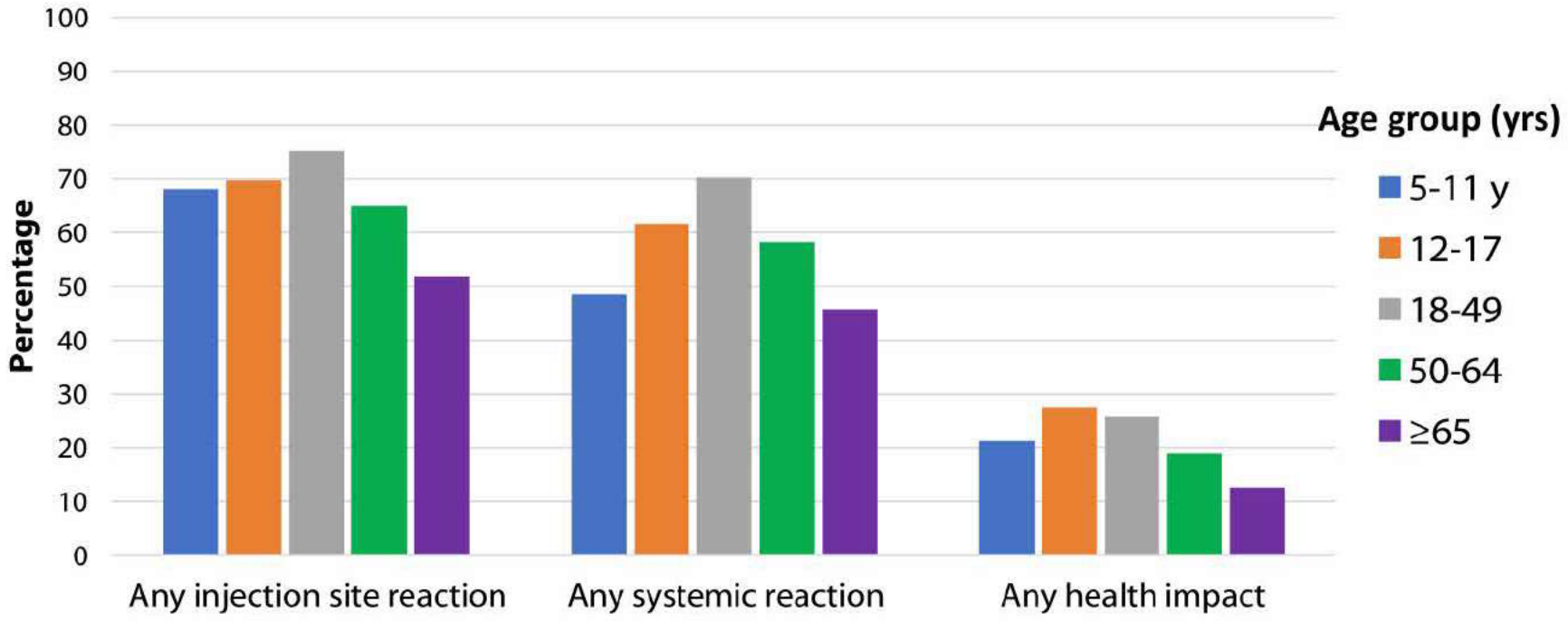
https://vsafe.cdc.gov

Reactions and health impacts reported by v-safe participants aged ≥5 years at least once 0-7 days after *first monovalent booster* dose, by age group



Data for participants aged ≥18 years as of October 23, 2022. Includes 677,009 participants who completed at least 1 survey in the first week after mRNA booster dose.
Data for participants aged 12-17 years as of February 20, 2022. Includes 3,418 participants who completed at least 1 survey in the first week after homologous booster dose.
Data for participants aged 5-11 years as of July 31, 2022. Includes 3,249 participants who completed at least 1 survey in the first week after homologous booster dose.

Reactions and health impacts reported by v-safe participants aged ≥5 years at least once 0-7 days after *bivalent booster dose*, by age group



Data for participants aged ≥12 years as of October 23, 2022. Includes 311,205 participants who completed at least 1 survey in the first week after booster dose.
Data for participants aged 5-11 years as of February 5, 2023. Includes 3,588 participants who completed at least 1 survey in the first week after booster dose.

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 27 Apr 2021 17:26:09 +0000
To: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD); Gee, Julianne (CDC/DDID/NCEZID/DHQP)
Subject: RE: [EXTERNAL] meeting to discuss data mining re: 4 month mRNA safety review

Hi Hannah,

Sorry, I do have standing meetings from 1-3:30 p.m. tomorrow. I do have availability from 3:30 to potentially 6 p.m., and Thursday has greater availability.

- John

From: Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]>
Sent: Tuesday, April 27, 2021 1:12 PM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: [EXTERNAL] meeting to discuss data mining re: 4 month mRNA safety review

John- would 1-2p tomorrow (Weds.) work for you? Looks tentatively blocked on your calendar right now. Thanks!

Hannah

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, April 27, 2021 12:13 PM
To: Gee, Julianne (CDC/DDID/NCEZID/DHQP) <[redacted]>; Rosenblum, Hannah (CDC/DDID/NCIRD/DVD) <[redacted]>
Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: [EXTERNAL] meeting to discuss data mining re: 4 month mRNA safety review

Hi Julianne,

Please see below email, and include Bethany Baer on the discussion. Thanks!

- John

From: Menschik, David <[redacted]>
Sent: Tuesday, April 27, 2021 12:11 PM
To: Nair, Narayan (FDA/CBER) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Welsh, Kerry (FDA/CBER) <[redacted]>; Baumblatt, Jane (FDA/CBER) <[redacted]>
Subject: RE: [EXTERNAL] meeting to discuss data mining re: 4 month mRNA safety review

Hi John,

Please include me and Bethany for the data mining aspects.
Best,
David

From: Nair, Narayan <[redacted]>
Sent: Tuesday, April 27, 2021 11:32 AM
To: Su, John (CDC) <[redacted]>; Menschik, David <[redacted]>
Cc: Welsh, Kerry <[redacted]>; Baumblatt, Jane <[redacted]>
Subject: RE: [EXTERNAL] meeting to discuss data mining re: 4 month mRNA safety review

Sorry hit send before I cc'ed them.

Narayan

From: Nair, Narayan
Sent: Tuesday, April 27, 2021 11:31 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Menschik, David <[redacted]>
Cc: Shimabukuro, Tom (CDC) <[redacted]>; Gee, Julianne M (CDC) <[redacted]>
Subject: RE: [EXTERNAL] meeting to discuss data mining re: 4 month mRNA safety review

Hi John,
Please include Kerry and Jane B. who are cc'ed on this email.

Narayan

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, April 27, 2021 9:28 AM
To: Nair, Narayan <[redacted]>; Menschik, David <[redacted]>
Cc: Shimabukuro, Tom (CDC) <[redacted]>; Gee, Julianne M (CDC) <[redacted]>
Subject: [EXTERNAL] meeting to discuss data mining re: 4 month mRNA safety review

Good morning,

(b)(5)

(b)(5) We'd like to include data mining results, and would like to touch base on the topic Would there be a good time this week to discuss, and who should be included? I think Kerry Walsh and Jane Baumblatt are reviewing Moderna and Pfizer?

Thanks!

- John

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 1 Sep 2022 21:37:01 +0000
To: Nair, Narayan
Cc: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: [EXTERNAL] Pneumovax data mining

Thanks Narayan

Pedro

From: Nair, Narayan <[redacted]>
Sent: Thursday, September 1, 2022 5:36 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: [EXTERNAL] Pneumovax data mining

Hi Pedro,
Yes, feel free to reach out to Brendan.

Narayan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, September 1, 2022 5:34 PM
To: Nair, Narayan <[redacted]>
Cc: Su, John (CDC) <[redacted]>; Shimabukuro, Tom (CDC) <[redacted]>
Subject: [EXTERNAL] Pneumovax data mining

Hi Narayan,

I hope you are doing well. I have been asked by Miwako Kobayashi, who is the lead CDC representative of the ACIP Work Group for Pneumococcal vaccines to write a short summary of the VAERS data on the safety of Pneumovax for an update on the Pneumococcal vaccine recommendations. This is for a MMWR Recommendations and reports issue the WG is working on. They are asking to have this by the end of September. This summary is going to be very short, with no details but it would be nice to include some information from the data mining analysis. in April of 2021 I asked Brendan Day for such an analysis for a presentation I did for the WG. So this would be something very similar but just the dates would change. I wanted to ask you if I can still reach out to Brendan for this request or if I should contact someone else.

Thank you

Pedro

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 10 Nov 2021 14:34:22 +0000
To: Day, Brendan
Cc: Nair, Narayan (FDA/CBER); Mba-Jonas, Adamma (CBER) (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: [EXTERNAL] RE: Data mining results for Prevnar 13 and Pneumovax 23

Thanks for the update Brendan

Pedro

From: Day, Brendan <[redacted]>
Sent: Wednesday, November 10, 2021 9:02 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Nair, Narayan (FDA/CBER) <[redacted]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: [EXTERNAL] RE: Data mining results for Prevnar 13 and Pneumovax 23

Hi Pedro,

Just following up to let you know that "injection-site necrosis" was recently added to section 6.2 Postmarketing Experience for Pneumovax 23.
https://www.fda.gov/media/80547/download

Brendan

From: Day, Brendan
Sent: Thursday, April 8, 2021 8:17 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Nair, Narayan <[redacted]>; Mba-Jonas, Adamma (CBER) <[redacted]>; Su, John (CDC) <[redacted]>
Subject: RE: [EXTERNAL] RE: Data mining results for Prevnar 13 and Pneumovax 23

Hi Pedro,

I don't have an outcome to tell you yet since our communication with the sponsor is ongoing, but as of now we plan on continuing to monitor these issues with routine surveillance. I hope that helps.

Brendan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, April 7, 2021 3:33 PM
To: Day, Brendan <[redacted]>
Cc: Nair, Narayan <[redacted]>; Mba-Jonas, Adamma (CBER) <[redacted]>; Su, John (CDC) <[redacted]>
Subject: RE: [EXTERNAL] RE: Data mining results for Prevnar 13 and Pneumovax 23

Hi Brendan,

Regarding the conversations with the sponsor you mentioned regarding the (b)(5) and (b)(5) (b)(5) I was just wondering.

Thanks

Pedro

From: Day, Brendan <[redacted]>
Sent: Tuesday, April 6, 2021 2:50 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Nair, Narayan (FDA/CBER) <[redacted]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: [EXTERNAL] RE: Data mining results for Prevnar 13 and Pneumovax 23

Hi Pedro,

You're welcome. Regarding the data mining signals (EB05>2) for Pneumovax 23, I want to emphasize that these data mining results are hypothesis generating and must be assessed within a broader context, including the known safety profile for the product. For Pneumovax 23 results, the majority of terms are either labeled or closely related to labeled adverse events or they are investigation-related terms (which I agree with you are often less informative than specific PTs for safety issues). Since I've been assigned the product (Nov 2019) there have been two data mining signals for Pneumovax 23 which have warranted further attention from our group: "injection site necrosis" and "necrotising fasciitis" (see Pneumovax 23 data mining - World-US signals - 4.5.21.xls). We have engaged the sponsor in our assessment of these issues and communication with the sponsor is still ongoing at the this time.

Brendan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Tuesday, April 6, 2021 10:55 AM
To: Day, Brendan <[redacted]>
Cc: Nair, Narayan <[redacted]>; Mba-Jonas, Adamma (CBER) <[redacted]>; Su, John (CDC) <[redacted]>
Subject: [EXTERNAL] RE: Data mining results for Prevnar 13 and Pneumovax 23

Hi Brendan,

Thanks for sending these data mining results. (b)(5) (b)(5) but most refer to laboratory results or tests. Others refer to local reactions (e.g. injection site erythema, inj site induration, etc) and I would think (b)(5) (b)(5) (b)(5) But I wanted to ask you if there is any particular PT that you find concerning or that should be monitored closely?

My interpretation is that (b)(5) (b)(5)

Thanks again for sending this.

Pedro

From: Day, Brendan <[redacted]>
Sent: Tuesday, April 6, 2021 8:40 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Nair, Narayan (FDA/CBER) <[redacted]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Data mining results for Prevnar 13 and Pneumovax 23

Hi Pedro,

I am the reviewer assigned Prevnar 13 and Pneumovax 23 for postmarketing surveillance in CBER. Please see the data mining explanation below and results attached. Note that our standard data mining runs stratify results for adults into three age groups (19-44.9, 45-64.9, and 65+). At this time, we are not able to stratify results into two age groups (18-64.9, 65+). -

The following data mining results were obtained for each product from Empirica Signal on April 5, 2021, with a data lock point of April 1, 2021. Data mining results were obtained using the following "Main Views" in Empirica Signal:

1. US signals summary table
    a. This table provides a summary view for the following data mining runs:
        i. Age group (Note: Adult 1 = 19-44.9 years, Adult 2 = 45-64.9 years, and Adult 3 = 65 and above)
        ii. Gender
        iii. Serious/fatal
2. US signals from age groups
    a. In addition to EB05 by age group provided in the above US signals summary table, this table also provides the number of reports for each event within a subgroup.
3. World/US signals
    a. This table compares data mining signals for the World vs. the US only (all age groups combined).

Note: There were no terms with EB05 > 2 for Prevnar 13 in the US signals summary table (including the US signals from age groups). Therefore, only the World/US signals table is included for Prevnar 13.

Empirica Signal is an application for generating statistical scores for combinations of drugs and events in a drug safety database. It applies a statistical algorithm called a Multi-item Gamma Poisson Shrinker (MPGS) to generate an Empirical Bayes Geometric Mean (EBGM), which is an improved estimate of the Relative Reporting Ratio. EB05 is the lower bound of the 90% confidence interval (EB05-EB95) for an EBGM. EB05 is a value such that there is about a 5% probability that the true value of the Relative Reporting Ratio lies below it. EB05 values greater than 2 are considered signals of disproportionate reporting (highlighted in the attached spreadsheets). An EB05 of 2 means that there is a 95% chance that the true Relative Reporting Ratio is at least 2.

Data mining covers the entire postmarketing period for this product, from initial licensure through the data lock date listed. The background database contains VAERS reports since 1990. Data mining findings are subject to a number of potential limitations and are to be regarded as "hypothesis generating." Data mining findings do not imply causality.

Please feel free to reach out with any questions.

Regards,
Brendan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 6 Apr 2021 18:59:26 +0000
To: Day, Brendan
Cc: Nair, Narayan (FDA/CBER); Mba-Jonas, Adamma (CBER) (FDA/CBER); Su, John (CDC/DDID/NCEZID/DHQP)
Subject: RE: [EXTERNAL] RE: Data mining results for Prevnar 13 and Pneumovax 23

Thanks for clarifying Brendan

Pedro

From: Day, Brendan <[redacted]>
Sent: Tuesday, April 6, 2021 2:50 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Nair, Narayan (FDA/CBER) <[redacted]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
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Brendan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, April 6, 2021 10:55 AM
To: Day, Brendan <[redacted]>
Cc: Nair, Narayan <[redacted]>; Mba-Jonas, Adamma (CBER) <[redacted]>; Su, John (CDC) <[redacted]>
Subject: [EXTERNAL] RE: Data mining results for Prevnar 13 and Pneumovax 23

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

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My interpretation is that (b)(5) (b)(5)

Thanks again for sending this.

Pedro

From: Day, Brendan <[redacted]>
Sent: Tuesday, April 6, 2021 8:40 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Nair, Narayan (FDA/CBER) <[redacted]>; Mba-Jonas, Adamma (CBER) (FDA/CBER) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: Data mining results for Prevnar 13 and Pneumovax 23

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    a. This table compares data mining signals for the World vs. the US only (all age groups combined).

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Data mining covers the entire postmarketing period for this product, from initial licensure through the data lock date listed. The background database contains VAERS reports since 1990. Data mining findings are subject to a number of potential limitations and are to be regarded as "hypothesis generating." Data mining findings do not imply causality.

Please feel free to reach out with any questions.

Regards,
Brendan

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 11 May 2021 12:48:50 +0000
To: Menschik, David
Subject: RE: [EXTERNAL] RE: Weekly data mining

No prob 😉

From: Menschik, David <[redacted]>
Sent: Tuesday, May 11, 2021 8:41 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: [EXTERNAL] RE: Weekly data mining

Oops – thanks for pointing that out!

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, May 11, 2021 8:36 AM
To: Menschik, David <[redacted]>
Subject: [EXTERNAL] RE: Weekly data mining

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi David,

I think I missed the enclosure…

- John

From: Menschik, David <[redacted]>
Sent: Tuesday, May 11, 2021 7:07 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all EUA SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 5/7/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tue, 4 May 2021 12:57:56 +0000
To: Menschik, David (FDA/CBER)
Subject: Re: [EXTERNAL] Re: Weekly data mining

(b)(5)

John R. Su, MD, PhD, MPH
CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd MS V18-4
Atlanta, GA 30329
[redacted](office)
[redacted](fax)

From: Menschik, David <[redacted]>
Sent: Tuesday, May 4, 2021 8:55:43 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: [EXTERNAL] Re: Weekly data mining

My initial guess, without looking at the cases, is that "weight" may refer to a box 19 term and can be considered an 'artifact' from individuals receiving a higher level of care - e.g., medically attended events frequently get weight measurements as part of routine intake with vital sign assessment, etc.

From: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Tuesday, May 04, 2021 8:00 AM
To: Shimabukuro, Tom (CDC) <[redacted]>; Menschik, David <[redacted]>
Cc: Zinderman, Craig E <[redacted]>; Nair, Narayan <[redacted]>; Alimchandani, Meghna <[redacted]>; Marquez, Paige L (CDC) <[redacted]>; Broder, Karen R (CDC) <[redacted]>; Harrington, Theresa (CDC) <[redacted]>
Subject: [EXTERNAL] Re: Weekly data mining

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Hi David,

Thanks for sharing! (b)(5)

(b)(5)

— John

John R. Su, MD, PhD, MPH

CAPT, USPHS
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Rd MS V18-4
Atlanta, GA 30329
[redacted] (office)
[redacted] (fax)

From: Menschik, David <[redacted]>
Sent: Tuesday, May 4, 2021 6:50:34 AM
To: Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Marquez, Paige L. (CDC/DDID/NCEZID/DHQP) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; Harrington, Theresa (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: RE: Weekly data mining

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Thanks,
David

From: Lale, Allison (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 1 Dec 2022 17:08:45 +0000
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: [EXTERNAL] RE: Weekly data mining

Thank you Pedro!

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, December 1, 2022 11:35 AM
To: Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: [EXTERNAL] RE: Weekly data mining

Hi Allison,

See Narayan's response

Thanks

Pedro

From: Nair, Narayan <[redacted]>
Sent: Thursday, December 1, 2022 11:14 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Alimchandani, Meghna (FDA/CBER) <[redacted]>; Zinderman, Craig E (FDA/CBER) <[redacted]>
Subject: RE: [EXTERNAL] RE: Weekly data mining

Hi Pedro,
I hope you are well. FYI - we have shifted some of our responsibilities in our Division so David will no longer be responsible for fielding questions about data mining. Feel free to contact me if questions come up. With regard to Alison's question, we have not had any disproportionality alerts from Data Mining for the mRNA COVID-19 vaccines for any new safety concerns (including none for Parsonage Turner Syndrome.)
A couple of key points (you probably are already familiar with these) :

- Results from data mining are considered hypothesis generating and do not, by themselves, demonstrate causal associations. They may serve as an indication for further investigation.
- The absence of disproportionality does not confirm the absence of a safety signal nor negate a signal detected by other methods.
- We generally try and avoid referring to disproportionality/data mining alerts as "signals" or "safety signals". From a regulatory perspective the terms signal and/or safety signal have certain connotations and may trigger actions so we try not conflate data mining alerts with signals.

I hope this is helpful. Thanks!

Narayan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Saturday, November 26, 2022 7:55 PM
To: Menschik, David <[redacted]>
Cc: Broder, Karen R (CDC) <[redacted]>; Lale, Allison (CDC) <[redacted]>; Nair, Narayan <[redacted]>
Subject: [EXTERNAL] RE: Weekly data mining

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Hi David,

I hope your weekend is going well. (b)(5)

(b)(5)

Thanks

Pedro

From: Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Saturday, November 26, 2022 6:28 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

Hi Pedro,

I was just wondering (b)(5)

(b)(5)

For example, we have an upcoming case of (b)(5)

(b)(5)

(b)(5)

Thanks,
Allison

p.s. Hope you had a good holiday!

From: Menschik, David <[redacted]>
Sent: Tuesday, July 5, 2022 7:42 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER)

<[redacted]>; Alimchandani, Meghna (FDA/CBER)
<[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>;
McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP)
<[redacted]>
Subject: Weekly data mining

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 7/1/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

From: Anyalechi, Ebelechukwu Gloria (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 12 Dec 2022 20:28:08 +0000
To: Broder, Karen (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Subject: RE: [EXTERNAL] RE: Weekly data mining

Thanks so much Karen and Pedro, I really appreciate this!
Gloria

From: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Monday, December 12, 2022 3:26 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Anyalechi, Ebelechukwu Gloria (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: RE: [EXTERNAL] RE: Weekly data mining

Thanks Pedro.
Karen

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Monday, December 12, 2022 2:53 PM
To: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Anyalechi, Ebelechukwu Gloria (CDC/DDID/NCEZID/DHQP) <[redacted]
Subject: FW: [EXTERNAL] RE: Weekly data mining

Hi Karen and Gloria,

I had asked Narayan this question some days ago and he responded back just now. No signals in FDA datamining. (b)(5)

(b)(5)

Pedro

From: Nair, Narayan <[redacted]
Sent: Monday, December 12, 2022 2:46 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]
Cc: Alimchandani, Meghna (FDA/CBER) <[redacted]; Zinderman, Craig E (FDA/CBER) <[redacted]
Subject: RE: [EXTERNAL] RE: Weekly data mining

Hi Pedro,
Sorry for the delay. I just got the final response from reviewers today. We have not found any we have not had any disproportionality alerts from Data Mining for the influenza vaccines for any new safety concerns

Narayan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Monday, December 12, 2022 2:43 PM
To: Nair, Narayan <[redacted]>
Cc: Alimchandani, Meghna <[redacted]>; Zinderman, Craig E <[redacted]>
Subject: RE: [EXTERNAL] RE: Weekly data mining

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Hi Narayan,

I hope your weekend went well. I sent this email some days ago but could not find a response. (b)(5)

(b)(5)

Thanks

Pedro

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Friday, December 2, 2022 4:04 PM
To: Nair, Narayan <[redacted]>
Cc: Alimchandani, Meghna (FDA/CBER) <[redacted]>; Zinderman, Craig E (FDA/CBER) <[redacted]>
Subject: RE: [EXTERNAL] RE: Weekly data mining

Hi Narayan,

(b)(5)

Thanks

Pedro

From: Nair, Narayan <[redacted]>
Sent: Friday, December 2, 2022 3:30 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Alimchandani, Meghna (FDA/CBER) <[redacted]>; Zinderman, Craig E (FDA/CBER) <[redacted]>
Subject: RE: [EXTERNAL] RE: Weekly data mining

Hi Pedro,
I just wanted to verify you are asking about all flu vaccines and specifically for this flu season – correct?

Narayan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Thursday, December 1, 2022 11:34 AM
To: Nair, Narayan <[redacted]>
Cc: Alimchandani, Meghna <[redacted]>; Zinderman, Craig E <[redacted]>
Subject: RE: [EXTERNAL] RE: Weekly data mining

Hi Narayan,

Thanks for the update. (b)(5)

(b)(5)

Thanks

Pedro

From: Nair, Narayan <[redacted]>
Sent: Thursday, December 1, 2022 11:14 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Alimchandani, Meghna (FDA/CBER) <[redacted]>; Zinderman, Craig E (FDA/CBER) <[redacted]>
Subject: RE: [EXTERNAL] RE: Weekly data mining

Hi Pedro,
I hope you are well. FYI - we have shifted some of our responsibilities in our Division so David will no longer be responsible for fielding questions about data mining. Feel free to contact me if questions come up. With regard to Alison's question, we have not had any disproportionality alerts from Data Mining for the mRNA COVID-19 vaccines for any new safety concerns (including none for Parsonage Turner Syndrome.)
A couple of key points (you probably are already familiar with these) :

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I hope this is helpful. Thanks!

Narayan

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Saturday, November 26, 2022 7:55 PM
To: Menschik, David <[redacted]>
Cc: Broder, Karen R (CDC) <krb2@cdc.gov>; Lale, Allison (CDC) <[redacted]>; Nair, Narayan <[redacted]>
Subject: [EXTERNAL] RE: Weekly data mining

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Hi David,

I hope your weekend is going well. (b)(5)

(b)(5)

Thanks

Pedro

From: Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Saturday, November 26, 2022 6:28 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

Hi Pedro,

I was just wondering (b)(5)

(b)(5)

For example, we have an upcoming case of (b)(5)

(b)(5)

(b)(5)

Thanks,
Allison

p.s. Hope you had a good holiday!

From: Menschik, David <[redacted]>
Sent: Tuesday, July 5, 2022 7:42 AM
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]>; Su, John (CDC/DDID/NCEZID/DHQP) <[redacted]>; Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER)

<[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>

Subject: Weekly data mining

Good morning all,

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Thanks,
David

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Mon, 12 Dec 2022 19:47:39 +0000
To: Nair, Narayan
Cc: Alimchandani, Meghna (FDA/CBER); Zinderman, Craig E (FDA/CBER)
Subject: RE: [EXTERNAL] RE: Weekly data mining

Thanks Narayan

Pedro

From: Nair, Narayan <[redacted]>
Sent: Monday, December 12, 2022 2:46 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Alimchandani, Meghna (FDA/CBER) <[redacted]>; Zinderman, Craig E (FDA/CBER) <[redacted]>
Subject: RE: [EXTERNAL] RE: Weekly data mining

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Subject: RE: [EXTERNAL] RE: Weekly data mining

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(b)(5)

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Sent: Friday, December 2, 2022 4:04 PM

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Cc: Alimchandani, Meghna (FDA/CBER) <[redacted]>; Zinderman, Craig E (FDA/CBER) <[redacted]>
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Hi Narayan,

(b)(5)

Thanks

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To: Menschik, David <[redacted]>
Cc: Broder, Karen R (CDC) <[redacted]>; Lale, Allison (CDC) <[redacted]>; Nair, Narayan <[redacted]>
Subject: [EXTERNAL] RE: Weekly data mining

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(b)(5)

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Cc: Zinderman, Craig E (FDA/CBER) <[redacted]>; Nair, Narayan (FDA/CBER) <[redacted]>; Alimchandani, Meghna (FDA/CBER) <[redacted]>; Broder, Karen (CDC/DDID/NCEZID/DHQP) <[redacted]>; McNeil, Michael (CDC/DDID/NCEZID/DHQP) <[redacted]>; Lale, Allison (CDC/DDID/NCEZID/DHQP) <[redacted]>
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Thanks,
David

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Thu, 2 Dec 2021 12:49:51 +0000
To: Menschik, David
Cc: Nair, Narayan (FDA/CBER)
Subject: RE: [EXTERNAL] Weekly data mining

Hi David,

Thanks so much for sending this. This will be very helpful

Pedro

From: Menschik, David <[redacted]>
Sent: Thursday, December 2, 2021 7:46 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Cc: Nair, Narayan (FDA/CBER) <[redacted]>
Subject: RE: [EXTERNAL] Weekly data mining

Hi Pedro,

The holiday was nice and hope yours was too. Attached please find the slides that we shared this past spring. Please see second slide for age stratifications (e.g., adult1 refers to 19-44 year-olds).

Best,
David

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[redacted]>
Sent: Wednesday, December 01, 2021 12:01 PM
To: Menschik, David <[redacted]>
Cc: Nair, Narayan <[redacted]>
Subject: [EXTERNAL] Weekly data mining

Hi David,

I hope you had a nice thanksgiving holiday week. (b)(5)

(b)(5)

I also wanted to ask you if you or someone there has a set of slides on the datamining FDA does, maybe a specific presentation on the topic that could be shared here? It's more for our own knowledge, not for a presentation or anything like that. I was being asked some questions here and thought that a set of slides on the topic, if available, would be helpful

Thanks

Pedro

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Sent: Wed, 1 Dec 2021 17:00:34 +0000
To: Menschik, David (FDA/CBER)
Cc: Nair, Narayan (FDA/CBER)
Subject: Weekly data mining
Attachments: USST_20211126.xls

Hi David,

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(b)(5)

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Thanks

Pedro

Drug	Event	VS EB05 20211	Serious EB05 2021	Fatal EB05 20211	Infant EB05 20211	Child EB05 20211	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 20211	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.208	1.822	0.903			0.584	1.591	2.067	2.001	2.831	1.654	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.222	1.759	0.891				1.642	2.258	2.032	2.932	1.492	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.001	1.361	0.979			0.455	1.323	1.944	1.88	2.358	1.842	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.977	6.902	0.88			0.52	0.996	0.809	0.68	2.466	1.554	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.062	6.992	0.885				0.965	0.727	0.767	1.628	1.471	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.932	1.347	0.906				1.502	1.403	1.601	2.386	1.135	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.989	2.168	0.896			0.497	2.297	2.068	3.385	4.295	1.484	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.212	1.674	0.88				1.869	1.906	1.147	2.428	1.423	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.519	1.89	0.898			0.427	1.706	2.448	2.429	2.768	2.059	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.867	1.591	0.896			0.386	1.231	2.411	1.181	2.238	1.336	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.303	6.896	0.877			0.569	0.887	1.702	1.906	2.194	1.875	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.228	1.599	0.966	0.512		0.435	1.853	1.99	2.45	2.801	1.64	
COVID19 (COVID19 (JANSSEN))	Anoxia	2.131	1.966	0.89				0.895	2.088	1.485	2.031	1.529	
COVID19 (COVID19 (JANSSEN))	Antiphospholipid antibody abnormal	1.978	1.278	0.879				1.284	1.7	1.89	2.84	0.918	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.947	1.605	0.891	0.61		0.329	1.204	2.627	1.716	2.423	1.301	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.817	1.59	0.89	0.509		0.293	1.282	2.352	1.679	2.224	1.304	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.785	1.295	0.884			0.332	1.509	1.798	1.661	2.086	1.35	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.964	1.499	0.904			0.399	1.459	2.27	1.907	2.311	1.544	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	2.078	1.606	0.913			0.455	1.412	2.362	2.004	2.482	1.478	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.564	2.618	0.892			0.508	1.865	2.615	6.813	4.599	1.133	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.852	1.539	0.908			0.273	1.215	2.077	1.636	2.551	1.142	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.811	1.684	0.875			0.225	1.428	2.235	1.471	2.185	0.995	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.817	1.233	0.884				1.059	2.012	1.56	2.022	1.497	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.978	1.381	1.368				1.372	1.966	1.906	2.151	1.786	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.722	2.204	0.877				1.739	2.906	1.134	2.42	2.29	
COVID19 (COVID19 (JANSSEN))	CSF red blood cell count positive	2.062	1.81	0.877				1.292	1.666	1.13	1.624	1.522	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.308	1.643	0.925			0.519	1.936	1.901	1.54	3.008	1.958	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.666	1.92	0.911			0.534	1.227	1.331	1.092	3.235	0.964	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.154	1.484	0.879				1.129	1.239	1.342	2.568	1.024	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.306	2.299	0.916			0.621	2.245	2.305	0.82	3.804	1.175	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.702	1.918	0.947	0.511		0.633	2.403	2.436	2.257	3.581	1.763	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.065	1.441	0.901			0.391	1.662	2.02	1.788	2.223	1.523	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.121	1.581	0.901			0.484	1.481	2.13	2.147	2.48	1.676	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.61	1.851	1.049			0.456	2.144	2.254	3.241	3.261	2.017	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.861	1.488	0.896				1.284	2.326	1.65	2.171	1.268	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.707	1.358	0.886	0.61		0.391	1.265	2.08	1.487	1.957	1.274	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.778	6.828	0.885			1.134	2.012	1.477	1.018	1.873	1.426	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.29	1.308	0.884			0.375	2.186	2.134	2.021	2.56	1.851	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.155	1.49	0.916	0.511		0.328	1.693	2.329	2.178	2.504	1.546	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.97	1.013	0.878			0.426	1.698	1.962	0.746	2.161	1.225	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.276	1.019	0.884			0.488	2.281	1.723	1.121	2.521	1.434	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.928	1.442	0.892			0.4	1.432	1.554	1.64	2.098	1.293	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.708	1.24	0.892				1.256	1.29	1.346	2.144	1.04	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.317	1.844	0.876				1.402	2.864	1.758	2.151	2.125	
COVID19 (COVID19 (JANSSEN))	Haemstocrit decreased	1.849	1.368	0.91	0.507		0.425	1.386	2.117	1.79	2.224	1.434	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.779	1.318	0.896	0.507		0.381	1.481	2.057	1.693	2.118	1.406	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.558	3.884	0.896				3.966	4.968	6.279	7.058	2.873	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.887	3.547	0.879			0.544	5.201	5.71	6.662	7.648	1.816	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.849	1.3	0.914				1.575	1.902	1.722	2.221	1.511	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.69	1.912	0.88			0.021	1.939	2.567	1.61	2.23	1.726	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.839	1.421	1.024			0.029	1.4	2.008	2.057	2.24	1.443	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.877	1.347	0.892	0.745		0.402	1.836	2.016	1.472	2.501	1.277	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.013	1.336	0.883				1.399	2.082	1.018	2.212	1.253	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.131	1.926	0.882				1.562	1.196	0.735	2.947	0.747	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.992	1.489	0.875				1.235	2.166	1.12	1.703	1.732	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.015	1.727					0.871	2.441	1.147	1.487	1.818	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.674	1.29	0.901			0.184	1.042	2.093	1.89	2.105	1.23	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.172	1.69	0.885			0.488	1.817	1.943	2.328	2.528	1.605	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.147	1.571	0.907	0.511		0.459	1.252	2.446	1.712	2.492	1.415	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.669	1.26	0.884			0.335	1.049	2.065	1.239	1.945	0.975	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.887	1.439	0.897			0.339	1.317	2.336	1.356	2.191	1.282	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.002	1.471	0.946			0.482	1.024	2.106	1.659	1.953	1.716	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.669	1.354	0.892	0.61		0.261	0.96	2.136	1.984	2.434	1.08	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.589	1.318	0.886			0.163	1.196	1.812	1.493	2.271	0.894	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.733	1.325	0.897			0.24	1.151	2.08	1.827	1.993	1.374	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.189	6.724					0.761	0.61		1.602	0.896	
COVID19 (COVID19 (JANSSEN))	Off label use	1.339	6.301	0.882			6.614	0.276	0.4	0.328	0.85	1.24	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.763	6.759					3.108	1.062		2.18		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.535	6.889				0.51	1.746	2.297	1.144	2.58	1.433	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.372	1.709	0.875				0.656	1.063	2.144	2.621	0.969	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.779	2.494	0.921	0.61		0.482	1.845	3.129	2.269	3.152	1.867	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.886	1.414	0.901	0.509		0.292	1.574	2.101	1.543	2.202	1.483	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.737	2.03	0.894			0.39	2.004	3.142	2.24	3.43	1.669	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.05	3.505	0.88				4.447	3.576	6.682	6.228	1.944	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.393					0.166	4.016	3.414	5.92	4.57	3.94	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.037	1.617	0.914	0.745		0.326	1.562	2.466	1.614	2.681	1.481	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.237	1.666	1.57	0.512		0.583	1.703	2.15	2.73	2.567	1.855	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.668	1.883	0.884				1.288	1.33	1.338	1.942	1.724	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.902	1.402	0.895	0.508		0.524	1.48	2.181	1.684	2.12	1.578	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.061	1.456	0.904	0.61		0.352	1.319	2.276	1.787	2.478	1.362	
COVID19 (COVID19 (JANSSEN))	Subarachnoid haemorrhage	1.79	1.132	1.466			0.544	1.52	1.05	0.972	2.048	0.782	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.42	1.35	0.884			0.535	1.585	1.978	1.522	2.324	1.753	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.585	1.206	0.877			0.544	1.134	0.828	0.645	2.098	0.67	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.221	2.55	1.617			0.529	1.898	2.365	1.196	2.684	3.083	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.028	6.796	0.88			0.665	3.244	6.762	15.691	7.784	6.058	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.375							0.635	0.572	0.568	1.026	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.104	1.616	0.88			0.514	1.413	1.667	1.352	2.165	1.398	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.347	1.966	0.926			0.38	1.734	2.443	1.783	2.642	1.771	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.677	2.131	1.507	0.512		0.651	1.965	2.362	3.479	2.822	2.166	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.216	1.812	0.876				1.776	1.219	0.642	2.131	0.907	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.404	1.47	0.896			0.646	1.965	2.165	2.5	2.771	1.72	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.75	1.935	0.905	0.512		0.527	2.307	2.307	3.091	3.304	2.118	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.65	1.767	0.901			0.447	2.331	2.009	1.897	2.524	1.883	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan	1.769	1.345	0.882	0.61			1.266	1.967	2.006	1.747	1.683	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.866	1.113	0.88				1.283	2.059	1.764	1.982	1.23	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.644	1.211	0.881	0.511		0.31	0.882	2.028	1.265	1.811	1.051	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.334	1.154	2.632			0.529	1.232	2.602	5.662	2.028	2.217	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.719	1.417	0.938			0.464	0.906	1.298	2.18	1.611	1.584	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.054	6.877					0.913	1.565	0.985	1.824	1.051	
COVID19 (COVID19 (JANSSEN))	Venogram	2.447	1.962	0.877				2.019	1.662	0.721	2.823	1.012	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.088	2.342				0.604	2.648	1.782	0.694	3.845	1.213	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.19	2.374	0.882				3.833	2.012	6.849	5.088	1.223	
COVID19 (COVID19 (JANSSEN))	White blood cell count decreased	1.736	1.317	0.882			0.175	1.65	1.538	1.645	2.004	1.217	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.376	6.833		7.937	0.895		1.206	0.512		1.322	0.941	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	0.86	0.878		0.661	2.091	0.747	0.566	0.375	0.595	0.568	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.36	6.928	0.884		3.677	2.722	0.109	0.044	0.42	2.391	2.463	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.057	2.011	0.876			2.245	2.006	1.961	1.566	1.3	2.115	
COVID19 (PFIZER-	Body height	1.944	1.019	0.882			0.584	0.927	1.382	2.213	1.923	1.507	
COVID19 (PFIZER-	Disease recurrence	2.051	1.072	0.88			0.667	1.509	1.695	1.946	2.01	1.573	
COVID19 (PFIZER-	Drug ineffective	2.89	1.795	1.019			1.017	1.715	1.782	1.979	2.04	1.995	
COVID19 (PFIZER-	Exposure via breast milk	0.791	6.847	0.881	17.415			0.407			0.461	1.325	
COVID19 (PFIZER-	Immunisation	1.741	1.221	0.884		0.915	1.153	1.446	1.717	2.053	1.851	1.586	
COVID19 (PFIZER-	Investigation	2.169	1.727	0.901			1.058	1.756	1.966	2.346	2.124	1.964	
COVID19 (PFIZER-	Product preparation issue	1.752	6.752			1.933	1.35	1.867	1.73	2.275	1.761	1.728	
COVID19 (PFIZER-	Weight	2.02	1.313	0.89			0.886	1.539	1.729	2.202	1.998	1.77	

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Fri, 8 Jul 2022 14:02:23 +0000
To: Thompson, PerStephanie (CDC/DDID/NCEZID/DHQP)
Cc: Mitchell, Elnetta (CDC/DDID/NCEZID/DHQP) (CTR)
Subject: Data mining reports from FDA
Attachments: RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, data mining limitations, RE: Weekly data mining, RE: Weekly data mining, FW: [EXTERNAL] FW: Weekly data mining, RE: Weekly data mining, FW: Weekly data mining, Weekly data mining, Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, Weekly data mining, RE: Data mining , Data mining , Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, Weekly data mining, RE: Weekly data mining, RE: Weekly data mining, Weekly data mining

Hi folks,

Please see enclosed.

- John

John R. Su, M.D., Ph.D., M.P.H.
CAPT, U.S. Public Health Service
Acting Deputy Director
Immunization Safety Office
Centers for Disease Control and Prevention
[redacted]
[redacted](office)
[redacted](FAX)

From: Menschik, David
Sent: Tue, 5 Apr 2022 10:41:45 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220401.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 4/1/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

Drug	Event	VS EB05 2022040	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.661	1.636	0.927			0.378	1.533	1.839	2.084	2.711	1.072	Reviewed
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.113	1.58	0.873				1.609	2.079	1.993	2.746	1.445	Reviewed
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	2.068	1.338	1.018			0.444	1.469	2.009	1.953	2.38	1.741	Reviewed
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.841	0.949	0.877			0.514	0.971	0.78	0.687	2.621	1.492	Other
COVID19 (COVID19 (JANSSEN))	Adverse event	2.016	1.093	0.883				0.917	0.853	0.732	1.893	1.571	Other
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.91	1.314	0.9				1.475	1.464	1.696	2.127	1.324	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.476	1.818	0.903			0.479	2.126	2.063	2.037	3.502	1.451	Reviewed
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.164	1.527	0.88				1.883	1.804	1.334	2.352	1.451	Not an AE
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.431	1.681	0.902			0.416	1.606	2.303	2.222	2.472	1.977	Reviewed
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.751	1.34	0.902			0.361	1.133	2.144	1.404	2.079	1.295	Other
COVID19 (COVID19 (JANSSEN))	Antibody test	2.368	0.833	0.871			0.597	0.804	1.061	1.796	1.998	1.092	Not an AE
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.219	1.492	0.961	0.613		0.419	1.816	2.043	2.232	2.725	1.872	Other
COVID19 (COVID19 (JANSSEN))	Areflexia	2.035	1.764	0.888				0.897	2.295	1.315	2.08	1.452	Reviewed
COVID19 (COVID19 (JANSSEN))	Arterial graft occlusion abnormal	1.748	1.116	0.877				1.11	1.284	1.33	2.111	0.983	Reviewed
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.963	1.485	0.907	0.61		0.365	1.202	2.421	1.81	2.412	1.359	Other
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.809	1.454	0.929	0.609		0.275	1.164	2.342	1.824	2.294	1.361	Other
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.782	1.278	0.923			0.316	1.445	1.818	1.79	2.141	1.608	Other
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.878	1.372	0.942			0.38	1.371	2.11	1.911	2.228	1.505	Other
COVID19 (COVID19 (JANSSEN))	Blood chloride decreased	1.846	1.255	0.916				1.031	2.027	1.557	1.941	1.542	Other
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.844	1.343	0.953			0.423	1.241	2.069	1.922	2.172	1.387	Other
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	2.966	2.255	0.86			0.484	1.69	1.98	0.913	4.095	1.069	Reviewed
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.81	1.332	0.924			0.252	1.119	1.919	1.812	2.437	1.192	Other
COVID19 (COVID19 (JANSSEN))	Blood potassium decreased	1.67	1.228	0.934			0.518	1.221	1.479	2.101	1.879	1.251	Other
COVID19 (COVID19 (JANSSEN))	Blood sodium decreased	1.817	1.323	0.902	0.609			1.339	2.038	1.73	1.934	1.618	Not an AE
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.663	1.354	0.881			0.294	1.386	1.996	1.218	2.058	0.909	Other
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.861	1.27	0.917				1.051	2.063	1.785	2.111	1.639	Other
COVID19 (COVID19 (JANSSEN))	Brain oedema	1.009	1.28	0.92				1.22	1.065	0.606	2.009	0.795	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	2.057	1.389	1.001				1.731	2.185	1.971	2.285	1.947	Other
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.668	2.079	0.873				1.834	2.996	1.039	2.58	2.232	Reviewed
COVID19 (COVID19 (JANSSEN))	CSF red blood cell count positive	1.964	1.763	0.873				1.409	1.978	0.99	2.014	1.498	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.328	1.616	0.928			0.511	1.684	1.935	1.476	3.358	1.15	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.836	1.965	0.925			0.519	1.353	1.621	1.175	3.934	1.093	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.361	1.635	0.876				1.115	1.293	1.605	3.311	1.236	Reviewed
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.156	2.124	0.907			0.515	2.223	2.267	0.874	3.804	1.231	Reviewed
COVID19 (COVID19 (JANSSEN))	Chest X-ray abnormal	1.772	1.273	0.944			0.336	1.344	1.893	1.846	2.061	1.602	Confounded
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.536	1.664	0.964	0.611		0.607	2.117	2.325	1.996	3.023	1.733	Reviewed
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.991	1.362	0.912			0.379	1.721	1.965	1.864	2.264	1.547	Not an AE
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.063	1.409	0.922			0.45	1.411	2.048	2.006	2.242	1.892	Reviewed
COVID19 (COVID19 (JANSSEN))	Death	1.551	1.169	0.954				1.136	1.601	1.512	2.028	1.51	Reviewed
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.579	1.782	0.972			0.452	2.178	2.301	2.965	3.258	2.008	Reviewed
COVID19 (COVID19 (JANSSEN))	Endotracheal intubation	1.928	1.384	1.248			0.386	1.359	2.136	1.831	2.1	1.816	Labeled
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.759	1.304	0.906			0.102	1.23	2.142	1.647	2.033	1.34	Other
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.763	1.307	0.923	0.61		0.293	1.262	2.149	1.747	2.074	1.413	Other
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.776	0.846	0.882			1.207	2.003	1.449	0.969	1.841	1.414	Labeled
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.3	1.285	0.892			0.436	2.212	2.181	1.909	2.544	1.716	Other
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.192	1.48	0.87	0.612		0.384	1.797	2.238	2.188	2.493	1.693	Reviewed
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.942	1.093	0.875			0.428	1.663	2.165	1.021	2.214	1.343	Not an AE
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.286	1.669	0.888			0.399	2.259	1.747	1.245	2.281	1.517	Labeled
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.853	1.271	0.898			0.396	1.239	1.72	1.821	2.133	1.258	Reviewed
COVID19 (COVID19 (JANSSEN))	Glomerular filtration rate decreased	1.767	1.152	0.931				0.999	1.928	1.556	2.051	1.369	Other
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.732	1.233	0.907				1.255	1.461	1.456	2.421	1.077	Other
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.345	1.853	0.882			0.43	1.64	2.947	1.655	2.418	2.166	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemstocrit decreased	1.815	1.294	0.946	0.606		0.458	1.329	2.025	1.823	2.202	1.427	Reviewed
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.787	1.255	0.936	0.606		0.388	1.405	1.963	1.693	2.112	1.408	Reviewed
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.527	3.691	0.891				4.19	5.618	4.782	7.4	3.362	Not an AE
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.177	3.451	0.873			0.541	4.714	5.822	6.741	7.271	2.853	Reviewed
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.891	1.307	0.94				1.462	2.066	1.833	2.354	1.638	Reviewed
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.057	1.774	0.871			0.619	1.959	2.54	1.431	2.253	1.735	Reviewed
COVID19 (COVID19 (JANSSEN))	Intensive care	1.609	1.493	1.006			0.629	1.426	2.116	2.016	2.314	1.993	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.831	1.244	0.887	0.746		0.382	1.559	1.926	1.466	2.337	1.287	Reviewed
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.015	1.224	0.878				1.39	2.064	0.914	2.087	1.253	Not an AE
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	1.697	1.49	0.877				1.399	1.15	0.71	2.31	0.711	Reviewed
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.901	1.365	0.866				1.288	2.179	1.027	1.688	1.731	Not an AE
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.69	1.695					1.08	2.751	1.04	1.756	1.817	Reviewed
COVID19 (COVID19 (JANSSEN))	Lung opacity	1.728	1.262	0.933				1.41	1.715	1.866	2.218	1.517	Other
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.68	1.252	0.921			0.228	1.004	2.102	1.892	2.073	1.324	Other
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage increased	1.378	1.111	0.9	0.607			1.035	1.493	1.25	2.03	0.657	Other
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.071	1.493	0.908			0.485	1.779	1.871	2.132	2.311	1.814	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.063	1.466	0.944	0.612		0.435	1.261	2.271	1.935	2.422	1.454	Reviewed
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.651	1.245	0.908			3.3	1.119	1.998	1.419	2.011	0.985	Other
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.924	1.41	0.921			0.325	1.236	2.407	1.605	2.195	1.45	Other
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.121	1.513	1.018			0.47	0.996	2.275	1.958	2.058	1.981	Reviewed
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.592	1.25	0.916	0.61		0.242	0.912	1.955	2.016	2.254	1.132	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.5	1.201	0.886			0.099	1.14	1.63	1.66	2.237	0.818	Other
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.721	1.28	0.916			0.272	1.094	2.104	1.832	1.983	1.424	Other
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.275	0.794					0.744	0.612		2.744	1.073	Other
COVID19 (COVID19 (JANSSEN))	Off label use	1.33	0.607	0.884			0.023	1.199	1.263	0.887	1.444	1.918	Not an AE
COVID19 (COVID19 (JANSSEN))	Oxygen saturation decreased	1.732	0.792					0.356	1		2.21		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.529	0.864				0.503	1.529	2.199	1.117	2.194	1.422	Not an AE
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	2.924	1.41	0.873				0.658	1.061	1.572	2.234	0.953	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count	2.708	2.294	0.917	0.611		0.468	1.8	2.911	2.582	3.05	1.886	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.858	1.307	0.906	0.607		0.281	1.451	2.102	1.569	2.194	1.461	Reviewed
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.735	1.847	0.892			0.382	2.105	2.728	2.138	3.195	1.865	Not an AE
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.023	3.429	0.875				4.318	3.641	0.799	5.922	2.351	Not an AE
COVID19 (COVID19 (JANSSEN))	Positive airway pressure therapy	1.861	1.276	0.944				1.014	2.003	1.62	2.122	1.596	Other
COVID19 (COVID19 (JANSSEN))	Product administered to patient of inappropriate age	1.623	0.841	0.874		0.72	2.027	0.075	0.062	0.519	1.661	1.802	Not an AE
COVID19 (COVID19 (JANSSEN))	Prolonged labour	1.068	1.066					4.262			2.814		Other
COVID19 (COVID19 (JANSSEN))	Protein total decreased	1.751	1.232	0.916	0.61		0.345	1.362	1.572	1.766	2.011	1.393	Other
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.948	1.447	0.936	0.746		0.307	1.455	2.31	1.72	2.49	1.484	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.233	1.577	1.06	0.613		0.581	1.762	2.049	2.56	2.498	1.872	Reviewed
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.697	1.482	0.901				1.099	1.55	1.359	2.108	1.652	Reviewed
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.822	1.296	0.93	0.607		0.516	1.371	2.012	1.723	2.063	1.509	Other
COVID19 (COVID19 (JANSSEN))	Red blood cell transfusion	1.712	1.203	0.886				1.176	1.287	1.21	2.022	0.956	Other
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.957	1.342	0.923	0.611		0.311	1.296	2.18	1.786	2.311	1.436	Other
COVID19 (COVID19 (JANSSEN))	Russell's viper venom time abnormal	1.349	1.011					2.328	0.5		1.088	0.731	Reviewed
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.396	1.67	0.878			0.528	1.814	1.987	1.612	2.614	1.743	Other
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.224	2.187	1.542			0.517	3.314	3.224	1.271	3.021	3.562	Other
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.023	6.768	0.875			0.644	3.588	6.579	15.105	7.73	5.725	Other
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.38							0.638	0.572	0.564	1.017	Other
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.076	1.406	0.886			0.503	1.407	1.598	1.502	2.118	1.394	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.257	1.751	0.937			0.388	1.595	2.437	1.798	2.478	1.777	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.682	2.095	1.717	0.613		0.726	1.976	2.409	3.559	2.936	2.33	Reviewed
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	5.022	3.937	0.892				1.911	2.596	0.573	5.552	1.53	Reviewed
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.213	1.628	0.874				1.885	1.268	0.626	2.181	0.903	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.401	1.447	0.911			0.711	1.932	2.225	2.236	2.685	1.779	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.662	1.811	0.925	0.612		0.519	2.414	2.249	2.787	3.25	2.071	Reviewed
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.47	1.681	0.917			0.424	2.19	2.075	1.974	2.501	1.802	Not an AE
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.889	1.085	0.876				1.235	2.033	1.679	1.882	1.325	Not an AE
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.532	1.159	0.896	0.612		3.3	0.844	2.101	1.276	1.688	1.225	Not an AE
COVID19 (COVID19 (JANSSEN))	Vascular failure	1.365	1.101	0.916			0.495	1.031	0.926	0.994	2.491	0.982	Other
COVID19 (COVID19 (JANSSEN))	Varicose vein	1.566	0.931					1.264	1.344	0.79	2.012	0.828	Other
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.039	0.893					0.921	1.665	1.032	1.798	1.119	Labeled
COVID19 (COVID19 (JANSSEN))	Venogram	2.263	1.796	0.871				1.995	1.648	0.71	2.585	1.079	Not an AE
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.607	2.092				3.6	2.388	1.74	0.663	3.151	1.268	Reviewed
COVID19 (COVID19 (JANSSEN))	Venogram normal	3.959	3.244	0.878				3.634	1.987	1.055	4.807	1.216	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.374	0.833		12.758	0.935		1.289	0.515		1.474	1.075	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.561	0.923	0.871	0.904	1.031	2.472	0.781	0.625	0.418	0.667	0.627	
COVID19 (COVID19 (MODERNA))	Mechanical urticaria	0.89	1.094				0.608	2.087	1.563	0.847	2.008	1.95	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	0.951	0.884		6.187	2.591	0.096	0.046	0.351	2.568	2.677	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.05	2.041	0.871			2.885	2.051	2.009	1.595	1.994	2.197	
COVID19 (COVID19 (MODERNA))	Vaccination complication	2.007	1.695	0.888			0.636	1.61	1.801	1.523	1.887	1.864	
COVID19 (COVID19 (PFIZER-	Body height	1.948	1.987	0.878		0.488	0.863	0.959	1.423	2.16	1.3	1.543	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.046	1.11	0.874		0.488	0.71	1.462	1.69	1.671	1.923	1.501	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.259	1.762	1.71	0.611	0.801	1.092	1.709	1.711	1.724	1.828	1.845	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.752	0.864	0.877	19.089			0.364			0.504	1.222	
COVID19 (COVID19 (PFIZER-	Immunisation	1.746	1.686	0.91		1.272	1.231	1.706	1.971	2.238	1.954	1.827	
COVID19 (COVID19 (PFIZER-	Investigation	2.164	1.751	0.924		0.705	1.073	1.776	1.931	2.226	1.974	1.881	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.758	0.793			1.444	1.364	1.852	1.736	2.166	1.594	1.561	
COVID19 (COVID19 (PFIZER-	Weight	2.024	1.336	0.888			0.922	1.55	1.731	2.107	1.901	1.757	

From: Menschik, David
Sent: Tue, 8 Mar 2022 10:23:56 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220304.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 3/4/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

Drug	Event	VS EB05 2022	Serious EB05 2022	Fatal EB05 2022	Infant EB05 2022	Child EB05 2022	Teen EB05 2022	Adult1 EB05 2022	Adult2 EB05 2022	Adult3 EB05 2022	Female EB05 2022	Male EB05 2022	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.086	1.705	0.933			0.597	1.606	1.961	2.093	2.764	1.508	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.163	1.652	0.872				1.673	2.105	2.082	2.851	1.489	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.07	1.341	1.024			0.449	1.444	2.043	1.93	2.378	1.734	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.859	6.956	0.871			0.518	0.974	0.804	0.686	2.588	1.471	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.018	1.08	0.878				0.924	0.769	0.737	1.844	1.508	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.969	1.321	0.5				1.436	1.437	1.755	2.151	1.307	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.525	1.872	0.901			0.485	2.134	2.063	2.082	3.627	1.476	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.166	1.548	0.875				1.854	1.865	1.36	2.347	1.47	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.454	1.686	0.898			0.423	1.683	2.325	2.199	2.511	2.002	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.788	1.4	0.893			0.367	1.171	2.059	1.385	2.143	1.308	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.311	6.824	0.864			0.581	0.616	1.066	1.87	2.033	1.755	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.237	1.517	0.972	0.613		0.427	1.839	2.034	2.293	2.783	1.866	Other
COVID19 (COVID19 (JANSEN))	Areflexia	2.109	1.82	0.883				0.861	2.388	1.351	2.022	1.513	Reviewed
COVID19 (COVID19 (JANSEN))	Arteriogram carotid abnormal	1.727	1.13	0.868				1.111	1.242	1.311	2.314	0.918	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.916	1.45	0.894	0.61		0.325	1.226	2.404	1.763	2.391	1.334	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.865	1.489	0.915	0.509		0.285	1.204	2.305	1.833	2.215	1.353	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.803	1.339	0.919			0.336	1.476	1.896	1.833	2.178	1.474	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.853	1.4	0.932			0.392	1.406	2.14	1.9	2.244	1.52	Other
COVID19 (COVID19 (JANSEN))	Blood chloride decreased	1.834	1.251	0.902				1.083	2.032	1.453	1.938	1.506	
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.887	1.402	0.961			0.439	1.292	2.058	2.007	2.267	1.41	Other
COVID19 (COVID19 (JANSEN))	Blood creatinine decreased	1.706	1.35	0.881	0.507		0.371	1.216	1.822	1.572	2.008	0.948	
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	3.064	2.332	0.887			0.503	1.804	1.926	0.853	4.257	1.045	Reviewed
COVID19 (COVID19 (JANSEN))	Blood lactate dehydrogenase increased	1.601	1.257	0.88	0.513			1.097	2.02	1.19	1.608	1.391	Not an AE
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.849	1.407	0.93			0.263	1.134	1.988	1.844	2.545	1.189	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.667	1.25	0.936			0.527	1.225	1.516	2.083	1.872	1.268	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.832	1.334	0.885	0.509			1.367	2.05	1.661	1.914	1.817	Not an AE
COVID19 (COVID19 (JANSEN))	Blood sodium increased	1.69	1.178	0.916				1.476	1.937	1.229	2.197	1.04	Other
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.668	1.387	0.873			0.225	1.429	1.969	1.205	2.063	0.926	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.871	1.282	0.908				1.088	2.068	1.775	2.112	1.644	Other
COVID19 (COVID19 (JANSEN))	Breath sounds abnormal	1.747	1.287	0.904				1.157	2	1.468	1.651	1.846	
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.048	1.417	1.148				1.736	2.207	1.976	2.315	1.95	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.662	2.121	0.867				1.765	3.013	1.075	2.594	2.216	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.339	1.639	0.928			0.513	1.684	1.947	1.455	3.282	1.171	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.971	2.031	0.932			0.521	1.412	1.667	1.18	3.958	1.124	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.257	1.634	0.866				1.121	1.277	1.618	3.218	1.216	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.242	2.197	0.909			0.517	2.256	2.33	0.879	3.911	1.244	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.775	1.273	0.936			0.346	1.36	1.899	1.813	2.054	1.591	Confounded
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.564	1.696	0.978	0.512		0.612	2.109	2.396	2.033	3.064	1.757	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.985	1.358	0.901			0.382	1.698	1.969	1.819	2.24	1.525	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.074	1.425	0.921			0.455	1.448	2.044	2.001	2.298	1.866	Reviewed
COVID19 (COVID19 (JANSEN))	Death	1.554	1.17	0.957				1.115	1.566	1.516	2.011	1.499	
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.586	1.774	0.998			0.456	2.167	2.261	3.008	3.267	1.996	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.941	1.466	1.261			0.373	1.375	2.129	1.601	2.021	1.671	Labeled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.771	1.318	0.894				1.273	2.142	1.605	2.044	1.312	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.767	1.425	0.911	0.61		0.301	1.306	2.146	1.747	2.088	1.42	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.779	6.844	0.877			1.266	2.015	1.06	0.877	1.881	1.488	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.304	1.3	0.89			0.438	2.212	2.194	1.928	2.551	1.752	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.169	1.463	0.972	0.512		0.31	1.713	2.262	2.211	2.462	1.813	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.959	1.096	0.869			0.43	1.645	2.065	1.028	3.157	1.373	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.304	1.084	0.881			0.494	2.258	1.756	1.289	2.342	1.806	Labeled
COVID19 (COVID19 (JANSEN))	Globulins increased	1.898	1.33	0.892			0.399	1.31	1.689	1.718	2.267	1.241	Reviewed
COVID19 (COVID19 (JANSEN))	Glomerular filtration rate decreased	1.772	1.171	0.932				1.043	1.962	1.531	2.007	1.396	
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.808	1.275	0.898				1.312	1.484	1.439	2.408	1.116	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.327	1.839	0.875				1.584	2.983	1.628	2.368	2.16	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.836	1.369	0.938	0.506		0.42	1.347	2.045	1.812	2.215	1.426	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.779	1.269	0.934	0.506		0.315	1.415	1.977	1.692	2.102	1.425	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.527	3.546	0.886				4.034	5.463	4.702	7.268	3.348	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.325	3.419	0.867			0.543	4.723	5.688	6.741	7.571	1.778	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.692	1.393	0.931				1.474	2.006	1.61	2.31	1.605	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.056	1.792	0.896			0.02	1.91	2.546	1.431	2.232	1.71	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.844	1.42	1.076			0.028	1.461	2.099	2.04	2.335	1.549	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.864	1.281	0.892	0.747		0.282	1.615	1.996	1.487	2.358	1.328	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.016	1.224	0.872				1.429	2.041	0.923	2.116	1.247	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.916	1.485	0.871				1.36	1.157	0.709	2.364	0.715	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.914	1.36	0.859				1.218	2.175	1.05	1.674	1.709	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.086	1.726					1.051	2.662	1.052	1.723	1.77	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.739	1.28	0.942				1.399	1.755	1.884	2.21	1.527	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.702	1.287	0.92			0.172	1.03	2.112	1.965	2.114	1.33	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage increased	1.362	1.117	0.896	0.507			1.023	1.535	1.18	2.009	0.884	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.052	1.548	0.909			0.473	1.805	1.913	2.174	2.351	1.857	Reviewed
Mean cell haemoglobin concentration decreased		2.112	1.513	0.937	0.512		0.446	1.263	2.321	1.944	2.403	1.516	Reviewed
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.903	1.425	0.91			0.336	1.283	2.379	1.536	2.231	1.401	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.098	1.533	1.014			0.473	0.989	2.272	1.935	2.002	1.996	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.584	1.271	0.901	0.509		0.255	0.927	1.968	2.027	2.301	1.132	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.525	1.234	0.861			0.129	1.19	1.704	1.56	2.278	0.905	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.752	1.328	0.922			0.233	1.128	2.136	1.893	2.046	1.442	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.19	6.782					0.744	0.612		2.712	1.052	Other
COVID19 (COVID19 (JANSEN))	Orthostatic hypotension	1.338	6.356	0.873			0.033	1.255	1.191	0.878	1.418	1.228	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.753	6.782					3.281	1.001		2.215		Other
COVID19 (COVID19 (JANSEN))	Packed red blood cell transfusion	1.771	1.281	0.885				1.214	1.18	1.289	2.138	0.922	Reviewed
COVID19 (COVID19 (JANSEN))	Pain assessment	2.551	6.868				0.513	0.539	2.216	1.038	2.231	1.401	Not an AE
COVID19 (COVID19 (JANSEN))	Peripheral embolism	2.925	1.414	0.867				0.657	1.062	1.578	2.238	0.953	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.767	2.259	0.91	0.511		0.471	1.609	3.014	2.395	3.086	1.873	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.868	1.304	0.906	0.508		0.288	1.488	2.074	1.523	2.177	1.444	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.727	1.82	0.887			0.386	2.063	2.711	2.023	3.134	1.643	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.027	3.384	0.868				4.319	5.578	6.814	6.273	1.862	Not an AE
COVID19 (COVID19 (JANSEN))	Poor quality product administered	1.308					0.942	2.133	1.756	1.596	2.527	2.266	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.81	1.294	0.937				1.037	1.981	1.669	2.082	1.629	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.628	6.837	0.868		0.72	2.006	0.081	0.002	0.461	1.648	1.789	
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.668	1.066					4.243			2.774		Other
COVID19 (COVID19 (JANSEN))	Protein total decreased	1.76	1.281	0.906	0.61		0.355	1.411	1.604	1.703	2.01	1.415	Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.975	1.495	0.933	0.746		0.316	1.523	2.337	1.894	2.538	1.503	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.233	1.585	1.469	0.513		0.582	1.761	2.058	2.562	2.467	1.889	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.644	1.468	0.897				1.686	1.562	2.017	2.111	1.867	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.844	1.313	0.925	0.507		0.527	1.37	2.06	1.712	2.055	1.534	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	2.019	1.398	0.926	0.511		0.33	1.33	2.276	1.797	2.358	1.491	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.363	1.02					2.306	0.499		1.094	0.731	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.357	1.495	0.873			0.53	1.814	1.969	1.525	2.598	1.701	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.23	2.148	1.486			0.522	3.076	3.213	1.27	2.967	3.466	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.022	6.767	0.869			0.645	3.586	6.631	15.064	7.771	5.826	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.378							0.637	0.571	0.568	1.017	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.108	1.421	0.882			0.508	1.384	1.588	1.539	2.2	1.352	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.303	1.752	0.936			0.372	1.612	2.387	1.764	2.472	1.745	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.663	2.089	1.701	0.513		0.729	1.977	2.394	3.535	2.997	2.302	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	4.989	2.663	0.887				1.654	1.355	0.572	5.757	1.238	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.233	1.75	0.868				1.882	1.162	0.629	2.042	0.908	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.411	1.477	0.907			0.725	1.946	2.233	2.265	2.754	1.764	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.709	1.831	0.928	0.512		0.52	2.449	2.243	2.851	3.311	2.066	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.509	1.696	0.918			0.437	2.152	2.042	2.107	2.511	1.88	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.969	1.09	0.871				1.242	2.008	1.73	1.991	1.501	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.543	1.176	0.887	0.512		0.305	0.895	2.095	1.225	1.713	1.205	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.367	3.097	2.494			0.485	1.613	3.05	6.265	2.438	2.567	Other
COVID19 (COVID19 (JANSEN))	Varicose vein	1.576	6.912					1.296	1.264	0.802	2.097	0.772	
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.035	6.896					0.882	1.663	1.037	1.811	1.088	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.284	1.77	0.866				1.944	1.609	0.71	2.64	1.908	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.621	2.083				0.602	2.377	1.673	0.666	3.231	1.208	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	4.067	3.275	0.872				3.758	2.051	0.929	4.88	1.234	Not an AE
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.374	0.83		11.346	0.935		1.267	0.514		1.422	1.016	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	6.906	0.864	0.605	1.018	2.439	0.78	0.615	0.406	0.653	0.619	
COVID19 (COVID19 (MODERNA))	Mechanical unicorn	0.901	1.072				0.621	2.036	1.528	0.816	1.662	1.922	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.987	0.878		5.943	2.555	0.103	0.047	0.378	2.548	2.654	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.15	2.04	0.867			2.662	2.034	2.068	1.593	1.882	2.19	
COVID19 (COVID19 (PFIZER-	Body height	1.947	6.966	0.872			0.641	0.944	1.365	2.169	1.914	1.535	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.048	1.114	0.868		0.488	0.711	1.462	1.687	1.88	1.937	1.506	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.292	1.783	1.737	0.512	0.781	1.086	1.721	1.733	1.758	1.872	1.872	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.792	6.863	0.871	17.407			0.376			0.41	1.258	
COVID19 (COVID19 (PFIZER-	Immunisation	1.744	1.679	0.912		1.271	1.232	1.813	1.98	2.244	1.971	1.834	
COVID19 (COVID19 (PFIZER-	Investigation	2.162	1.779	0.92		0.669	1.078	1.781	1.906	2.252	2.031	1.892	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.754	6.792			1.454	1.379	1.857	1.742	2.181	1.617	1.58	
COVID19 (COVID19 (PFIZER-	Weight	2.023	1.357	0.883			3.9	1.537	1.75	2.139	1.94	1.773	

From: Menschik, David
Sent: Tue, 1 Mar 2022 10:57:20 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); McNeil, Michael (CDC/DDID/NCEZID/DHQP); Lale, Allison (CDC/DDID/NCEZID/DHQP)
Subject: RE: Weekly data mining
Attachments: USST_20220225.xls

Good morning all,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 2/25/22). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

Drug	Event	VS EB05 2022(25	Serious EB05 2022	Fatal EB05 2022(3	Infant EB05 2022(0	Child EB05 2022(0	Teen EB05 2022(0	Adult1 EB05 2022(	Adult2 EB05 2022(	Adult3 EB05 2022(	Female EB05 2022(	Male EB05 2022(0	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.666	1.686	0.913			0.597	1.576	1.565	1.668	2.665	1.48	Reviewed
COVID19 (COVID19 (JANSEN))	Activated partial thromboplastin time shortened	2.174	1.672	0.873				1.676	2.11	2.12	2.877	1.5	Reviewed
COVID19 (COVID19 (JANSEN))	Acute respiratory failure	2.068	1.34	1.02			0.452	1.419	2.034	1.888	2.318	1.722	Reviewed
COVID19 (COVID19 (JANSEN))	Adverse drug reaction	2.871	6.961	0.87			0.518	0.973	0.865	0.689	2.573	1.469	Other
COVID19 (COVID19 (JANSEN))	Adverse event	2.618	1.064	0.877				0.925	0.765	0.75	1.824	1.51	Other
COVID19 (COVID19 (JANSEN))	Angiogram abnormal	1.913	1.35	0.901				1.437	1.462	1.777	2.157	1.326	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral abnormal	2.555	1.881	0.902			0.485	2.134	2.015	2.138	3.674	1.437	Reviewed
COVID19 (COVID19 (JANSEN))	Angiogram cerebral normal	2.154	1.522	0.873				1.874	1.811	1.242	2.373	1.407	Not an AE
COVID19 (COVID19 (JANSEN))	Angiogram pulmonary abnormal	2.443	1.686	0.898			0.425	1.651	2.327	2.163	2.535	1.963	Reviewed
COVID19 (COVID19 (JANSEN))	Anion gap decreased	1.872	1.421	0.893			0.388	1.168	2.216	1.407	2.171	1.308	Other
COVID19 (COVID19 (JANSEN))	Antibody test	2.309	6.817	0.863			0.563	0.811	1.075	1.909	2.092	1.744	Not an AE
COVID19 (COVID19 (JANSEN))	Anticoagulant therapy	2.229	1.516	0.96	0.612		0.427	1.834	2.026	2.246	2.77	1.832	Other
COVID19 (COVID19 (JANSEN))	Areflexia	2.118	1.809	0.876				0.86	2.258	1.385	1.884	1.519	Reviewed
COVID19 (COVID19 (JANSEN))	Arteriogram carotid abnormal	1.78	1.118	0.868				1.106	1.178	1.366	2.284	0.868	Reviewed
COVID19 (COVID19 (JANSEN))	Basophil count decreased	1.89	1.431	0.886	0.61		0.325	1.21	2.339	1.771	2.38	1.314	Other
COVID19 (COVID19 (JANSEN))	Basophil percentage decreased	1.767	1.477	0.906	0.508		0.286	1.206	2.251	1.83	2.203	1.328	Other
COVID19 (COVID19 (JANSEN))	Blood albumin decreased	1.791	1.306	0.9			0.397	1.456	1.873	1.767	2.162	1.419	Other
COVID19 (COVID19 (JANSEN))	Blood calcium decreased	1.878	1.38	0.912			0.394	1.378	2.113	1.86	2.224	1.482	Other
COVID19 (COVID19 (JANSEN))	Blood chloride increased	1.897	1.397	0.944			0.462	1.292	2.176	1.944	2.281	1.391	Other
COVID19 (COVID19 (JANSEN))	Blood fibrinogen decreased	3.124	2.342	0.886			0.504	1.803	1.908	0.857	4.253	1.048	Reviewed
COVID19 (COVID19 (JANSEN))	Blood magnesium increased	1.836	1.391	0.926			0.263	1.14	1.961	1.812	2.462	1.193	Other
COVID19 (COVID19 (JANSEN))	Blood potassium decreased	1.681	1.236	0.92			0.527	1.192	1.5	2.071	1.855	1.235	Other
COVID19 (COVID19 (JANSEN))	Blood sodium decreased	1.819	1.324	0.881	0.509			1.331	2.019	1.665	1.897	1.597	Not an AE
COVID19 (COVID19 (JANSEN))	Blood sodium increased	1.652	1.162	0.912				1.476	1.532	1.135	2.148	0.998	Other
COVID19 (COVID19 (JANSEN))	Blood urea decreased	1.675	1.36	0.866			0.225	1.398	1.953	1.213	2.045	0.891	Other
COVID19 (COVID19 (JANSEN))	Blood urea increased	1.854	1.257	0.89				1.068	2.044	1.711	2.087	1.59	Other
COVID19 (COVID19 (JANSEN))	COVID-19 pneumonia	2.04	1.419	1.122				1.731	2.186	1.923	2.281	1.912	Other
COVID19 (COVID19 (JANSEN))	CSF protein increased	2.715	2.108	0.896				1.762	2.907	1.077	2.482	2.2	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral haemorrhage	2.32	1.623	0.922			0.514	1.681	1.883	1.448	3.168	1.145	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral mass effect	2.867	1.885	0.912			0.622	1.409	1.383	1.174	3.703	0.993	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral thrombosis	2.279	1.699	0.862				1.12	1.281	1.617	3.124	1.295	Reviewed
COVID19 (COVID19 (JANSEN))	Cerebral venous sinus thrombosis	3.243	2.168	0.907			0.517	2.257	2.226	0.877	3.847	1.189	Reviewed
COVID19 (COVID19 (JANSEN))	Chest X-ray abnormal	1.776	1.27	0.926			0.368	1.329	1.836	1.791	2.033	1.564	Confounded
COVID19 (COVID19 (JANSEN))	Computerised tomogram head abnormal	2.566	1.695	0.956	0.511		0.614	2.102	2.327	2.028	3.045	1.741	Reviewed
COVID19 (COVID19 (JANSEN))	Computerised tomogram head normal	1.991	1.363	0.902			0.384	1.698	1.967	1.804	2.238	1.516	Not an AE
COVID19 (COVID19 (JANSEN))	Computerised tomogram thorax abnormal	2.073	1.428	0.914			0.456	1.435	2.031	1.979	2.283	1.648	Reviewed
COVID19 (COVID19 (JANSEN))	Deep vein thrombosis	2.585	1.77	0.998			0.457	2.155	2.263	3.018	3.248	1.974	Reviewed
COVID19 (COVID19 (JANSEN))	Endotracheal intubation	1.94	1.376	1.153			0.375	1.348	2.094	1.734	1.952	1.816	Labeled
COVID19 (COVID19 (JANSEN))	Eosinophil count decreased	1.752	1.307	0.88				1.256	2.095	1.612	2.021	1.29	Other
COVID19 (COVID19 (JANSEN))	Eosinophil percentage decreased	1.773	1.408	0.902	0.509		0.301	1.301	2.098	1.734	2.077	1.384	Other
COVID19 (COVID19 (JANSEN))	Feeling cold	1.779	6.836	0.872			1.206	2.013	1.455	0.967	1.81	1.416	Labeled
COVID19 (COVID19 (JANSEN))	Fibrin D dimer	2.305	1.241	0.886			0.44	2.184	2.15	1.816	2.484	1.693	Other
COVID19 (COVID19 (JANSEN))	Fibrin D dimer increased	2.161	1.443	0.904	0.512		0.314	1.663	2.241	2.102	2.42	1.602	Reviewed
COVID19 (COVID19 (JANSEN))	Fibrin D dimer normal	1.963	1.1	0.868			0.432	1.646	2.062	1.033	2.163	1.372	Not an AE
COVID19 (COVID19 (JANSEN))	Gaze palsy	2.305	1.09	0.881			0.405	2.26	1.752	1.302	2.352	1.608	Labeled
COVID19 (COVID19 (JANSEN))	Glabellar tap test	1.877	1.389	0.886			0.4	1.339	1.836	1.697	2.244	1.264	Reviewed
COVID19 (COVID19 (JANSEN))	Glucose urine present	1.799	1.236	0.896				1.31	1.37	1.465	2.344	1.068	Other
COVID19 (COVID19 (JANSEN))	Guillain-Barre syndrome	2.338	1.846	0.871				1.579	2.978	1.633	2.34	2.172	Reviewed
COVID19 (COVID19 (JANSEN))	Haematocrit decreased	1.839	1.299	0.919	0.508		0.424	1.33	2.007	1.775	2.19	1.411	Reviewed
COVID19 (COVID19 (JANSEN))	Haemoglobin decreased	1.771	1.257	0.906	0.507		0.317	1.4	1.966	1.641	2.078	1.397	Reviewed
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test	5.57	3.618	0.886				4.091	5.267	5.38	7.214	3.016	Not an AE
COVID19 (COVID19 (JANSEN))	Heparin-induced thrombocytopenia test positive	6.408	3.449	0.866			0.543	4.721	5.662	6.746	7.557	1.837	Reviewed
COVID19 (COVID19 (JANSEN))	Hypoxia	1.885	1.299	0.931				1.468	1.977	1.776	2.23	1.561	Reviewed
COVID19 (COVID19 (JANSEN))	Immunoglobulin therapy	2.104	1.806	0.885			0.02	1.924	2.54	1.44	2.247	1.882	Reviewed
COVID19 (COVID19 (JANSEN))	Intensive care	1.843	1.418	1.055			0.029	1.46	2.063	2.013	2.312	1.537	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio increased	1.883	1.276	0.884	0.747		0.394	1.589	1.971	1.453	2.338	1.316	Reviewed
COVID19 (COVID19 (JANSEN))	International normalised ratio normal	2.016	1.237	0.871				1.43	2.045	0.922	2.114	1.252	Not an AE
COVID19 (COVID19 (JANSEN))	Jugular vein thrombosis	1.917	1.522	0.866				1.374	1.165	0.709	2.414	0.714	Reviewed
COVID19 (COVID19 (JANSEN))	Lumbar puncture	1.999	1.341	0.856				1.215	2.163	1	1.678	1.674	Not an AE
COVID19 (COVID19 (JANSEN))	Lumbar puncture abnormal	2.066	1.733					1.054	2.615	1.059	1.694	1.782	Reviewed
COVID19 (COVID19 (JANSEN))	Lung opacity	1.72	1.269	0.932				1.396	1.726	1.824	2.188	1.501	Other
COVID19 (COVID19 (JANSEN))	Lymphocyte percentage decreased	1.669	1.283	0.91			0.173	1.02	2.1	1.864	2.118	1.31	Other
COVID19 (COVID19 (JANSEN))	Magnetic resonance imaging head abnormal	2.09	1.534	0.898			0.478	1.802	1.88	2.127	2.311	1.832	Reviewed
COVID19 (COVID19 (JANSEN))	Mean cell haemoglobin concentration decreased	2.1	1.479	0.921	0.512		0.449	1.248	2.317	1.842	2.386	1.444	Reviewed
COVID19 (COVID19 (JANSEN))	Mean platelet volume increased	1.867	1.391	0.9			0.398	1.265	2.345	1.445	2.231	1.396	Other
COVID19 (COVID19 (JANSEN))	Mechanical ventilation	2.057	1.524	1.018			0.476	0.991	2.264	1.862	1.954	1.975	Reviewed
COVID19 (COVID19 (JANSEN))	Monocyte percentage increased	1.58	1.255	0.892	0.509		0.257	0.911	1.936	2.008	2.293	1.104	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage decreased	1.489	1.202	0.872			0.129	1.186	1.648	1.201	2.203	0.844	Other
COVID19 (COVID19 (JANSEN))	Neutrophil percentage increased	1.746	1.32	0.911			0.233	1.115	2.117	1.884	2.043	1.417	Other
COVID19 (COVID19 (JANSEN))	Nonspecific reaction	2.153	6.793					0.749	0.612		2.393	1.05	Other
COVID19 (COVID19 (JANSEN))	Off label use	1.34	0.56	0.877			8.028	1.193	1.175	0.851	1.405	1.931	Not an AE
COVID19 (COVID19 (JANSEN))	On and off phenomenon	1.754	6.762					3.297	1		2.218		Other
COVID19 (COVID19 (JANSEN))	Packed red blood cell transfusion	1.73	1.217	0.884				1.213	1.178	1.148	2.028	0.865	Reviewed
COVID19 (COVID19 (JANSEN))	Pain assessment	2.552	6.875				0.513	1.55	2.206	1.044	2.22	1.428	Not an AE
COVID19 (COVID19 (JANSEN))	Peripheral embolism	2.932	1.467	0.906				0.056	1.009	1.562	2.461	0.953	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count	2.76	2.241	0.906	0.511		0.472	1.799	2.996	2.444	3.064	1.779	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet count decreased	1.866	1.294	0.892	0.509		0.289	1.476	2.078	1.472	2.168	1.413	Reviewed
COVID19 (COVID19 (JANSEN))	Platelet count normal	2.727	1.884	0.884			0.287	2.091	2.709	1.971	3.113	1.836	Not an AE
COVID19 (COVID19 (JANSEN))	Platelet factor 4	6.027	3.381	0.867				4.302	2.565	0.813	6.276	1.862	Not an AE
COVID19 (COVID19 (JANSEN))	Poor quality product administered	1.306					0.565	2.951	2.386	3.114	3.581	3.106	Not an AE
COVID19 (COVID19 (JANSEN))	Positive airway pressure therapy	1.834	1.299	0.938				1.054	1.968	1.631	2.029	1.626	Other
COVID19 (COVID19 (JANSEN))	Product administered to patient of inappropriate age	1.628	6.839	0.866		0.72	2.008	0.08	0.062	0.462	1.644	1.789	
COVID19 (COVID19 (JANSEN))	Prolonged labour	1.098	1.064					4.216			2.718		Other
COVID19 (COVID19 (JANSEN))	Prothrombin time prolonged	1.976	1.497	0.928	0.746		0.323	1.513	2.326	1.692	2.527	1.508	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary embolism	2.23	1.581	1.444	0.513		0.584	1.752	2.037	2.568	2.475	1.863	Reviewed
COVID19 (COVID19 (JANSEN))	Pulmonary thrombosis	2.645	1.477	0.894				1.679	1.572	2.02	2.088	1.872	Reviewed
COVID19 (COVID19 (JANSEN))	Red blood cell count decreased	1.842	1.303	0.906	0.507		0.529	1.364	2.063	1.673	2.046	1.51	Other
COVID19 (COVID19 (JANSEN))	Red cell distribution width increased	2.012	1.387	0.92	0.511		0.333	1.324	2.277	1.747	2.358	1.452	Other
COVID19 (COVID19 (JANSEN))	Russell's viper venom time abnormal	1.364	1.02					2.324	0.499		1.098	0.731	Reviewed
COVID19 (COVID19 (JANSEN))	Superficial vein thrombosis	2.398	1.5	0.872			0.531	1.811	1.968	1.543	2.608	1.711	Other
COVID19 (COVID19 (JANSEN))	Suspected COVID-19	3.236	2.157	1.443			0.522	3.076	3.101	1.229	2.931	3.056	Other
COVID19 (COVID19 (JANSEN))	Therapy non-responder	7.023	6.775	0.867			0.646	3.59	6.68	15.047	7.802	1.84	Other
COVID19 (COVID19 (JANSEN))	Therapy partial responder	2.384							0.638	0.573	0.568	1.018	Other
COVID19 (COVID19 (JANSEN))	Thrombectomy	2.108	1.432	0.88			0.508	1.381	1.582	1.543	2.199	1.36	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombocytopenia	2.301	1.76	0.941			0.372	1.604	2.38	1.773	2.476	1.741	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis	2.661	2.08	1.066	0.513		0.734	1.977	2.365	3.516	2.902	2.287	Reviewed
COVID19 (COVID19 (JANSEN))	Thrombosis with thrombocytopenia syndrome	4.09	2.524	0.886				1.651	0.899	0.574	5.186	1.68	Reviewed
COVID19 (COVID19 (JANSEN))	Transverse sinus thrombosis	2.225	1.753	0.868				1.886	1.19	0.63	2.038	0.908	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler	2.417	1.476	0.908			0.728	1.925	2.25	2.369	2.754	1.779	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler abnormal	2.714	1.836	0.924	0.512		0.521	2.448	2.242	2.853	3.311	2.061	Reviewed
COVID19 (COVID19 (JANSEN))	Ultrasound Doppler normal	2.509	1.704	0.92			0.438	2.121	2.053	2.101	2.522	1.855	Not an AE
COVID19 (COVID19 (JANSEN))	Ultrasound scan normal	1.887	1.097	0.871				1.226	2.64	1.727	1.885	1.327	Not an AE
COVID19 (COVID19 (JANSEN))	Urobilinogen urine increased	1.546	1.176	0.886	0.512		0.306	0.902	2.026	1.256	1.743	1.172	Not an AE
COVID19 (COVID19 (JANSEN))	Vaccination failure	1.367	3.069	2.444			0.494	1.589	3.076	6.184	2.41	2.502	Other
COVID19 (COVID19 (JANSEN))	Vasodilatation	2.036	6.892					0.884	1.658	1.033	1.811	1.086	Labeled
COVID19 (COVID19 (JANSEN))	Venogram	2.308	1.795	0.863				1.942	1.622	0.709	2.634	1.915	Not an AE
COVID19 (COVID19 (JANSEN))	Venogram abnormal	2.608	2.092				0.602	2.361	1.67	0.67	3.232	1.211	Reviewed
COVID19 (COVID19 (JANSEN))	Venogram normal	4.067	2.275	0.871				3.767	2.051	0.928	4.678	1.233	Not an AE
COVID19 (MODERNA))	Exposure via breast milk	1.374	6.836		9.058	0.936		1.238	0.515		1.375	0.894	
COVID19 (COVID19 (MODERNA))	Intentional product misuse	0.09	1.893	0.862	0.005	1.015	2.441	0.782	0.621	0.4	0.693	0.915	
COVID19 (MODERNA))	Mechanical urticaria	0.901	1.028				0.64	2.111	1.575	0.825	2.002	2.03	
COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.365	6.986	0.877		5.962	2.567	0.105	0.048	0.38	2.544	2.846	
COVID19 (MODERNA))	Product dose omission issue	2.051	2.04	0.866			2.395	1.995	1.961	1.566	1.993	2.106	
COVID19 (COVID19 (PFIZER-	Body height	1.948	6.988	0.871			0.639	0.943	1.374	2.148	1.898	1.519	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.047	1.096	0.867		0.485	0.71	1.453	1.676	1.868	1.923	1.491	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.251	1.783	1.724	0.512	0.778	1.077	1.707	1.716	1.751	1.846	1.842	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.792	6.849	0.87	17.744			0.391			0.473	1.325	
COVID19 (COVID19 (PFIZER-	Immunisation	1.743	1.688	0.911		1.271	1.224	1.792	1.983	2.209	1.933	1.796	
COVID19 (COVID19 (PFIZER-	Investigation	2.162	1.777	0.908		0.668	1.075	1.767	1.92	2.23	2.015	1.879	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.754	6.792			1.458	1.375	1.849	1.732	2.165	1.612	1.576	
COVID19 (COVID19 (PFIZER-	Weight	2.023	1.358	0.881			0.698	1.544	1.74	2.133	1.938	1.763	

From: Menschik, David
Sent: Tue, 21 Dec 2021 15:43:58 +0000
To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Su, John (CDC/DDID/NCEZID/DHQP); Moro, Pedro (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211217.xls

Good morning,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 12/17/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

Drug	Event	VS EB05 2021(1)	Serious EB05 2021	Fatal EB05 2021	Infant EB05 2021	Child EB05 2021	Teen EB05 2021	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.139	1.747	0.902			0.681	1.535	1.961	1.94	2.861	1.376	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.284	1.812	0.887				1.704	2.267	2.202	3.074	1.563	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.967	1.319	0.984			0.461	1.35	1.853	1.821	2.228	1.639	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.52	0.912	0.88			0.522	0.953	0.867	0.662	2.508	1.572	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.028	1.029	0.883				0.961	0.672	0.785	1.597	1.515	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.967	1.373	0.906				1.432	1.441	1.757	2.334	1.229	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.823	2.104	0.909			0.496	2.224	2.096	3.072	4.148	1.513	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.177	1.623	0.877				1.925	1.853	1.111	2.357	1.427	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.467	1.808	0.903			0.429	1.619	2.36	2.397	2.654	2	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.773	1.435	0.886			0.376	1.191	1.978	1.098	2.11	1.269	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.308	0.838	0.873			0.589	0.911	1.745	1.987	2.122	1.865	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.231	1.558	0.965	0.512		0.441	1.842	1.958	2.347	2.74	1.835	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.103	1.899	0.885				0.873	2.044	1.442	1.931	1.506	
COVID19 (COVID19 (JANSSEN))	Aspiration cerebral abnormal	1.939	1.231	0.879				1.189	1.134	1.082	2.731	0.914	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.905	1.527	0.888	0.509		0.338	1.179	2.519	1.705	2.296	1.34	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.778	1.521	0.888	0.509		0.305	1.238	2.285	1.67	2.125	1.324	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.756	1.285	0.882			0.343	1.446	1.888	1.601	2.054	1.379	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.923	1.449	0.898			0.413	1.438	2.214	1.853	2.261	1.536	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.986	1.508	0.912			0.467	1.353	2.322	1.869	2.364	1.445	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.41	2.516	0.89			0.507	1.783	2.65	0.786	4.465	1.106	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.836	1.431	0.914			0.28	1.187	2.046	1.587	2.348	1.194	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.745	1.552	0.873			0.238	1.43	2.1	1.363	2.156	0.936	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.763	1.223	0.881				1.053	2.006	1.567	1.91	1.529	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.978	1.443	1.384				1.596	2.036	1.973	2.311	1.83	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.71	2.213	0.878				1.81	3.007	1.1	2.466	2.301	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.335	1.786	0.925			0.521	1.882	1.92	1.486	3.472	1.109	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.76	2.003	0.91			0.53	1.31	1.307	1.194	3.968	0.931	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.215	1.572	0.876				1.101	1.222	1.394	2.764	1.001	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.303	2.313	0.924			0.523	2.337	2.364	0.809	3.978	1.214	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.638	1.866	0.851	0.511		0.636	2.3	2.366	2.16	3.432	1.74	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.969	1.401	0.9			0.392	1.057	1.966	1.783	2.184	1.516	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.094	1.525	0.919			0.468	1.413	2.087	2.082	2.371	1.643	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.668	1.895	0.98			0.482	2.118	2.277	3.027	3.171	2.008	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.781	1.359	0.892				1.264	2.241	1.498	2.052	1.254	
COVID19 (COVID19 (JANSSEN))	Eosinophil percentage decreased	1.681	1.313	0.884	0.61		0.311	1.262	2.037	1.407	1.873	1.302	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.781	0.834	0.883			0.129	2.002	1.471	0.997	1.858	1.423	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.288	1.302	0.884			0.375	2.204	2.134	1.968	2.547	1.867	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.149	1.456	0.929	0.511		0.338	1.659	2.298	2.138	2.448	1.555	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.96	1.011	0.876			0.437	1.693	2.019	0.734	2.148	1.302	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.269	1.089	0.887			0.406	2.35	1.771	1.164	2.451	1.561	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.852	1.316	0.886			0.403	1.435	1.936	1.518	2.111	1.212	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.752	1.251	0.888				1.302	1.33	1.313	2.183	1.058	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.287	1.656	0.876				1.516	2.666	1.677	2.157	2.163	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.837	1.344	0.909	0.506		0.44	1.368	2.111	1.759	2.191	1.452	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.771	1.301	0.903	0.507		0.332	1.426	2.042	1.618	2.073	1.436	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	3.44	3.89	0.881				4.009	4.382	6.187	7.191	2.99	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.498	3.555	0.877			0.544	4.694	5.745	0.762	7.708	1.712	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.882	1.321	0.915				1.507	1.946	1.735	2.266	1.548	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.115	1.927	0.88			0.535	1.958	2.65	1.531	3.319	1.748	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.856	1.44	1.113			0.532	1.433	2.029	2.074	2.268	1.502	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.879	1.325	0.894	0.747		0.413	1.613	2.008	1.444	2.458	1.291	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	2.029	1.342	0.881				1.39	2.089	0.995	2.148	1.279	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.056	1.883	0.88				1.499	1.197	0.724	2.925	0.733	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.895	1.441	0.873				1.234	2.15	1.089	1.709	1.889	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.023	1.812					0.99	2.656	1.112	1.685	1.829	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.663	1.279	0.897			0.192	1.043	2.113	1.836	2.091	1.244	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.141	1.64	0.885			0.489	1.843	1.891	2.208	2.495	1.567	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.12	1.526	0.906	0.511		0.464	1.193	2.43	1.721	2.4	1.378	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.661	1.232	0.883			0.309	1.004	2.046	1.315	1.91	0.944	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.874	1.417	0.901			0.349	1.251	2.321	1.418	2.144	1.335	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.094	1.511	0.964			0.487	1.009	2.173	1.695	1.982	1.785	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.647	1.296	0.886	0.61		0.27	0.951	2.023	1.948	2.353	1.075	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.553	1.265	0.881			0.172	1.212	1.757	1.396	2.204	0.891	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.732	1.321	0.895			0.249	1.15	2.119	1.782	2.001	1.387	
COVID19 (COVID19 (JANSSEN))	Nonspecific reaction	2.188	0.725					0.761	0.611		1.958	0.895	
COVID19 (COVID19 (JANSSEN))	Off label use	1.34	0.228	0.878			7.528	1.25	1.161	0.813	1.392	1.952	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.752	0.76					3.17	1.002		2.183		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.522	0.864				0.513	1.677	2.364	1.131	2.511	1.479	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.205	1.648	0.877				0.656	1.063	1.834	2.65	0.962	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.762	2.458	0.916	0.61		0.472	1.886	3.167	2.578	3.194	1.838	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.899	1.397	0.901	0.508		0.298	1.564	2.145	1.498	2.208	1.495	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.13	1.978	0.892			0.394	2.027	2.978	2.176	3.288	1.709	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.063	3.513	0.878				4.493	3.726	0.681	6.271	1.847	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.305					0.577	4.068	3.443	6.177	4.557	4.085	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	2.029	1.566	0.922	0.745		0.339	1.566	2.436	1.602	2.597	1.51	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.23	1.634	1.542	0.512		0.592	1.691	2.094	2.698	2.511	1.842	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.068	1.557	0.894				1.603	1.645	1.923	1.957	1.781	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.838	1.398	0.898	0.507		0.342	1.428	2.104	1.639	2.082	1.668	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.017	1.407	0.903	0.61		0.357	1.241	2.32	1.726	2.369	1.402	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.378	1.278	0.882			0.531	1.639	1.891	1.452	2.377	1.845	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.227	2.533	1.676			0.53	2.026	2.207	1.166	2.644	3.024	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.028	6.789	0.878			0.646	3.52	6.721	15.803	7.878	5.992	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.373							0.636	0.572	0.568	1.024	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.152	1.551	0.891			0.516	1.407	1.664	1.362	2.214	1.353	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.34	1.947	0.94			0.379	1.695	2.49	1.809	2.866	1.767	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.678	2.131	1.786	0.512		0.65	1.95	2.383	3.463	2.805	2.195	
COVID19 (COVID19 (JANSSEN))	Thrombosis with thrombocytopenia syndrome	2.911	2.073	0.887				0.954	0.766		1.731	3.68	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.18	1.772	0.877				1.732	1.267	0.638	2.022	0.908	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.42	1.447	0.897			0.652	1.894	2.193	2.431	2.774	1.718	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.743	1.897	0.906	0.512		0.528	2.314	2.26	2.983	3.247	2.104	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.469	1.692	0.904			0.446	2.267	1.961	1.636	2.492	1.824	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.859	1.106	0.878				1.245	2.043	1.757	1.956	1.239	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.363	1.219	2.674			0.533	1.302	2.684	5.882	2.121	2.224	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.734	1.273	0.934			0.464	0.881	1.227	2.022	1.663	1.481	
COVID19 (COVID19 (JANSSEN))	Vasculitis	2.026	0.877					0.909	1.576	0.981	1.797	1.054	
COVID19 (COVID19 (JANSSEN))	Venogram	2.429	1.977	0.875				2.219	1.698	0.719	2.975	1.06	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	2.964	2.312				0.607	2.759	1.797	0.686	3.971	1.195	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.189	2.315	0.88				3.966	1.935	0.837	4.999	1.221	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.378	0.834		7.579	0.94		1.219	0.513		1.332	0.943	
COVID19 (COVID19 (MODERNA))	Interchange of vaccine products	0.59	0.939	0.875		0.65	2.231	0.767	0.585	0.384	0.611	0.585	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.366	0.934	0.883		4.537	2.812	0.1	0.054	0.416	2.438	2.522	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.003	2.021	0.876			2.359	2.002	1.948	1.571	1.903	2.111	
COVID19 (COVID19 (PFIZER-	Body height	1.945	1.018	0.88			0.589	0.944	1.374	2.211	1.928	1.514	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.046	1.97	0.877			0.661	1.506	1.665	1.828	2.012	1.94	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.29	1.726	1.57		0.505	1.016	1.725	1.781	1.855	2.034	1.975	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.751	0.847	0.878	17.588			0.402			0.451	1.326	
COVID19 (COVID19 (PFIZER-	Immunisation	1.743	1.466	0.894		1.317	1.22	1.026	1.663	2.194	1.961	1.739	
COVID19 (COVID19 (PFIZER-	Investigation	2.16	1.736	0.901		0.565	1.048	1.769	1.972	2.352	2.128	1.965	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.751	0.752			1.729	1.425	1.875	1.752	2.278	1.733	1.886	
COVID19 (COVID19 (PFIZER-	Weight	3.651	1.922	0.886			0.688	1.917	1.741	2.196	3.661	1.702	

From: Menschik, David
Sent: Tue, 9 Nov 2021 13:33:46 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211105.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 11/5/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

Drug	Event	US EB05 20211105	Serious EB05 2021	Fatal EB05 20211	Infant EB05 20211	Child EB05 20211	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 20211	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.19	1.827	0.892			0.395	1.595	1.926	1.873	2.91	1.321	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.277	1.841	0.883				1.673	2.295	2.074	3.12	1.478	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.972	1.32	0.961			0.462	1.283	1.78	1.819	2.271	1.534	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	2.977	0.878	0.875				0.86	0.721	0.722	2.352	1.532	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.062	0.992	0.876				0.945	0.745	0.718	1.633	1.388	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.896	1.312	0.903				1.495	1.346	1.512	2.345	1.085	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.05	2.202	0.89			0.498	2.245	2.062	3.44	4.433	1.362	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.203	1.672	0.872				1.79	1.822	1.198	2.443	1.336	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.534	1.931	0.888			0.433	1.714	2.492	2.36	2.764	2.059	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.914	1.657	0.887			0.364	1.289	2.463	1.041	2.35	1.295	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.35	0.872	0.872			0.572	0.898	1.738	1.863	2.108	1.924	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.238	1.656	1.106	0.612		0.433	1.869	2.011	2.522	2.855	1.628	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.12	1.948	0.878				0.899	1.917	1.527	1.84	1.546	
COVID19 (COVID19 (JANSSEN))	Arteriogram carotid abnormal	[illegible]	1.244	[illegible]				1.161	[illegible]	1.416	2.702	[illegible]	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.965	1.651	0.877	0.509		0.335	1.202	2.585	1.711	2.37	1.29	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.751	1.559	0.874	0.508		0.292	1.271	2.34	1.438	2.148	1.202	
COVID19 (COVID19 (JANSSEN))	Blood albumin decreased	1.765	1.28	0.875			0.333	1.472	1.785	1.662	2.114	1.22	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.946	1.502	0.886			0.402	1.421	2.273	1.819	2.304	1.475	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	2.02	1.565	0.897			0.452	1.439	2.271	1.863	2.438	1.36	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.412	2.595	0.885			0.51	1.857	2.118	0.738	4.418	1.075	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.839	1.559	0.888			0.26	1.179	2.087	1.507	2.575	1.046	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.712	1.544	0.87			0.217	1.359	2.02	1.296	2.064	0.877	
COVID19 (COVID19 (JANSSEN))	Blood urea increased	1.762	1.209	0.872				1.042	1.904	1.527	2.016	1.394	
COVID19 (COVID19 (JANSSEN))	COVID-19 pneumonia	1.938	1.334	1.067				1.322	1.818	1.812	2.028	1.892	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.708	2.215	0.872				1.673	2.737	1.162	2.403	2.212	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.328	1.867	0.918			0.521	2.143	1.868	1.492	3.52	1.108	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.364	1.86	0.893			0.537	1.256	1.23	0.997	2.863	0.959	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.108	1.527	0.873				1.124	1.201	1.362	2.471	1.041	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.402	2.432	0.899			0.523	2.534	2.465	0.822	4.118	1.193	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.732	1.909	0.930	0.611		0.635	2.308	2.462	2.266	3.638	1.744	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	2.026	1.492	0.896			0.404	1.692	2.018	1.768	2.248	1.516	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.116	1.605	0.907			0.462	1.502	2.125	2.056	2.437	1.63	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.616	1.894	1.001			0.66	2.176	2.298	1.235	3.243	2.035	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.817	1.505	0.871				1.268	2.363	1.516	2.133	1.212	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.779	0.802	0.872			1.131	2.003	1.495	0.992	1.883	1.414	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.278	1.271	0.881			0.376	2.207	2.077	1.847	2.505	1.644	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.156	1.512	0.912	0.611		0.33	1.705	2.327	2.212	2.588	1.485	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.93	0.997	0.873			0.423	1.696	1.931	0.75	2.194	1.182	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.329	1.02	0.88			0.418	2.278	1.761	1.134	2.608	1.429	
COVID19 (COVID19 (JANSSEN))	Globulins increased	1.857	1.382	0.882			0.403	1.373	1.514	1.499	2.014	1.219	
COVID19 (COVID19 (JANSSEN))	Glucose urine present	1.756	1.261	0.882				1.171	1.244	1.39	2.046	1.047	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.303	1.886	0.872				1.394	2.825	1.783	2.161	2.091	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.833	1.366	0.896	0.506		0.426	1.37	2.108	1.72	2.238	1.345	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.755	1.303	0.897	0.507		0.327	1.423	1.98	1.596	2.088	1.336	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.605	3.68	0.884				4.009	4.841	6.183	6.916	2.874	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	[illegible]	[illegible]	[illegible]			[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	
COVID19 (COVID19 (JANSSEN))	Hypoxia	1.803	1.234	0.89				1.312	1.798	1.612	2.08	1.405	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.074	1.931	0.875			0.019	1.872	2.504	1.651	2.205	1.683	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.791	1.414	1.01			0.029	1.408	1.948	1.959	2.207	1.38	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.834	1.315	0.882	0.746		0.395	1.639	1.886	1.425	2.378	1.23	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.922	1.215	0.879				1.416	1.905	0.899	2.088	1.197	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.104	1.961	0.874				1.602	1.122	0.744	2.831	0.755	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.897	1.531	0.871				1.231	2.162	1.155	1.705	1.723	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.022	1.764					0.896	2.323	1.163	1.488	1.78	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.628	1.267	0.888			0.182	1.001	2.077	1.779	2.077	1.141	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.174	1.718	0.882			0.502	1.773	1.996	2.307	2.536	1.587	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	2.08	1.524	0.889	0.611		0.46	1.295	2.348	1.507	2.31	1.283	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin decreased	1.641	1.227	0.874			0.339	1.034	2.093	1.024	1.913	0.895	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.773	1.209	0.877			0.347	1.26	2.207	1.077	2.072	1.123	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.04	1.495	0.935			0.494	0.993	2.025	1.671	1.927	1.663	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.617	1.376	0.887	0.61		0.283	0.965	2.13	1.974	2.512	1.027	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.566	1.317	0.876			0.131	1.221	1.623	1.313	2.337	0.909	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage increased	1.682	1.295	0.883			0.241	1.106	2.044	1.712	1.962	1.276	
COVID19 (COVID19 (JANSSEN))	Off label use	1.387	0.21	0.872			5.909	0.298	0.429	0.361	0.865	1.236	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.752	0.758					3.059	0.968		2.173		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.575	0.874				0.517	1.767	2.297	1.169	2.631	1.469	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.393	1.716	0.874				0.656	1.069	2.083	2.544	0.966	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.752	2.503	0.922	0.61		0.483	1.86	3.196	1.786	3.138	1.837	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.855	1.406	0.893	0.509		0.291	1.595	2.019	1.466	2.187	1.411	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.73	2.067	0.888			3.4	2.067	3.09	2.201	3.461	1.683	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.018	3.523	0.875				4.382	3.335	0.685	6.151	1.933	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.227					0.866	4.034	3.298	6.151	4.62	3.842	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.95	1.566	0.903	0.744		0.326	1.514	2.321	1.53	2.548	1.379	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.246	1.679	1.511	0.612		0.583	1.697	2.15	2.68	2.581	1.829	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.046	1.532	0.883				1.546	1.453	2.066	1.867	1.001	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.885	1.392	0.88	0.507		0.528	1.496	2.137	1.602	2.115	1.496	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	2.043	1.44	0.884	0.509		0.356	1.307	2.291	1.639	2.458	1.264	
COVID19 (COVID19 (JANSSEN))	Subarachnoid haemorrhage	1.738	1.178	[illegible]			[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.282	1.2	0.879			0.538	1.498	1.78	1.377	1.957	1.749	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.665	1.349	0.876			0.547	1.132	0.827	0.647	2.857	0.67	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.215	1.643	1.727			0.531	1.892	2.334	1.206	2.677	3.109	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	7.077	0.797	0.875			0.647	3.642	6.746	15.322	8.003	5.996	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.289							0.635	0.576	0.569	1.025	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.116	1.675	0.886			0.516	1.416	1.686	1.384	2.27	1.346	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.374	2.044	0.916			0.39	1.846	2.378	1.688	2.817	1.701	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.68	2.17	1.864	0.612		0.571	2.007	2.389	3.532	2.858	2.166	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.255	1.907	0.874				1.974	1.224	0.644	2.402	0.904	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.397	1.445	0.893			0.648	1.928	2.165	2.371	2.786	1.66	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.752	1.971	0.892	0.612		0.534	2.388	2.299	3.024	3.225	2.153	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.53	1.811	0.892			0.454	2.494	1.983	1.777	2.651	1.805	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.933	1.152	0.875				1.358	2.076	1.782	2.056	1.263	
COVID19 (COVID19 (JANSSEN))	Urobilinogen urine increased	1.673	1.267	0.876	0.511		0.309	0.86	2.082	1.291	1.858	1.045	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.257	2.99	2.501			0.537	1.179	2.423	5.159	1.904	2.087	
COVID19 (COVID19 (JANSSEN))	Vaccine breakthrough infection	1.685	1.419	0.92			0.48	0.975	1.262	2.048	1.646	1.554	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.095	0.881					0.93	1.624	0.979	1.87	1.055	
COVID19 (COVID19 (JANSSEN))	Venogram	2.66	2.009					2.174	1.738	0.721	3.015	1.045	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.411	2.523				0.605	2.98	1.889	0.703	4.221	1.195	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.282	2.509	0.874				3.954	2.152	0.846	5.237	1.192	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.353	0.833		7.466	0.885		1.192	0.513		1.318	0.982	
COVID19 (COVID19 (MODERNA))	Headache	0.966	0.962	0.884	6.091		0.304	0.941	0.981	1.012	0.953	1.014	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.344	0.933	0.88		1.158	2.624	0.12	0.006	0.491	2.348	2.404	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.045	2.006	0.873			2.214	2.003	1.947	1.572	1.898	2.117	
COVID19 (COVID19 (PFIZER-	Body height	1.932	1.02	0.877			0.599	0.927	1.336	2.191	1.905	1.499	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.047	1.057	0.874			0.636	1.502	1.695	1.949	2.007	1.576	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.274	1.723	1.46			1.025	1.723	1.784	1.924	2.034	1.968	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.74	0.846	0.876	14.049			0.413			0.431	1.162	
COVID19 (COVID19 (PFIZER-	Investigation	2.142	1.712	0.897			1.057	1.739	1.932	2.319	2.112	1.933	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.32	0.299	0.866		3.489	0.323	0.174	0.062	0.301	0.298	0.344	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.774	0.752				1.345	1.86	1.807	2.29	1.793	1.735	
COVID19 (COVID19 (PFIZER-	Weight	[illegible]	[illegible]	[illegible]			[illegible]	[illegible]	[illegible]	2.2	[illegible]	[illegible]	

From: Menschik, David
Sent: Tue, 26 Oct 2021 11:13:30 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211022.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/22/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

Drug	Event	VS EB05 2021(22	Serious EB05 2021	Fatal EB05 2021(I	Infant EB05 2021(	Child EB05 2021(	Teen EB05 2021(	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 2021((	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	2.512	1.79	0.886			0.602	1.642	1.856	1.661	2.774	1.214	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.088	1.699	0.873				1.576	2.15	1.71	2.634	1.388	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.86	1.257	0.93			0.478	1.209	1.763	1.62	2.131	1.418	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.157	6.902	0.874				0.861	0.753	0.737	2.475	1.821	
COVID19 (COVID19 (JANSSEN))	Adverse event	2.043	1.015	0.877				1.019	0.653	0.723	1.611	1.455	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.821	1.247	0.886				1.373	1.362	1.369	2.051	1.098	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	2.957	2.191	0.886			0.503	1.859	2.102	3.387	4.211	1.383	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.113	1.805	0.872				1.726	1.75	1.09	2.215	1.341	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.546	1.969	0.886			0.486	1.686	2.549	2.272	2.818	2.035	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.974	1.695	0.885			0.373	1.298	2.453	0.996	2.266	1.319	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.337	0.803	0.871			0.081	0.898	1.732	1.939	2.098	1.921	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.228	1.672	0.956	0.512		0.443	1.863	2.064	2.47	2.874	1.589	
COVID19 (COVID19 (JANSSEN))	Areflexia	2.011	1.886	0.873				0.862	1.867	1.331	1.681	1.492	
COVID19 (COVID19 (JANSSEN))	Aneurysm cerebral abnormal	1.81	1.188	0.872				0.899	1.178	1.369	2.134	0.939	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.811	1.507	0.875	0.508		0.338	1.186	2.424	1.418	2.149	1.201	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.655	1.478	0.873	0.508		3.3	1.26	2.211	1.247	1.978	1.153	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.833	1.421	0.88			0.613	1.352	2.211	1.583	2.103	1.424	
COVID19 (COVID19 (JANSSEN))	Blood chloride increased	1.938	1.491	0.891			0.467	1.33	2.292	1.653	2.316	1.292	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.237	2.584	0.882			0.515	1.67	2.113	0.737	4.428	1.903	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.762	1.479	0.882			0.263	1.134	2.018	1.36	2.4	0.997	
COVID19 (COVID19 (JANSSEN))	Blood urea decreased	1.691	1.564	0.871			0.203	1.339	2.039	1.198	2.01	0.863	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.647	2.206	0.871				1.617	2.612	1.173	2.345	2.13	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.233	1.828	0.907			0.527	1.723	1.914	1.452	3.284	1.095	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.513	1.969	0.894			0.542	1.148	1.362	0.997	3.271	0.974	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.027	1.436	0.872				0.973	1.194	1.354	2.291	1.035	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.398	2.491	0.886			0.528	2.574	2.522	0.823	4.072	1.217	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.717	1.984	0.904	0.511		0.647	2.259	2.46	2.206	3.928	1.772	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head normal	1.969	1.451	0.886			0.413	1.648	2.079	1.589	2.15	1.486	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.076	1.599	0.894			0.477	1.452	2.15	1.893	2.371	1.594	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.576	1.663	0.922			0.473	2.199	2.246	3.24	3.174	2.009	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.765	1.462	0.87				1.298	2.286	1.373	2.051	1.169	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.278	1.336	0.881			0.382	2.194	2.069	1.89	2.55	1.583	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.127	1.487	0.908	0.511		0.338	1.632	2.392	2.076	2.852	1.449	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.964	1.007	0.872			0.433	1.712	1.968	0.769	2.206	1.207	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.321	1.009	0.88			0.423	2.341	1.79	0.989	2.591	1.413	
COVID19 (COVID19 (JANSSEN))	Guillain-Barré syndrome	2.265	1.907	0.874				1.333	2.877	1.765	2.15	2.109	
COVID19 (COVID19 (JANSSEN))	Haematocrit decreased	1.758	1.326	0.86	0.506		0.439	1.281	2.072	1.62	2.132	1.286	
COVID19 (COVID19 (JANSSEN))	Haemoglobin decreased	1.707	1.28	0.887	0.507		0.34	1.375	1.971	1.497	2.041	1.277	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.627	3.707	0.853				4.089	4.85	5.522	7.11	2.291	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.755	3.489	0.873			0.553	5.044	5.353	6.667	7.467	1.208	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.054	1.943	0.872			0.02	1.856	2.475	1.554	2.182	1.858	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.749	1.4	0.955			0.029	1.352	1.964	1.823	2.128	1.347	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.783	1.286	0.872	0.746		0.409	1.586	1.943	1.27	2.211	1.231	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.901	1.238	0.878				1.359	1.944	0.907	2.038	1.202	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.124	2.016	0.873				1.589	1.137	0.744	2.681	0.764	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.661	1.484	0.87				1.199	2.153	2.076	1.883	1.665	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	2.047	1.825					0.902	2.361	1.175	1.515	1.788	
COVID19 (COVID19 (JANSSEN))	Lymphocyte percentage decreased	1.535	1.201	0.877			0.184	1.012	2.016	1.514	1.91	1.09	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.171	1.745	0.876			0.515	1.778	1.907	2.315	2.511	1.595	
COVID19 (COVID19 (JANSSEN))	Mean cell haemoglobin concentration decreased	1.966	1.403	0.873	0.511		0.488	1.344	2.226	1.251	2.171	1.207	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.717	1.227	0.872			0.357	1.23	2.275	0.863	2.053	1.017	
COVID19 (COVID19 (JANSSEN))	Mechanical ventilation	2.018	1.515	0.936			3.5	0.955	2.023	1.626	1.915	1.832	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.531	1.302	0.881	0.61		0.225	0.987	2.003	1.734	2.337	0.972	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.561	1.32	0.875			0.13	1.225	1.806	1.243	2.351	0.791	
COVID19 (COVID19 (JANSSEN))	Off label use	1.469	0.23	0.872			5.899	0.347	0.502	0.41	0.925	1.339	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.764	6.758					2.979	1.068		2.203		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.541	6.855				0.532	1.827	2.172	1.171	2.541	1.459	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.441	1.789	0.873				0.656	1.067	2.551	2.379	0.972	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.719	2.497	0.922	0.511		0.466	1.003	3.104	1.796	3.124	1.791	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.842	1.419	0.894	0.508		0.299	1.549	2.033	1.469	2.147	1.413	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.754	2.1	0.887			0.41	2.104	3.036	2.353	3.445	1.71	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6.067	3.544	0.874				4.321	3.004	6.686	6.083	2.004	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.151					0.883	3.986	2.903	6.155	4.56	3.718	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.878	1.519	0.893	0.744		0.269	1.495	2.33	1.333	2.38	1.338	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.309	1.872	1.006	0.512		0.591	1.654	2.139	1.557	2.535	1.796	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.027	1.549	0.881				1.514	1.481	2.077	1.902	1.807	
COVID19 (COVID19 (JANSSEN))	Red blood cell count decreased	1.847	1.377	0.877	0.507		0.566	1.435	2.121	1.543	2.056	1.468	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.971	1.493	0.88	0.509		0.383	1.308	2.186	1.546	2.347	1.211	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.247	1.182	0.876			0.543	1.4	1.776	1.406	1.893	1.744	
COVID19 (COVID19 (JANSSEN))	Superior sagittal sinus thrombosis	1.56	1.237	0.872			0.553	1.033	0.825	0.65	2.148	0.668	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.219	2.742	1.941			0.537	2.045	2.341	1.163	2.685	3.191	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.998	6.737				0.651	3.574	6.684	15.215	7.891	5.883	
COVID19 (COVID19 (JANSSEN))	Therapy partial responder	2.128							0.604	0.58	0.569	1.021	
COVID19 (COVID19 (JANSSEN))	Thrombectomy	2.067	1.676	0.886			0.527	1.413	1.582	1.405	2.083	1.405	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.259	2.009	0.9			0.491	1.702	2.316	1.642	2.742	1.621	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.665	2.178	1.814	0.512		0.582	2.002	2.09	3.528	2.861	2.147	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.274	1.957	0.873				1.949	1.209	0.646	2.322	0.913	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.332	1.809	0.884			0.48	1.691	2.14	2.219	2.691	1.66	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.74	1.985	0.887	0.512		0.547	2.306	2.283	3.137	3.193	2.141	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.551	1.814	0.886			0.483	2.656	1.973	1.642	2.617	1.844	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.948	1.156	0.878				1.361	2.138	1.747	2.056	1.289	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.182	2.797	2.377			0.583	1.15	2.337	4.791	1.834	2.013	
COVID19 (COVID19 (JANSSEN))	Vasodilatation	2.063	6.881					0.868	1.585	0.972	1.773	1.012	
COVID19 (COVID19 (JANSSEN))	Venogram	2.674	2.031					2.176	1.749	0.721	3.085	0.993	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.356	2.532				0.608	2.931	1.87	0.703	4.161	1.169	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.164	2.444	0.873				3.685	2.181	0.851	5.132	1.122	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.334	6.831		7.31	0.871		1.197	0.513		1.314	0.953	
COVID19 (COVID19 (MODERNA))	Headache	0.969	6.963	0.876	5.803		0.305	0.945	0.985	1.014	0.955	1.025	
COVID19 (COVID19 (MODERNA))	No adverse event	1.157	6.844	0.878		0.273	2.025	0.917	0.903	0.762	1.091	1.205	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.373	6.944	0.878		1.223	2.6	0.12	0.051	0.534	2.378	2.422	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	2.42	1.966	0.872			2.16	1.966	1.903	1.07	1.84	2.102	
COVID19 (COVID19 (PFIZER-	Body height	1.931	1.011	0.876			0.602	0.875	1.32	2.197	1.908	1.489	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.058	1.049	0.872			0.639	1.515	1.68	1.943	2.014	1.801	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.268	1.711	0.965			1.013	1.736	1.799	1.952	2.058	1.991	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.708	6.818	0.875	11.694			0.396			0.407	1.177	
COVID19 (COVID19 (PFIZER-	Investigation	2.151	1.702	0.896			1.035	1.734	1.935	2.31	2.122	1.934	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.314	6.328	0.866		4.084	0.317	0.188	0.052	0.29	0.291	0.337	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.757	6.752				1.35	1.865	1.85	2.301	1.808	1.752	
COVID19 (COVID19 (PFIZER-	Weight	2.038	1.324	0.882			0.853	1.521	1.726	2.202	2.011	1.777	

From: Menschik, David
Sent: Tue, 5 Oct 2021 10:01:55 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Cc: Zinderman, Craig E (FDA/CBER); Nair, Narayan (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Broder, Karen (CDC/DDID/NCEZID/DHQP); Harrington, Theresa (CDC/DDID/NCIRD/OD)
Subject: RE: Weekly data mining
Attachments: USST_20211001.xls

Good morning John and Tom,

Attached please find a list of all (i.e., unvetted and regardless of notability) PTs with data mining alerts (i.e., EB05 ≥2) for all SARS-CoV-2 vaccine VAERS reports from our weekly 'US Signals Summary Table' ('as of date' 10/1/21). Please feel free to share this hypothesis generating output with your team/command chain, though this is not intended to be shared more broadly.

Thanks,
David

Drug	Event	US EB05 202110	Serious EB05 2021	Fatal EB05 202110	Infant EB05 20211	Child EB05 20211	Teen EB05 20211	Adult1 EB05 2021	Adult2 EB05 2021	Adult3 EB05 2021	Female EB05 2021	Male EB05 202110	Comment
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged	1.936	1.684	0.886			0.497	1.33	1.736	1.597	2.374	1.144	
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time shortened	2.04	1.717	0.878				1.515	2.043	1.71	2.297	1.459	
COVID19 (COVID19 (JANSSEN))	Acute respiratory failure	1.81	1.261	0.923			0.489	1.221	1.553	1.642	2.057	1.344	
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction	3.059	6.903	0.882				0.894	0.746	0.752	2.48	1.584	
COVID19 (COVID19 (JANSSEN))	Angiogram abnormal	1.744	1.195	0.86				1.373	1.318	1.199	2.027	0.992	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal	3.074	2.278	0.886			0.511	1.937	1.948	3.949	4.31	1.414	
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral normal	2.084	1.651	0.878				1.797	1.614	1.082	2.038	1.392	
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal	2.511	1.987	0.888			0.456	1.691	2.497	2.152	2.881	1.932	
COVID19 (COVID19 (JANSSEN))	Anion gap decreased	1.69	1.439	0.882			0.386	1.137	2.251	0.776	1.94	1.189	
COVID19 (COVID19 (JANSSEN))	Antibody test	2.171	6.819	0.878			0.591	0.829	1.676	1.778	1.947	1.797	
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy	2.203	1.689	1.347	0.612		0.446	1.539	1.998	2.376	2.866	1.944	
COVID19 (COVID19 (JANSSEN))	Anetleria	2.142	2.09	0.879				0.883	2.046	1.339	1.668	1.58	
COVID19 (COVID19 (JANSSEN))	Basophil count decreased	1.623	1.298	0.882	0.509		0.396	1.022	2.422	1.118	1.821	1.132	
COVID19 (COVID19 (JANSSEN))	Basophil percentage decreased	1.808	1.398	0.882	0.509		0.398	1.141	2.663	1.214	1.797	1.286	
COVID19 (COVID19 (JANSSEN))	Blood calcium decreased	1.66	1.303	0.879			0.416	1.262	2.001	1.381	1.851	1.311	
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased	3.059	2.535	0.886			0.523	1.296	1.999	0.756	4.328	0.906	
COVID19 (COVID19 (JANSSEN))	Blood magnesium increased	1.602	1.39	0.885			0.36	1.094	1.894	1.191	2.088	0.977	
COVID19 (COVID19 (JANSSEN))	CSF protein increased	2.581	2.226	0.878				1.542	2.54	1.208	2.221	2.058	
COVID19 (COVID19 (JANSSEN))	Cerebral haematoma	1.776	1.223	0.894				1.341	0.941		2.655	0.818	
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage	2.26	1.888	0.911			0.54	1.784	1.928	1.479	3.348	1.09	
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect	2.411	1.932	0.893			0.551	1.047	1.203	1.042	3.365	0.854	
COVID19 (COVID19 (JANSSEN))	Cerebral thrombosis	2.049	1.549	0.879				1.005	1.09	1.499	2.341	1.016	
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis	3.217	2.421	0.891			0.537	2.495	2.567	0.748	3.837	1.196	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal	2.76	2.075	0.932	0.611		0.649	2.281	2.446	2.329	3.566	1.781	
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal	2.174	1.729	0.906			0.492	1.51	2.172	2.091	2.488	1.648	
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis	2.542	1.84	0.904			0.481	2.167	2.195	3.16	3.107	1.987	
COVID19 (COVID19 (JANSSEN))	Eosinophil count decreased	1.937	1.275	0.882				1.073	2.245	1.218	1.795	1.953	
COVID19 (COVID19 (JANSSEN))	Feeling cold	1.864	0.79	0.875			1.161	2.013	1.536	1.008	1.915	1.421	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer	2.32	1.327	0.886			0.392	2.206	2.089	1.965	2.572	1.801	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased	2.108	1.471	0.896	0.611		0.347	1.635	2.305	1.997	2.627	1.403	
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal	1.871	6.985	0.876			0.442	1.613	1.862	0.785	2.104	1.12	
COVID19 (COVID19 (JANSSEN))	Gaze palsy	2.253	0.93	0.88			0.439	2.324	1.663	0.882	2.671	1.244	
COVID19 (COVID19 (JANSSEN))	Guillain-Barre syndrome	2.339	1.962	0.877				1.342	2.879	1.687	2.112	1.12	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test	5.36	3.473	0.889				3.398	4.402	6	6.68	1.982	
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive	6.307	3.114	0.88			0.561	4.385	3.443	6.669	6.978	1.969	
COVID19 (COVID19 (JANSSEN))	Immunoglobulin therapy	2.028	1.959	0.88			0.619	1.851	2.461	1.516	2.099	1.647	
COVID19 (COVID19 (JANSSEN))	Intensive care	1.68	1.396	0.956			0.593	1.317	1.809	1.828	2.044	1.298	
COVID19 (COVID19 (JANSSEN))	International normalised ratio increased	1.74	1.284	0.874	0.745		0.421	1.58	1.777	1.249	2.063	1.222	
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal	1.54	1.276	0.885				1.373	1.923	0.934	2.062	1.192	
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis	2.161	2.058	0.88				1.5	1.17	0.746	2.727	0.714	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture	1.83	1.446	0.877				1.194	2.09	1.081	1.674	1.61	
COVID19 (COVID19 (JANSSEN))	Lumbar puncture abnormal	1.963	1.784					0.926	2.23	1.091	1.445	1.711	
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal	2.162	1.866	0.862			0.522	1.677	1.887	2.299	2.544	1.6	
COVID19 (COVID19 (JANSSEN))	Mean platelet volume increased	1.553	1.108	0.875			0.364	1.098	2.143	0.629	1.854	0.892	
COVID19 (COVID19 (JANSSEN))	Monocyte percentage increased	1.4	1.221	0.888	0.509		0.22	0.877	1.872	1.677	2.125	0.881	
COVID19 (COVID19 (JANSSEN))	Neutrophil percentage decreased	1.378	1.193	0.879			0.112	1.128	1.941	1.028	2.093	0.863	
COVID19 (COVID19 (JANSSEN))	Off label use	1.608	6.237	0.878			5.549	0.383	0.573	0.376	1.022	1.434	
COVID19 (COVID19 (JANSSEN))	On and off phenomenon	1.789	6.757					2.892	1.014		2.295		
COVID19 (COVID19 (JANSSEN))	Pain assessment	2.515	6.875				0.54	1.839	2.139	1.095	2.539	1.395	
COVID19 (COVID19 (JANSSEN))	Peripheral embolism	3.723	1.906	0.879				0.656	1.075	2.447	2.21	0.996	
COVID19 (COVID19 (JANSSEN))	Platelet count	2.729	2.468	0.928	0.612		0.504	1.97	3.141	1.683	3.232	1.714	
COVID19 (COVID19 (JANSSEN))	Platelet count decreased	1.862	1.432	0.892	0.509		0.31	1.558	2.041	1.339	2.133	1.352	
COVID19 (COVID19 (JANSSEN))	Platelet count normal	2.772	2.16	0.89			0.416	2.112	3.064	2.553	3.484	1.892	
COVID19 (COVID19 (JANSSEN))	Platelet factor 4	6	3.558	0.88				4.279	3.638	6.689	5.968	2.984	
COVID19 (COVID19 (JANSSEN))	Poor quality product administered	1.008					0.856	3.865	2.946	5.888	4.388	3.636	
COVID19 (COVID19 (JANSSEN))	Prothrombin time prolonged	1.761	1.432	0.884	0.744		0.273	1.368	2.192	1.271	2.211	1.235	
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism	2.204	1.683	0.945	0.612		0.804	1.642	2.129	2.54	2.504	1.802	
COVID19 (COVID19 (JANSSEN))	Pulmonary thrombosis	2.01	1.99	0.884				1.561	1.402	2.007	1.88	1.595	
COVID19 (COVID19 (JANSSEN))	Red cell distribution width increased	1.772	1.245	0.876	0.509		0.374	1.123	1.908	1.405	2.012	1.143	
COVID19 (COVID19 (JANSSEN))	Superficial vein thrombosis	2.213	1.089	0.882			0.552	1.377	1.735	1.354	1.894	1.66	
COVID19 (COVID19 (JANSSEN))	Suspected COVID-19	3.017	2.584	1.572			0.546	1.985	2.309	0.773	2.561	2.979	
COVID19 (COVID19 (JANSSEN))	Therapy non-responder	6.976	6.813				6.686	3.471	6.68	15.272	8.03	5.677	
COVID19 (COVID19 (JANSSEN))	Thrombocytopenia	2.169	1.938	0.891			0.412	1.756	2.233	1.413	2.623	1.5	
COVID19 (COVID19 (JANSSEN))	Thrombosis	2.634	2.217	1.751	0.612		0.599	2.028	2.393	3.522	2.827	2.159	
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis	2.153	1.847	0.88				1.768	1.178	0.653	2.171	0.857	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler	2.264	1.275	0.883			0.667	1.736	2.065	2.13	2.542	1.635	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal	2.827	2.056	0.894	0.612		0.551	2.353	2.299	3.511	3.31	2.185	
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal	2.48	1.765	0.884			0.473	2.7	1.735	1.466	2.411	1.78	
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal	1.927	1.137	0.882				1.345	2.081	1.731	2.033	1.274	
COVID19 (COVID19 (JANSSEN))	Vaccination failure	1.527	2.641	2.128			0.577	1.052	2.281	4.826	2.008	2.183	
COVID19 (COVID19 (JANSSEN))	Venogram	2.61	2.059					2.059	1.77	0.631	2.878	1.016	
COVID19 (COVID19 (JANSSEN))	Venogram abnormal	3.21	2.469				0.619	2.71	1.992	0.705	4.101	1.936	
COVID19 (COVID19 (JANSSEN))	Venogram normal	4.265	2.502	0.88				3.57	2.517	0.875	5.292	1.993	
COVID19 (COVID19 (MODERNA))	Exposure via breast milk	1.268	6.786		3.524	0.778		1.179	0.517		1.281	0.886	
COVID19 (COVID19 (MODERNA))	Headache	0.964	6.955	0.876	2.343		0.303	0.941	0.965	1.011	0.954	1.022	
COVID19 (COVID19 (MODERNA))	No adverse event	1.246	0.84	0.884		0.292	2.014	0.915	0.926	0.781	1.124	1.218	
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age	2.353	6.909	0.882		1.203	2.528	0.173	0.295	0.598	2.401	2.438	
COVID19 (COVID19 (MODERNA))	Product dose omission issue	1.319	6.889	0.873			2.084	1.041	1.187	1.007	1.908	1.05	
COVID19 (COVID19 (PFIZER-	Body height	1.935	6.994	0.882			0.603	0.88	1.266	2.236	1.915	1.473	
COVID19 (COVID19 (PFIZER-	Disease recurrence	2.053	1.052	0.878			0.64	1.47	1.663	1.967	2.022	1.566	
COVID19 (COVID19 (PFIZER-	Drug ineffective	2.269	1.704	0.936			1.098	1.751	1.92	2.038	2.075	1.886	
COVID19 (COVID19 (PFIZER-	Exposure via breast milk	0.66	6.846	0.882	7.751			0.384			0.407	1.131	
COVID19 (COVID19 (PFIZER-	Investigation	2.155	1.7	0.897			1.005	1.723	1.907	2.354	2.13	1.93	
COVID19 (COVID19 (PFIZER-	Product administered to patient of inappropriate age	0.305	6.357	0.875		3.331	0.305	0.259	0.102	0.329	0.282	0.329	
COVID19 (COVID19 (PFIZER-	Product preparation issue	1.852	6.658				1.361	1.68	1.915	2.336	1.847	1.775	
COVID19 (COVID19 (PFIZER-	Weight	2.046	1.287	0.887			0.623	1.51	1.704	2.241	2.034	1.756	

From: Menschik, David
Sent: Wed, 22 Sep 2021 16:33:23 +0000
To: Su, John (CDC/DDID/NCEZID/DHQP)
Subject: data mining limitations
Attachments: mRNA_6mo_safety review-update98forOS_091521.docx

Hi John,

In the mRNA vaccine review article that we're co-authors on, we recently expanded data mining limitations section as per attached work-in-progress draft (Hannah indicated acceptance of the language) and excerpt below for convenience:

> EB data mining has multiple limitations[22] including that an absence of a disproportionality alert does not rule out presence of a safety problem. Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionately scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be muted by COVID-19 vaccine reports contributing substantially to the comparator group, particularly if both mRNA COVID-19 vaccines are associated with the same adverse event.

Thought it might be helpful to share this manuscript update with you, especially if folks on your end may be placing excess value on data mining alerts (EB05>2) or the absence of specific data mining alerts.

Best,
David

PS: If you'd like to discuss more, happy to do so by phone (better suited than email...)

Reactogenicity and Adverse Events during the First Six Months of mRNA COVID-19 Vaccination in the United States: A Prospective Observational Study of Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe

Hannah G. Rosenblum, MD[1,2]; Julianne M. Gee, MPH[1]; Ruiling Liu, PhD[1]; Paige L. Marquez, MSPH[1]; Bicheng Zhang, MS[1]; Penelope Strid, MPH[1], Winston E. Abara, MD[1]; Michael M. McNeil, MD, MPH[1]; Lauri E. Markowitz, MD[1]; Tanya R. Myers, PhD[1]; Anne M. Hause, PhD, MSPH[1]; John R. Su, MD, PhD[1]; Bethany Baer, MD[3]; David Menschik, MD, MPH[3]; Tom T. Shimabukuro, MD, MPH, MBA[1], David K. Shay, MD, MPH[1]

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC) or the Food and Drug Administration (FDA)

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Abstract (word count: 233/250)

Background: In December 2020, two mRNA-based COVID-19 vaccines were authorized for use in the United States. Vaccine safety was monitored using Vaccine Adverse Event Reporting System (VAERS), a national passive surveillance system, and v-safe, an active surveillance system.

Methods: VAERS and v-safe data from December 14, 2020—June 14, 2021 were analyzed. Empirical Bayesian data mining was used to identify disproportional reporting of events by vaccine in VAERS. Proportions of v-safe participants reporting local and systemic reactions or health impacts the week following first and second vaccine doses were determined.

Findings: During the analytic period, 298,792,852 total doses of mRNA vaccines were administered in the United States. VAERS received and processed 340,522 reports; 92·1% were classified as non-serious; 6·6%: serious, non-death; and 1·3% as death. Over half of 7,914,583 v-safe participants self-reported local and systemic reactogenicity, more frequently after dose 2. Injection-site pain, fatigue, and headache were most commonly reported during days 0–7 following vaccination. Reactogenicity was reported most frequently one day after vaccination and rapidly declined; most reported reactions were mild. More reports of being unable to work or do normal activities occurred after dose 2 (32·1%) than dose 1 (11·9%); <1% of participants reported seeking medical care after vaccination.

Interpretation: Safety data from >298 million doses of mRNA COVID-19 vaccine administered in the first 6 months of the U.S. vaccination program show the majority of reported adverse events were mild and short in duration.

Funding: No external sources of funding were used. CDC received nonfinancial technical support to develop and maintain the v-safe infrastructure from Oracle.

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Introduction

In December 2020, two messenger RNA (mRNA) coronavirus disease 2019 (COVID-19) vaccines (BNT162b2 developed by Pfizer-BioNTech and mRNA-1273 developed by Moderna) were granted Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) as 2-dose series and recommended for use by the Advisory Committee on Immunization Practices (ACIP).[1,2] The mRNA vaccine platform uses lipid nanoparticles as a carrier system for the mRNA which encodes the SARS-COV-2-spike protein. In clinical trials, both mRNA COVID-19 vaccines had acceptable safety profiles.[3,4] Reactogenicity (i.e., local and systemic reactions) was observed after receipt of vaccine in clinical trials of both vaccines; the most frequently reported symptoms included injection site pain, fatigue, and headache. Reactogenicity was more frequently reported following dose 2, and more common among participants aged <65 years.[3-5]

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Post-authorization safety monitoring is necessary to better understand the safety profiles of mRNA-based COVID-19 vaccines in larger and more heterogeneous populations.[6] Phased administration of COVID-19 vaccines in the United States began with healthcare workers and residents of long-term care facilities and expanded to the general population by spring 2021; however, implementation plans varied by state.[7] The Vaccine Adverse Event Reporting System (VAERS), a spontaneous reporting (i.e., passive surveillance) system,[8] and v-safe,[9] a new active monitoring system, were the primary safety data sources used in initial reports of adverse events following administration of COVID-19 vaccines in the United States vaccination program.[10-11] Since the inception of the program, regular vaccine safety updates from these systems have been provided through websites, publications, and presentations to advisory committees.[10-14] Here, we review VAERS and v-safe safety data during the first six months of the U.S. vaccination program, when over 298 million doses of mRNA COVID-19 vaccines were administered.

Methods

VAERS

VAERS is an established, national spontaneous reporting system that serves as an early warning system for detecting potential safety problems for vaccines authorized or licensed in the United States.[8] Co-administered by Centers for Disease Control and Prevention (CDC) and FDA, VAERS accepts reports from health care providers, manufacturers, and the public. VAERS reports include information about the vaccinated person, type of vaccine administered, and the adverse event (AE) experienced. For this analysis, VAERS reports submitted and processed by June 14, 2021 were included.[15] Processed reports were those checked for data quality, de-duplicated, and coded using the Medical Dictionary for Regulatory Activities (MedDRA) terminology.[8] Each VAERS report may be assigned more than one MedDRA Preferred Term (PT); PTs do not necessarily indicate a medically confirmed diagnosis, and include signs and symptoms of illness and results of diagnostic tests.

Based on the Code of Federal Regulations,[16] VAERS reports were classified as serious if any of the following were documented: hospitalization, prolongation of existing hospitalization, permanent disability, life-threatening illness, congenital anomaly or birth defect, or death. Adverse events of special interest (AESI)[17] were selected for enhanced COVID-19 vaccine safety monitoring based on biologic plausibility, previous vaccine safety experience, and theoretical concerns related to COVID-19.[17] Death certificates and autopsy reports were requested for death reports. CDC physicians reviewed VAERS reports and available death certificates for each decedent to form an impression about cause of death. Causes of death were further categorized into the following groups, using the National Center for Health Statistics the 15 most common major *International Classification of Disease, Tenth Revision (ICD-10)* diagnostic categories reported on U.S. death certificates[18]: COVID-19 disease; other (i.e., diagnosis did not belong in one of the other pre-specified categories); or unknown/unclear if a likely cause could not be determined.

V-safe

V-safe is a voluntary smartphone-based system that uses text messaging and secure web-based surveys to actively monitor vaccine safety, and has been specifically designed to gather information about COVID-19 vaccine AEs, particularly for common local injection site and systemic reactions.[19] V-safe participants receive text messages that link to web-based health check-ins and respond to questions in surveys following vaccination, initially daily (days 0–7), then weekly (days 14–42) and lastly at 3, 6 and 12 months post vaccination. The system resets to the initial survey frequency after receipt of dose 2. We analyzed survey reports from days 0–7 for reactogenicity, severity[9] (mild, moderate, severe), and health impact (i.e., unable to perform normal daily activities, unable to work, and/or received care from a medical professional). Participants who reported receiving medical care were contacted by v-safe staff and VAERS reports were completed if clinically indicated.

Data analyses

We conducted descriptive analyses of available VAERS and v-safe data from December 14, 2020–June 14, 2021 following first and second doses of BNT162b2 and mRNA-1273 vaccines. For VAERS, bivariate analyses included sex, age groups, race/ethnicity, serious AEs, time from vaccination to reported death (i.e., onset interval) for death reports, cause of death for death reports, and vaccine type/manufacturer administered. Unadjusted, crude reporting rates to VAERS were calculated for AEs using the total number of doses of mRNA vaccine administered during the six-month period. COVID-19 vaccine administration data were provided through CDC's COVID-19 Data Tracker.[20]

Empirical Bayesian (EB) data mining was used to detect disproportional reporting of post-vaccine outcomes by vaccine received among all VAERS serious and non-serious reports received by June 14, 2021.[21] This statistical method calculates observed to expected PT pairings by comparing a specific vaccine-PT pair to all vaccine-PT pairs in VAERS, adjusting for age, sex, and year of vaccination.[22]

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These ratios are ranked by the lower 5% bound of the EB geometric mean confidence interval (EB05) and a standard alert threshold of EB05 >2 was used. An EB05 >2 represents a high degree of confidence that a vaccine-PT pair was reported at least twice as frequently as expected. In addition to overall ratios, ratios were calculated for age group, sex, serious reports, and death reports.

V-safe participants who responded to at least one health check-in survey during day 0–7 after vaccination were included in analyses. Descriptive statistics were calculated for participants characteristics (sex, age, race/ethnicity), reaction (type and severity) and health impact by manufacturer, dose number, and number of days following vaccination.

SAS software, version 9.4 (SAS Institute; Cary, NC, USA) was used for analyses. Both VAERS and v-safe conduct surveillance as a public health function and are exempt from institutional review board review. Activities were reviewed by the CDC and were conducted in accordance with applicable federal law and CDC policy (See: 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.).

Results

During December 14, 2020–June 14, 2021, a total of 298,792,852 doses of mRNA COVID-19 vaccines were administered in the United States: 167,177,332 were BNT162b2 and 131,639,515 were mRNA-1273 (Supplemental Table 1). A greater proportion of vaccines were administered to females (53·2%) compared with males (45·8%). The median age at vaccination was 50 years (inter-quartile range [IQR]: 33–65) for BNT162b2 and 56 years (IQR: 39–68) for mRNA-1273, respectively. Non-Hispanic White persons accounted for 38·4% of vaccine recipients; however, race/ethnicity was unknown for 34·9% of all vaccine recipients.

VAERS

During the analytic period, VAERS received and processed a total of 340,522 reports: 164,669 were following BNT162b2 and 175,816 were following mRNA-1273 vaccine administration (Table 1). Of these reports, 92·1% were classified as non-serious, 6·6% were serious, not resulting in a death (non-death), and 1·3% were deaths. Seventy-two percent of reports were among females, and 45·3% of reports were among vaccine recipients aged 18–49 years; median age was 50 years (IQR: 36–64). Fifty percent of those reporting race/ethnicity identified as non-Hispanic White; for 22·1%, race/ethnicity was unknown. The most common MedDRA PTs among non-serious reports were headache (20·4%), fatigue (16·6%), pyrexia (16·3%), chills (15·7%), and pain (15·2%). The most common MedDRA PTs among serious reports were dyspnea (15·4%), death (14·1%), pyrexia (11·0%), fatigue (9·7%), and headache (9·5%). The reporting rate to VAERS was 1,049 non-serious reports per million doses, and 90 serious reports per million doses (Table 2). Among the pre-specified AESIs, reporting rates ranged from 0·1 narcolepsy reports per million doses administered to 32 COVID-19 disease reports per million doses administered.

There were 4,496 reports of death in VAERS (Table 3). After review, 24 reports were excluded because of miscoding of death or duplicate reporting. Of the 4,472 reports of deaths analyzed, 2,087 (46·7%) were reported following BNT162b2 and 2,385 (53·3%) following mRNA-1273. Females accounted for 42·6% of reported deaths; the median age of decedents was 76 years (IQR: 66–86). More than 80% of deaths were reported among individuals aged 60 years or older (reporting rate of death per million doses administered by age group: 60–69 years, 2·6; 70–79 years, 3·7; 80–89 years, 3·8; ≥90 years, 2·1).18·3% of decedents were identified as long-term care facility residents. Death certificates or autopsy reports were available for clinical review for 808 (18·1%) reports of deaths analyzed (Table 4). Among these 808 reports, causes of death were most commonly diseases of the heart (46·5%) and COVID-19 disease (12·6%). Causes of death among reports with death certificate or autopsy available are shown by age in Figure 1 and Supplemental Table 2. Among the 3,664 reports of death without a death certificate or

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autopsy, causes of death were most commonly unknown/unclear (54·1%), diseases of the heart (17·0%), and COVID-19 disease (8·7%). Supplemental Table 3 displays specific impressions within each category of cause of death, for all deaths, and for those with death certificate or autopsy. Time interval to death following vaccination was available for 4,119 reports (92·1%) and the median time interval was 10·0 days (range: 0—161 days) after vaccination. The greatest number of reports of deaths occurred on day 1 (10·5%) and day 2 (7·0%) following vaccination (Supplemental Figure 1).

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EB Data Mining

No adverse health outcome alerts were identified in EB data mining. However, five mRNA COVID-19 alerts with disproportionality (EB05>2) were identified during the surveillance period. For BNT162b2 vaccine, 'product preparation issue' alerted among all reports (EB05: 2·09; N=757), and among adults ≥65 years (EB05: 2·10; N=205), females (EB05: 2·03; N=394), and males (EB05: 2·01; N=350). Two terms for BNT162b2 vaccine alerted in adults ≥65 years: 'investigation' (EB05: 2.06; N=163) and 'weight' (EB05: 2·01; N=139). For mRNA-1273 vaccine, two terms alerted among all reports: 'poor quality product administered' (EB05: 2·43; N=1,506), and 'product temperature excursion issue' (EB05: 2·17; N=720).

v-safe

During the analytic period, 7,914,583 mRNA COVID-19 vaccine recipients enrolled in v-safe and completed at least one post-vaccination health survey during days 0–7 after vaccination (Table 5). The median age of v-safe participants was 50 years (IQR: 36–63), 62·9% were female, and 59·4% identified as non-Hispanic White. A total of 6,775,515 participants completed at least one survey during day 0–7 after dose 1 (3,455,778 following BNT162b2 and 3,319,737 following mRNA-1273). Of these participants, 68·6% reported a local injection site reaction and 52·7% reported a systemic reaction. Of the 5,674,420 participants who completed a survey after dose 2, a greater percentage reported an injection site

reaction (71·7%) and/or a systemic reaction (70·8%) (Table 6). Local injection site reactions were reported more frequently after mRNA-1273 (dose 1: 73·3%; dose 2: 78·4%) than after BNT162b2 (dose 1: 64·0%; dose 2: 65·3%). A similar pattern was found for systemic reactions after mRNA-1273 (dose 1: 54·3%; dose 2: 75·8%) versus BNT162b2 (dose 1: 51·3%; dose 2: 66·1%). The most frequently reported events after dose 1 of either mRNA vaccine included injection site pain (66·2%), fatigue (33·9%), and headache (27·0%); these reactions were also more frequent after dose 2: injection site pain (68·6%), fatigue (55·7%), headache (46·2%). Differences in proportions of reactogenicity by dose number were similar after stratifying by age group (<65 vs. ≥65 years) and sex. More reactogenicity was reported among younger participants aged <65 years and by females. (Supplemental Table 4).

Proportions of reported severity of reactions by manufacturer, dose number, and day since vaccination are shown in Figure 2. The majority of reported symptoms were mild. Participants reported moderate and severe reactogenicity most commonly on day 1 after dose 2 of either vaccine. The proportion of participants who reported symptoms was greatest on day 1 and then decreased on subsequent days. The highest proportion of participants reported severe symptoms on day 1 following dose 2 of mRNA-1273 (Supplemental Table 6). On all other days, proportions of participants reporting severe symptoms did not exceed 3.0% for any individual symptom (Supplemental Tables 5 and 6).

Reported health impact was greater following dose 2 of either mRNA vaccine (32·1%) compared with dose 1 (11·9%) and after mRNA-1273 of either dose compared with BNT162b2 (Table 6). After dose 1 of either mRNA vaccine, 9·7% of participants were unable to do normal activities and 4·5% were unable to work. After dose 2 of BNT162b2, 20·5% were unable to do normal activities, and 12·3% were unable to work. After dose 2 of mRNA-1273, 32·8% were unable to do normal activities, and 20·0% were unable to work. Less than 1·0% reported receiving medical care after receiving either dose from either manufacturer. Fewer participants reported an emergency room visit (dose 1: 0·1%; dose 2: 0·2%) or hospitalization (dose 1: 0·03%; dose 2: 0·04%).

When stratified by sex, females reported a health impact more frequently than males, peaking on day 1 after vaccination (Supplemental Figure 2). Following dose 2 of mRNA-1273 vaccine, 41·4% of females reported in the day 1 survey an inability to perform normal activities, and 23·5% an inability to work. Among males receiving dose 2 of mRNA-1273 on the day 1 survey, 25·6% were unable to perform normal activity and 16·9% were unable to work (Supplemental Table 7).

Discussion

During the first six months of the U.S. COVID-19 vaccination program, over 298 million doses of mRNA vaccines were administered. COVID-19 vaccine safety in the United States has been monitored with well-established systems, including the Vaccine Safety Datalink[23] and VAERS, and a system developed specifically for COVID-19 vaccine safety monitoring, known as v-safe. The post-authorization safety profile for mRNA COVID-19 vaccines after six months of use in the United States is largely consistent with data presented in the pre-authorization clinical trials.[3,4] Data from U.S. safety monitoring systems have been presented regularly to ACIP's COVID-19 Vaccine Safety Technical Subgroup (VaST) work group[24] and at public ACIP meetings.[25] Data have been presented concerning cases of clinically serious AEs, including anaphylaxis,[13] thrombosis with thrombocytopenia syndrome (TTS),[26] myocarditis,[27] and Guillain-Barré Syndrome (GBS)[28] reported following receipt of COVID-19 vaccines. ACIP has assessed the benefit-risk balance of each of the currently authorized U.S. COVID-19 vaccines; these evaluations have not prompted any changes in U.S. COVID-19 immunization recommendations.[13,27,28]

Our main findings are similar to those obtained from diary-based reporting in pre-authorization clinical trials and early post-authorization reports – data from all reports demonstrate substantial local and systemic reactogenicity.[3-5,10,11] In both VAERS and v-safe, local injection site and systemic reactions were commonly reported, and in v-safe, transient reactions were reported more frequently following mRNA-1273 compared with BNT162b2, and more frequently following dose 2. Overall, females and individuals

aged <65 years reported AEs and reactions more frequently. These findings are similar to those from a large-scale study about reactogenicity conducted in the United Kingdom.[29] Host characteristics known to influence reactogenicity, including age, sex, and the presence of underlying medical conditions, might be associated with this pattern of findings.[30] Females have more vigorous antibody responses[31] to certain vaccines and also tend to report more severe local and systemic reactions to influenza vaccine.[32] Females may also be more likely than males to respond to surveys[33,34] and we hypothesize that younger individuals may be more comfortable with smartphone-based surveys and more likely to respond to survey questions.[35,36]

The impact of vaccination on daily life activities was most frequently reported on the first day after vaccination. Reports about the health impact measures used in v-safe, while self-assessed and subjective, correlate with reports about reactogenicity patterns: more health impact was reported by females than males, by participants aged <65 years compared with older participants, by persons receiving dose 2 compared with dose 1, and by those who received mRNA-1273 versus BNT162b2. Reports of seeking medical care (including telehealth and urgent care) after receipt of either dose of mRNA vaccine were rare, suggesting that reactogenicity was transient and manageable at home. Among those who did report seeking medical care, only a small proportion visited an emergency department or were hospitalized. Reactogenicity and its associated health effects, even if transient, may deter some persons from seeking vaccination. An April 2021 survey conducted by the Kaiser Family Foundation found that nearly half (48%) of unvaccinated adults aged <50 years expressed concern about missing work due to vaccine side effects; this concern was reported by 55% of unvaccinated Black adults and 64% of unvaccinated Hispanic adults.[37] Employees who are provided time off may be more likely to get vaccinated, even after controlling for other demographic factors that might influence vaccine uptake.[38] These data suggest that employee work policies that accommodate days off for vaccination and recovery from side effects may increase vaccination coverage.[39]

Increased public awareness, widespread promotion of VAERS, and outreach and education to healthcare providers about COVID-19 EUA AE reporting requirements are likely all contributing factors to the high volume of VAERS reports following mRNA COVID-19 vaccines as compared to established adult vaccinations.[8] For mRNA COVID-19 vaccines in this six-month period, VAERS has processed and received more than six times the number of average reports per year (typically 50,000 reports are received per year for all vaccines in all age groups).For example, the number of reports of death in VAERS following mRNA vaccine in this period exceeds the number of deaths reported to VAERS for all other vaccines in a summary report from 1997–2013 by eight times.[40] The concentrated reporting of deaths on days 1 and 2 following vaccination may represent reporting bias, as the likelihood to report a serious AE may increase when it occurs in close temporal proximity to vaccination.

Comparing deaths reported to VAERS following mRNA vaccination by cause to national mortality data[41] is challenging, as more common causes of deaths in younger individuals (for example, accidents or suicide) may be less likely to be reported to VAERS. The overrepresentation of diseases of the heart as cause of death in general may be driven by non-specific causes of death on death certificates such as cardiac arrest or cardiopulmonary arrest, which are terminal events, but might be chosen if no immediate explanation is available. Additional studies are needed to characterize deaths in VAERS …???

During the 6-month period we analyzed, patterns of reports to VAERS are similar to other vaccines that are routinely administered to adults and the majority of reported events were non-serious.[42,43,44,45] None of the EB data mining alerts suggested an unexpected vaccine safety problem. Serious AEs have been detected following receipt of COVID-19 vaccines during U.S. safety monitoring and reviewed in detail.[26-28] Early reports of anaphylaxis prompted recommendations about specific clinical management including screening and recommendation of a post-observation period following vaccination.[46] After myocarditis was observed following mRNA vaccination,[47,48] particularly in males aged <30 years, CDC issued clinical guidance and management recommendations,[49] and presented a benefit-risk assessment to ACIP.[27] The risk of TTS[26] and GBS[28] is elevated following receipt of Janssen COVID-19 vaccine (Ad26.COV2.S) and have not been associated with mRNA COVID-19 vaccines to date.

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This reporting may also reflect a true event. This hypothesis can easily be tested in VAERS. Please discuss whether a similar pattern of reporting has been observed with other vaccines. For example, one can check whether a similar time pattern has been observed for the shingles vaccine, or the flu vaccine, and compare patterns.
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This study has several strengths and several limitations. Strengths include a large sample size and comprehensive capture of national data from two complementary surveillance systems. Data on doses administered are available for estimating reporting rates for VAERS, as the U.S. government provides all COVID-19 and collects administration data from jurisdictions. Therefore, the reporting rates calculated here use the number of mRNA vaccine doses administered as a denominator,[50] while for other vaccines the only denominators available are doses distributed, which is variably larger than dose administered. V-safe data illustrating the effects of mRNA vaccination on daily activities and work during the week following vaccination provide new information has not previously available. Limitations include that VAERS data are based on passive surveillance, and may therefore be subject to underreporting, and variable or incomplete reporting.[8] For this analysis, reports of death in VAERS were individually reviewed by physicians and follow-up is ongoing to obtain additional records for reports of death missing death certificates, autopsy reports, or other medical records; however, not all other serious AE reports were individually reviewed. VAERS reports require interpretation to determine if AE reports meet clinical case definitions.[51] ~~Though~~ EB data mining has multiple limitations[22] including that ~~is used to screen for safety alerts,~~ an absence of an disproportionality alert does not rule out presence of a safety problem. Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionately scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be muted by COVID-19 vaccine reports contributing substantially to the comparator group, particularly if both mRNA COVID-19 vaccines are associated with the same adverse event. Routine screening of VAERS reports may also not be sensitive enough to pick up true associations, particularly if they occur in specific age groups. V-safe is voluntary and requires smartphone access. Participants are asked about pre-specified reactions; this report focused on the first 7 days post-vaccination. Because a subset of all vaccine recipients chose to participate in v-safe, the results likely are not generalizable to the entire vaccinated population in the United States. Participants in v-safe may also be lost to follow up as there is not a requirement for continuous enrollment.

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During the first six months of the U.S. COVID-19 vaccination program, more than 50% of the eligible population received at least one dose of COVID-19 vaccine.[20] VAERS and v-safe data from this period demonstrate a post-authorization safety profile for mRNA COVID-19 vaccines that is consistent with pre-authorization trials[3,4] and early post-authorization surveillance reports.[10,11] Serious AEs have been identified following mRNA vaccinations; however, based on the most current information, these events are rare. Vaccines are the most effective tool to preventing serious COVID-19 disease outcomes and the benefits of immunization in preventing serious morbidity and mortality clearly favor vaccination.[26-28] VAERS and v-safe, two complementary surveillance systems, will continue to provide data needed to inform immunization policy makers, medical and immunization providers, and the public about the safety of COVID-19 vaccination.

Research in context

Evidence before this study

We searched PubMed for articles published through July 12, 2021, using the terms ("BNT162b2" or "mRNA-1273" or "mRNA COVID-19 vaccine") AND ("reactogenicity" or "side-effects" or "adverse effects" or "health impact") not restricted by language or type of publication. Among 100 results, publications describing the health impacts following vaccination by BNT162b2 or mRNA-1273 are limited. Available literature from the United States included reports of manufacturer-sponsored phase 1–3 clinical trials. Additionally, we found seven published articles from the United States, one published article from United Kingdom and two preprints from the United States investigating reactogenicity and adverse events in mRNA vaccination. These articles discussed reactogenicity and adverse events following mRNA vaccination. No study included the period through June 2021.

Added value of this study

In this large, observational study, we assessed reactogenicity, health impact, and adverse events reported following mRNA COVID-19 vaccination during the first six months of the U.S. vaccination program. We found that reported reactions to mRNA vaccination were mostly mild in severity and transient in duration, and the great majority of reports were non-serious. Reactions and health impact were reported more frequently in females compared to males, and in individuals aged <65 years compared to older individuals. Health impact information for adults from v-safe is presented here for the first time. Deaths, overall and for specific causes by age, were reported.

Implications of all the available evidence

The findings from complementary surveillance systems from the first six months of mRNA vaccination in the United States are consistent with pre-authorization clinical trials and early post-authorization reports. Mild-to-moderate transient reactogenicity should be anticipated, particularly among younger recipients and female recipients. As these data inform immunization policy recommendations and clinical considerations, the federal monitoring system continues to update the benefit-risk balance of vaccine

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recommendations, particularly in the setting of the association of specific serious adverse events and COVID-19 vaccination.

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***Table* 1: Characteristics of reports received and processed by Vaccine Adverse Events Reporting System (VAERS) for mRNA COVID-19 vaccines—December 14, 2020–June 14, 2021**

	Both mRNA vaccines† (n=340,522)	BNT162b2 vaccine (n=164,669)	mRNA-1273 vaccine (n=175,816)
Reports			
Non-serious adverse event reports	313,499 (92·1)	150,486 (91·4)	162,977 (92·7)
Serious reports, including death	27,023 (7·9)	14,183 (8·6)	12,839 (7·3)
Serious, non-death adverse event reports	22,527 (6·6)	12,078 (7·3)	10,448 (5·9)
Death	4,496 (1·3)	2,105 (1·3)	2,391 (1·4)
Sex			
Female	246,085 (72·3)	116,587 (70·8)	129,475 (73·6)
Male	88,311 (25·9)	45,157 (27·4)	43,140 (24·5)
Unknown	6,126 (1·8)	2,925 (1·8)	3,201 (1·8)
Age (years)			
16–17	6,874 (2·0)	3,283 (2·0)	3,591 (2·0)
18–49	154,171 (45·3)	76,385 (46·4)	77,773 (44·2)
50–64	84,949 (24·9)	40,367 (24·5)	44,572 (25·4)
65–74	49,755 (14·6)	20,048 (12·2)	29,702 (16·9)
75–84	21,418 (6·3)	9,021 (5·5)	12,392 (7·1)
≥85	7,595 (2·2)	3,564 (2·2)	4,027 (2·3)
Unknown	15,760 (4·6)	12,001 (7·3)	3,759 (2·1)
Race/Ethnicity			
Hispanic/Latino	23,480 (6·9)	11,217 (6·8)	12,260 (7·0)
Non-Hispanic			
White	169,877 (49·9)	73,398 (44·6)	96,469 (54·9)
Black	10,446 (3·1)	5,104 (3·1)	5,342 (3·0)
Asian	10,172 (3·0)	5,038 (3·1)	5,131 (2·9)
American Indian or Alaska Native	1,414 (0·4)	615 (0·4)	799 (0·5)
Native Hawaiian or Other Pacific Islander	441 (0·1)	209 (0·1)	232 (0·1)
Multiple races	3,542 (1·0)	1,578 (1·0)	1,964 (1·1)
Other races	1,684 (0·5)	808 (0·5)	876 (0·5)
Unknown race	2,593 (0·8)	1,422 (0·9)	1,171 (0·7)
Unknown ethnicity			
White	28,787 (8·5)	15,497 (9·4)	13,289 (7·6)
Black	4,189 (1·2)	2,524 (1·5)	1,662 (1·0)
Asian	2,435 (0·7)	1,396 (0·9)	1,039 (0·6)
American Indian or Alaska Native	724 (0·2)	348 (0·2)	375 (0·2)
Native Hawaiian or Other Pacific Islander	105 (0·03)	56 (0·03)	49 (0·03)
Multiple races	590 (0·2)	301 (0·2)	289 (0·2)
Other races	4,709 (1·4)	2,838 (1·7)	1,870 (1·1)
Unknown race and ethnicity	75,334 (22·1)	42,320 (25·7)	32,999 (18·8)
Signs or symptoms most frequently reported, non-serious*			
Headache	64,064 (20·4)	30,907 (20·5)	33,154 (20·3)
Fatigue	52,048 (16·6)	24,805 (16·5)	27,241 (16·7)
Pyrexia	51,023 (16·3)	22,185 (14·7)	28,837 (17·7)
Chills	49,234 (15·7)	21,638 (14·4)	27,595 (16·9)
Pain	47,745 (15·2)	21,506 (14·3)	26,238 (16·1)
Nausea	37,333 (11·9)	18,066 (12·0)	19,267 (11·8)
Dizziness	37,257 (11·9)	20,307 (13·5)	16,950 (10·4)
Pain in extremity	31,753 (10·1)	14,098 (9·4)	17,653 (10·8)
Injection site pain	28,949 (9·2)	10,462 (7·0)	18,487 (11·3)
Injection site erythema	22,351 (7·1)	2,991 (2·0)	19,360 (11·9)
Signs or symptoms most frequently reported, serious*			
Dyspnea	4,175 (15·4)	2,210 (15·6)	1,965 (15·3)
Death‡	3,802 (14·1)	1,753 (12·4)	2,039 (15·9)
Pyrexia	2,986 (11·0)	1,469 (10·4)	1,517 (11·8)
Fatigue	2,608 (9·7)	1,395 (9·8)	1,213 (9·4)
Headache	2,567 (9·5)	1,360 (9·6)	1,207 (9·4)
Chest pain	2,300 (8·5)	1,310 (9·2)	990 (7·7)
Nausea	2,228 (8·2)	1,160 (8·2)	1,068 (8·3)
Pain	2,222 (8·2)	1,195 (8·4)	1,027 (8·0)
Asthenia	2,194 (8·1)	1,084 (7·6)	1,110 (8·6)
Dizziness	2,069 (7·7)	1,111 (7·8)	958 (7·5)

Data are n (%).
*Symptoms refers to MedDRA preferred terms (PTs) and are ordered by most frequently reported for both vaccines. MedDRA PTs are not mutually exclusive.
†Total includes reports without a vaccine manufacturer listed.
‡Not all reports of death were coded with the MedDRA PT of 'death'

***Table* 2: Frequency and reporting rates of adverse events of special interest reported to Vaccine Adverse Event Reporting System (VAERS) by recipients of mRNA COVID-19 vaccine—December 14, 2020–June 14, 2021**

	Both mRNA vaccines		BNT162b2 vaccine		mRNA-1273 vaccine	
	n	Reports per million doses*	n	Reports per million doses†	n	Reports per million doses‡
Non-serious adverse event reports	313,499	1,049·2	150,486	900·2	162,977	1,238·1
Serious reports, including death	27,023	90·4	14,183	84·8	12,839	97·5
Serious, non-death adverse event reports	22,527	75·4	12,078	72·2	10,448	79·4
Reports§ of adverse events of special interest**						
COVID-19	9,344	31·3	7,184	43·0	2,160	16·4
Coagulopathy††	4,320	14·5	2,343	14·0	1,977	15·0
Seizure	2,733	9·1	1,478	8·8	1,255	9·5
Stroke‡‡	1,937	6·5	981	5·9	955	7·3
Bells' Palsy	1,918	6·4	1,057	6·3	861	6·5
Anaphylaxis	1,639	5·5	972	5·8	667	5·1
Myopericarditis	1,307	4·4	813	4·9	494	3·8
Acute Myocardial Infarction	1,118	3·7	610	3·6	508	3·9
Appendicitis	383	1·3	258	1·5	125	1·0
Guillain-Barré Syndrome	293	1·0	154	0·9	139	1·1
Multisystem Inflammatory Syndrome in Adults	119	0·4	60	0·4	59	0·4
Transverse Myelitis	98	0·3	55	0·3	43	0·3
Narcolepsy	21	0·1	12	0·1	9	0·1

*298,792,852 doses of mRNA vaccine were administered in the study period.
†167,177,332 doses of BNT162b2 vaccine were administered in the study period.
‡131,639,515 doses of mRNA-1273 vaccine were administered in the study period.
§These represent reports, not confirmed by case definition.
**Reported death is an adverse event of special interest but counts appear in following tables. Events are not mutually exclusive.
††Coagulopathy is an aggregate term capturing three specific adverse events: 1) thrombocytopenia, 2) deep venous thrombosis/pulmonary embolism, and 3) disseminated intravascular coagulopathy.
‡‡No vaccine manufacturer was provided for one report of stroke.

***Table* 3: Characteristics of deaths reported to Vaccine Adverse Event Reporting System (VAERS) by recipients of mRNA COVID-19 vaccine—December 14, 2020–June 14, 2021**

	Both mRNA vaccines (n=4,472*)		BNT162b2 vaccine (n=2,087)		mRNA-1273 vaccine (n=2,385)	
	n (%)	Reports per million doses†	n (%)	Reports per million doses‡	n (%)	Reports per million doses§
Sex						
Female	1,906 (42·6)	6·4	918 (44·0)	5·5	988 (41·4)	7·5
Male	2,486 (55·6)	8·3	1,117 (53·5)	6·7	1,369 (57·4)	10·4
Unknown	80 (1·8)	0·3	52 (2·5)	0·3	28 (1·2)	0·2
Age (years)						
16–17	6 (0·1)	0·02	6 (0·3)	0·04	..	..
18–29	51 (1·1)	0·2	27 (1·3)	0·2	24 (1·0)	0·2
30–39	94 (2·1)	0·3	50 (2·4)	0·3	44 (1·8)	0·3
40–49	151 (3·4)	0·5	74 (3·5)	0·4	77 (3·2)	0·6
50–59	328 (7·3)	1·1	132 (6·3)	0·8	196 (8·2)	1·5
60–69	765 (17·1)	2·6	354 (17·0)	2·1	411 (17·2)	3·1
70–79	1,118 (25·0)	3·7	497 (23·8)	3·0	621 (26·0)	4·7
80–89	1,128 (25·2)	3·8	529 (25·3)	3·2	599 (25·1)	4·6
≥90	637 (14·2)	2·1	302 (14·5)	1·8	335 (14·0)	2·5
Unknown	194 (4·3)	0·6	116 (5·6)	0·7	78 (3·3)	0·6

*Of 4,496 deaths, 24 were excluded as they could not be confirmed or were duplicate reports upon review.
†298,792,852 doses of mRNA vaccine were administered in the study period.
‡167,177,332 doses of BNT162b2 vaccine were administered in the study period.
§131,639,515 doses of mRNA-1273 vaccine were administered in the study period.

***Table* 4: Most common causes of death among reports received and processed by Vaccine Adverse Event Reporting System (VAERS) following mRNA COVID-19 vaccination (n=4,472)—December 14, 2020–June 14, 2021**

	Death or autopsy certificate available			No death certificate or autopsy available		
ICD-10 Major Group	**Both mRNA vaccines** (n=808)	**BNT162b2 vaccine** (n=401)	**mRNA-1273 vaccine** (n=407)	**Both mRNA vaccines** (n=3,664)	**BNT162b2 vaccine** (n=1,686)	**mRNA-1273 vaccine** (n=1,978)
All reported deaths						
Diseases of the heart	376 (46·5)	161 (40·1)	215 (52·8)	622 (17·0)	296 (17·6)	326 (16·5)
COVID-19 disease	102 (12·6)	62 (15·5)	40 (9·8)	317 (8·7)	178 (10·6)	139 (7·0)
Other	68 (8·4)	38 (9·5)	30 (7·4)	141 (3·8)	68 (4·0)	73 (3·7)
Cerebrovascular diseases	53 (6·6)	28 (7·0)	25 (6·1)	207 (5·6)	101 (6·0)	106 (5·4)
Dementia	41 (5·1)	20 (5·0)	21 (5·2)	9 (0·2)	3 (0·2)	6 (0·3)
Chronic lower respiratory diseases	28 (3·5)	17 (4·2)	11 (2·7)	29 (0·8)	10 (0·6)	19 (1·0)
Malignant neoplasms	27 (3·3)	15 (3·7)	12 (2·9)	68 (1·9)	42 (2·5)	26 (1·3)
Unknown/unclear	27 (3·3)	9 (2·2)	18 (4·4)	1,984 (54·1)	844 (50·1)	1,140 (57·6)
Septicemia	23 (2·8)	12 (3·0)	11 (2·7)	72 (2·0)	47 (2·8)	25 (1·3)
Influenza and pneumonia	22 (2·7)	18 (4·5)	4 (1·0)	113 (3·1)	52 (3·1)	61 (3·1)
Accidents/unintentional injuries	11 (1·4)	3 (0·7)	8 (2·0)	22 (0·6)	8 (0·5)	14 (0·7)
Renal disease	8 (1·0)	5 (1·2)	3 (0·7)	25 (0·7)	7 (0·4)	18 (0·9)
Hematologic disease, other than malignancy	7 (0·9)	5 (1·2)	2 (0·5)	19 (0·5)	9 (0·5)	10 (0·5)
Pneumonitis due to solids and liquids	6 (0·7)	3 (0·7)	3 (0·7)	8 (0·2)	5 (0·3)	3 (0·2)
Diabetes mellitus	4 (0·5)	1 (0·2)	3 (0·7)	6 (0·2)	4 (0·2)	2 (0·1)
Chronic liver disease and cirrhosis	4 (0·5)	3 (0·7)	1 (0·2)	7 (0·2)	4 (0·2)	3 (0·2)
Intentional self-harm	1 (0·1)	1 (0·2)	0 (0·0)	15 (0·4)	8 (0·5)	7 (0·4)

Data are n (%).

(new) ***Table 5:*** **Observed deaths vs. expected deaths in a 7-day risk period (need footnotes to Abara paper)**

Commented [RH(32]: Note this is the 5th VAERS table (compared to 2 v-safe and 1 v-safe figure) and the 3rd table regarding death

	Expected		Observed (reported in VAERS)					
	All-cause death rates per million vaccinated persons		Both mRNA vaccines n (rate per vaccinated persons)		BNT162b2 vaccine n (rate per million doses administered)		mRNA-1273 vaccine n (rate per million doses administered)	
	Within 7 days of vaccination	Within 42 days of vaccination	Within 7 days of vaccination	Within 42 days of vaccination	Within 7 days of vaccination	Within 42 days of vaccination	Within 7 days of vaccination	Within 42 days of vaccination
Age (years)								
16–24**	14.2	85.1	14	26	9	17	5	9
25–34	25.5	152.7	32	56	18	31	14	25
35–44	37.4	224.5	54	97	28	47	26	50
45–54	77.0	461.7	118	200	55	91	63	109
55–64	169.8	1,018.6	247	453	99	201	148	252
65–74	343.2	2,059.4	457	878	207	385	250	493
75–84	857.2	5,143.0	412	908	180	396	232	512
≥85	2,601.4	15,608.3	437	980	202	448	235	532
Unknown	--	--	28	40	13	16	15	24
Total	165.6	993.3	1,799	3,638	811	1,632	988	2,006

*calculated from Abara paper per 10,000,000

**Abara paper is 15-24. Age 15 was not included in this paper

Need 42 day columns?

***Table* 5: Demographic characteristics of v-safe participants reporting receipt of mRNA COVID-19 vaccine and completing at least one health survey 0-7 days after vaccination—December 14, 2020–June 14, 2021**

Characteristics	Both mRNA vaccines (n = 7,914,583)	BNT162b2 vaccine		mRNA-1273 vaccine	
		Dose 1 n=3,455,778	Dose 2 n=2,920,526	Dose 1 n= 3,319,737	Dose 2 n=2,753,894
Sex					
Female	4,975,209 (62·9)	2,150,068 (62·2)	1,861,599 (63·7)	2,073,542 (62·5)	1,779,200 (64·6)
Male	2,860,738 (36·1)	1,272,011 (36·8)	1,032,941 (35·4)	1,210,622 (36·5)	947,612 (34·4)
Other	8,872 (0·1)	4,027 (0·1)	3,464 (0·1)	3,443 (0·1)	2,947 (0·1)
Unknown	69,764 (0·9)	29,672 (0·9)	22,522 (0·8)	32,130 (1·0)	24,135 (0·9)
Age (years)					
16–17	73,347 (0·9)	63,865 (1·8)	38,530 (1·3)	946 (0·03)	473 (0·02)
18–49	3,791,839 (47·9)	1,726,465 (50·0)	1,431,627 (49·0)	1,505,760 (45·4)	1,219,210 (44·3)
50–59	1,500,981 (19·0)	653,799 (18·9)	574,422 (19·7)	627,214 (18·9)	531,200 (19·3)
60–64	739,381 (9·3)	315,404 (9·1)	279,350 (9·6)	316,768 (9·5)	270,831 (9·8)
65–74	1,344,721 (17·0)	516,227 (14·9)	452,928 (15·5)	643,663 (19·4)	557,279 (20·2)
≥75	464,314 (5·9)	180,018 (5·2)	143,669 (4·9)	225,386 (6·8)	174,901 (6·4)
Race/Ethnicity					
Hispanic	782,301 (9·9)	346,197 (10·0)	288,263 (9·9)	316,460 (9·5)	256,185 (9·3)
Non-Hispanic					
White	4,701,715 (59·4)	2,059,560 (59·6)	1,896,823 (64·9)	1,979,056 (59·6)	1,830,413 (66·5)
Black	443,938 (5·6)	202,598 (5·9)	176,164 (6·0)	178,981 (5·4)	153,667 (5·6)
Asian	467,932 (5·9)	215,713 (6·2)	196,173 (6·7)	154,498 (4·7)	138,793 (5·0)
American Indian or Alaska Native	27,899 (0·4)	11,161 (0·3)	9,194 (0·3)	13,486 (0·4)	11,410 (0·4)
Native Hawaiian or Other Pacific Islander	19,393 (0·2)	8,500 (0·2)	7,373 (0·3)	7,689 (0·2)	6,664 (0·2)
Multiple races	110,326 (1·4)	50,954 (1·5)	46,129 (1·6)	41,977 (1·3)	38,772 (1·4)
Other races	42,230 (0·5)	19,252 (0·6)	16,757 (0·6)	15,885 (0·5)	13,880 (0·5)
Unknown race	23,420 (0·3)	10,249 (0·3)	9,090 (0·3)	9,502 (0·3)	8,270 (0·3)
Unknown ethnicity*					
White	115,766 (1·5)	48,084 (1·4)	38,674 (1·3)	52,143 (1·6)	42,070 (1·5)
Black	26,865 (0·3)	11,602 (0·3)	8,570 (0·3)	11,993 (0·4)	8,406 (0·3)
Asian	33,146 (0·4)	14,134 (0·4)	11,844 (0·4)	11,356 (0·3)	9,153 (0·3)
American Indian or Alaska Native	3,142 (0·04)	1,206 (0·03)	848 (0·03)	1,582 (0·05)	1,151 (0·04)
Native Hawaiian or Other Pacific Islander	1,945 (0·02)	815 (0·02)	659 (0·02)	800 (0·02)	613 (0·02)
Multiple races	6,370 (0·1)	2,902 (0·1)	2,408 (0·1)	2,478 (0·1)	2,041 (0·1)
Other races	13,148 (0·2)	5,681 (0·2)	4,528 (0·2)	5,414 (0·2)	4,263 (0·2)
Unknown race and ethnicity*	129,647 (1·6)	56,481 (1·6)	45,410 (1·6)	54,969 (1·7)	44,340 (1·6)
Unavailable†	965,400 (12·2)	390,689 (11·3)	161,619 (5·5)	461,468 (13·9)	183,803 (6·7)
Pregnant at time of vaccination	86,801 (1·1)	39,884 (1·2)	39,163 (1·3)	25,255 (0·8)	25,428 (0·9)
Pregnancy test positive after vaccination	27,370 (0·3)	1,548 (0·04)	11,677 (0·4)	4,009 (0·1)	10,199 (0·4)

Data are n (%).

*Unknown indicates that v-safe participants selected unknown or preferred not to say.
†Unavailable refers to information that was not collected or missing in v-safe.

***Table 6*: Reported local and systemic reactions*, and reported health impact following mRNA COVID-19 vaccines reported days 0–7 after vaccination to v-safe, by manufacturer and dose—December 14, 2020 – June 14, 2021**

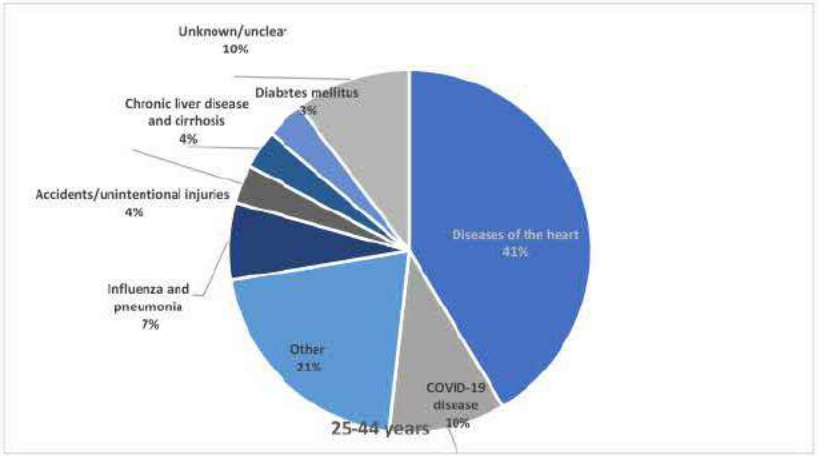
	Both mRNA vaccines		BNT162b2 vaccine		mRNA-1273 vaccine	
	Dose 1 (n=6,775,515)	Dose 2 (n=5,674,420)	Dose 1 (n=3,455,778)	Dose 2 (n=2,920,526)	Dose 1 (n=3,319,737)	Dose 2 (n=2,753,894)
Any injection site reaction	4,644,989 (68·6)	4,068,447 (71·7)	2,212,051 (64·0)	1,908,124 (65·3)	2,432,938 (73·3)	2,160,323 (78·4)
Injection site pain	4,488,402 (66·2)	3,890,848 (68·6)	2,140,843 (61·9)	1,835,398 (62·8)	2,347,559 (70·7)	2,055,450 (74·6)
Swelling	703,790 (10·4)	976,946 (17·2)	246,230 (7·1)	309,718 (10·6)	457,560 (13·8)	667,228 (24·2)
Redness	353,788 (5·2)	640,739 (11·3)	116,108 (3·4)	167,127 (5·7)	237,680 (7·2)	473,612 (17·2)
Itching	376,076 (5·6)	605,633 (10·7)	145,596 (4·2)	191,132 (6·5)	230,480 (6·9)	414,501 (15·1)
Any systemic reaction	3,573,429 (52·7)	4,018,920 (70·8)	1,771,509 (51·3)	1,931,643 (66·1)	1,801,920 (54·3)	2,087,277 (75·8)
Fatigue	2,295,205 (33·9)	3,158,299 (55·7)	1,127,904 (32·6)	1,475,646 (50·5)	1,167,301 (35·2)	1,682,653 (61·1)

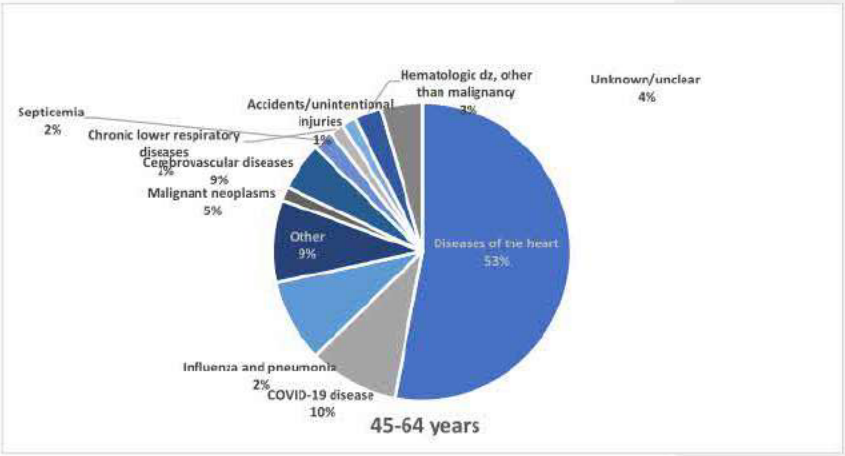
Headache	1,831,471 (27·0)	2,623,721 (46·2)	893,992 (25·9)	1,189,444 (40·7)	937,479 (28·2)	1,434,277 (52·1)
Myalgia	1,423,336 (21·0)	2,478,170 (43·7)	653,821 (18·9)	1,085,365 (37·2)	769,515 (23·2)	1,392,805 (50·6)
Chills	631,546 (9·3)	1,680,185 (29·6)	263,617 (7·6)	642,856 (22·0)	367,929 (11·1)	1,037,329 (37·7)
Fever	642,092 (9·5)	1,679,577 (29·6)	274,650 (7·9)	656,454 (22·5)	367,442 (11·1)	1,023,123 (37·2)
Joint pain	642,006 (9·5)	1,440,927 (25·4)	285,812 (8·3)	591,877 (20·3)	356,194 (10·7)	849,050 (30·8)
Nausea	562,273 (8·3)	901,103 (15·9)	267,160 (7·7)	384,525 (13·2)	295,113 (8·9)	516,578 (18·8)
Diarrhea	383,576 (5·7)	419,044 (7·4)	190,542 (5·5)	198,618 (6·8)	193,034 (5·8)	220,426 (8·0)
Abdominal pain	233,511 (3·4)	359,107 (6·3)	113,872 (3·3)	158,251 (5·4)	119,639 (3·6)	200,856 (7·3)
Rash	85,766 (1·3)	99,878 (1·8)	41,565 (1·2)	42,662 (1·5)	44,201 (1·3)	57,216 (2·1)
Vomiting	55,710 (0·8)	91,727 (1·6)	25,336 (0·7)	36,761 (1·3)	30,374 (0·9)	54,966 (2·0)
With reported health impact*	808,963 (11·9)	1,821,421 (32·1)	361,834 (10·5)	740,529 (25·4)	447,129 (13·5)	1,080,892 (39·2)
Unable to do normal activity	658,330 (9·7)	1,501,679 (26·5)	290,207 (8·4)	598,584 (20·5)	368,123 (11·1)	903,095 (32·8)
Unable to work	305,709 (4·5)	911,366 (16·1)	135,063 (3·9)	360,411 (12·3)	170,646 (5·1)	550,955 (20·0)
Reported medical care	56,647 (0·8)	53,077 (0·9)	27,358 (0·8)	25,568 (0·9)	29,289 (0·9)	27,509 (1·0)
Telehealth	19,562 (0·3)	19,770 (0·3)	9,318 (0·3)	9,238 (0·3)	10,244 (0·3)	10,532 (0·4)
Clinic	18,671 (0·3)	16,793 (0·3)	9,109 (0·3)	8,487 (0·3)	9,562 (0·3)	8,306 (0·3)
Emergency visit	9,907 (0·1)	8,907 (0·2)	5,087 (0·1)	4,494 (0·2)	4,820 (0·1)	4,413 (0·2)
Hospitalization	1,896 (0·03)	2,053 (0·04)	915 (0·03)	1,001 (0·03)	981 (0·03)	1,052 (0·04)

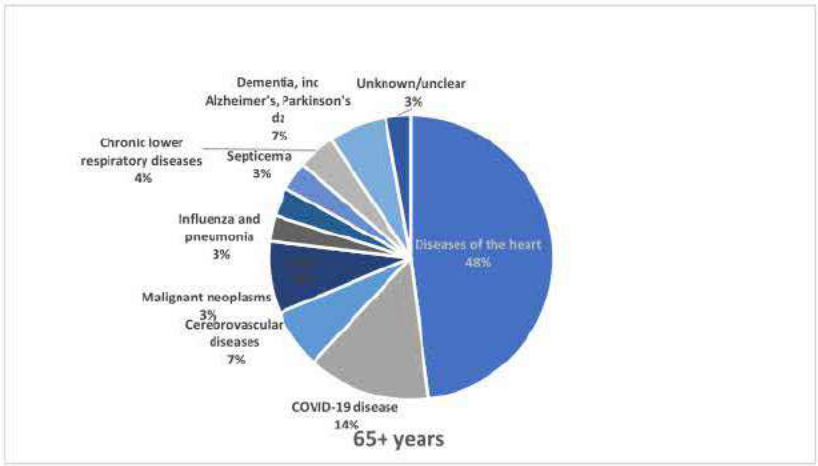
Data are n (%).
*Reports of local and systemic reactions, and reports of health impact are not mutually exclusive.

***Figure 1*: Percent distribution of the 10 leading causes of death, by age, among reported deaths with death certificate or autopsy to Vaccine Adverse Event Reporting System (VAERS) December 14, 2020–June 14, 2021 following mRNA vaccination**

Commented [RH(33]: make supplemental or delete? Data is captured in supplemental table 2







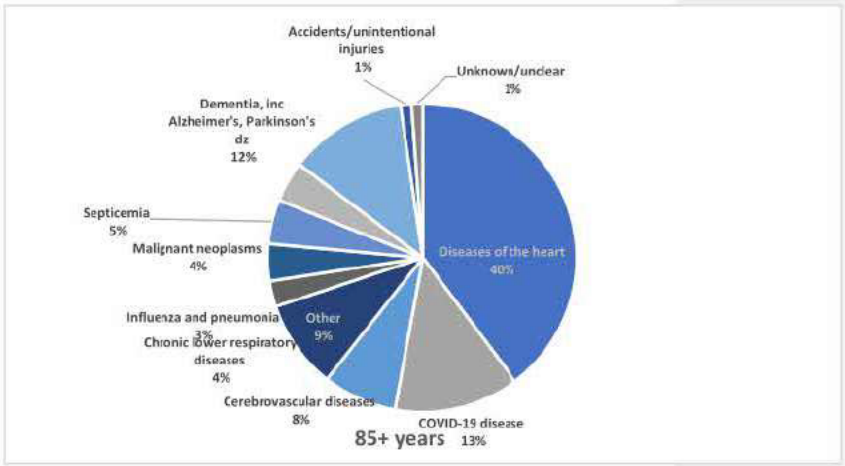
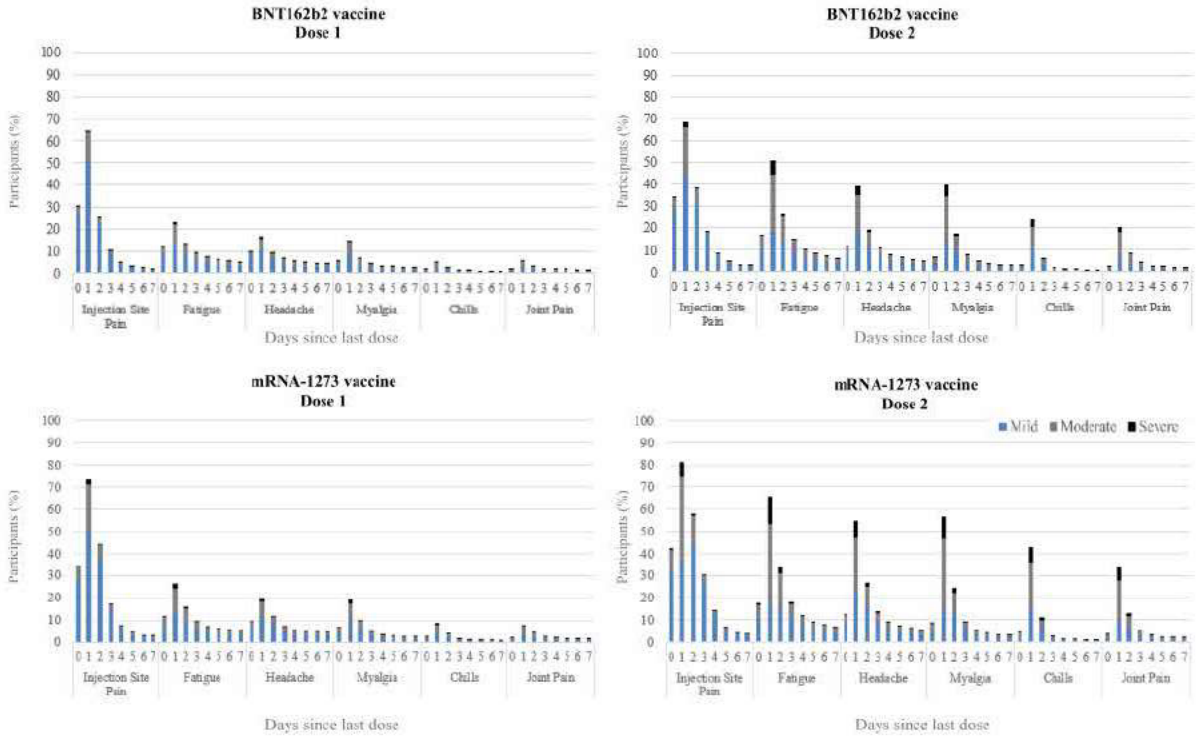


Figure 2: **Local and systemic reactions* to mRNA COVID-19 vaccine reported in v-safe, by manufacturer, dose, days after vaccination, and severity†**



*Top five reactions determined by reported frequency after second dose of both mRNA COVID-19 vaccines in v-safe, excluding fever because it was not rated mild, moderate, or severe.
†Mild was defined as "noticeable symptoms but they aren't a problem", moderate was defined as "symptoms that limit normal activities, and severe symptoms "make normal daily activities difficult or impossible"

***Supplemental Table* 1: mRNA COVID-19 vaccine doses administered in the United States—December 14, 2020–June 14, 2021**

Characteristics	Both mRNA vaccines† (n=298,792,852)	BNT162b2 vaccine† (n=167,177,332)	mRNA-1273 vaccine† (n=131,639,515)
Sex			
Female	155,969,573 (53·2)	86,507,992 (53·5)	69,461,582 (52·8)
Male	134,373,958 (45·8)	73,768,602 (45·6)	60,605,356 (46·1)
Unknown	2,868,979 (1·0)	1,452,344 (0·9)	1,416,634 (1·1)
Age (years)			
16–17*	5,506,763 (1·8)	5,365,855 (3·2)	140,908 (0·1)
18–49	126,288,626 (42·3)	74,999,327 (44·9)	51,289,299 (39·0)
50–64	79,207,752 (26·5)	43,595,972 (26·1)	35,611,780 (27·1)
65–74	51,699,307 (17·3)	25,402,217 (15·2)	26,297,090 (20·0)
75–84	27,731,181 (9·3)	13,555,128 (8·1)	14,176,053 (10·8)
≥85	8,359,223 (2·8)	4,248,648 (2·5)	4,110,575 (3·1)
Unknown	23,995 (0·01)	10,185 (0·01)	13,810 (0·01)
Race/Ethnicity			
Hispanic	31,599,632 (10·8)	17,964,345 (11·1)	13,635,287 (10·4)
Non-Hispanic			
White	112,698,875 (38·4)	61,996,607 (38·3)	50,702,268 (38·6)
Asian	11,789,429 (4·0)	7,258,033 (4·5)	4,531,396 (3·4)
Black	16,848,436 (5·7)	9,665,586 (6·0)	7,182,849 (5·5)
American Indian or Alaska Native	1,738,938 (0·6)	842,263 (0·5)	896,674 (0·7)
Native Hawaiian or Other Pacific Islander	508,285 (0·2)	295,634 (0·2)	212,651 (0·2)
Multiple races	8,856,800 (3·0)	5,037,828 (3·1)	3,818,972 (2·9)
Other races	6,949,404 (2·4)	4,161,353 (2·6)	2,788,051 (2·1)
Unknown race and ethnicity	102,227,532 (34·9)	54,511,493 (33·7)	47,716,039 (36·3)

Data are n (%).
*mRNA-1273 vaccine was not authorized for individuals <18 years during this period, reported mRNA-1273 doses are either from clinical trials or were administered or reported in error
†Totals reflect the number of doses in age categories. Missing doses for sex and race/ethnicity are due to certain jurisdictions that report data in aggregate.

***Supplemental Table* 2: Causes of death among reported deaths to Vaccine Adverse Event Reporting System (VAERS) December 14, 2020–June 14, 2021 following mRNA vaccination, by age**

Reports of death with death cert or autopsy ICD-10 Major Group All	All 808	16-24 n=4		25-34 n=5		35-44 n=24		45-54 n=37		55-64 n=101		65-74 n=171		75-84 n=202		85+ n=264	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Diseases of the heart	376	1	25.0	2	40.0	10	41.7	21	56.8	50	49.5	98	57.3	91	45.0	103	39.0
COVID-19 disease	102	1	25.0	1	20.0	2	8.3	2	5.4	11	10.9	19	11.1	32	15.8	34	12.9
Cerebrovascular diseases	53	0	0	0	0	0	0	4	10.8	8	7.9	8	4.7	13	6.4	20	7.6
Other	68	0	0	1	20.0	5	20.8	2	5.4	10	9.9	11	6.4	15	7.4	24	9.1
Influenza and pneumonia	22	0	0	0	0	2	8.3	0	0	2	2.0	4	2.3	7	3.5	7	2.7
Malignant neoplasms	27	0	0	0	0	0	0	2	5.4	5	5.0	2	1.2	8	4.0	10	3.8
Septicemia	23	0	0	0	0	0	0	1	2.7	2	2.0	2	1.2	6	3.0	12	4.5
Chronic lower respiratory diseases	28	0	0	0	0	0	0	0	0	2	2.0	11	6.4	4	2.0	11	4.2
Dementia, inc Alzheimer's, Parkinson's dz	41	0	0	0	0	0	0	0	0	1	1.0	1	0.6	7	3.5	32	12.1
Accidents/unintentional injuries	11	0	0	0	0	1	4.2	0	0	2	2.0	2	1.2	3	1.5	3	1.1
Renal dz, incl nephritis and chronic dz	8	0	0	0	0	0	0	1	2.7	0	0	3	1.8	3	1.5	1	0.4
Hematologic dz, other than malignancy	7	0	0	0	0	0	0	1	2.7	3	3.0	0	0	1	0.5	2	0.8
Intentional self-harm	1	1	25.0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pneumonitis due to solids and liquids	6	0	0	0	0	0	0	0	0	1	1.0	0	0	3	1.5	2	0.8
Chronic liver disease and cirrhosis	4	0	0	1	20.0	0	0	0	0	1	1.0	1	0.6	1	0.5	0	0
Diabetes mellitus	4	0	0	0	0	1	4.2	0	0	0	0	2	1.2	1	0.5	0	0
Unknown/unclear	27	1	25.0	0	0	3	12.5	3	8.1	3	3.0	7	4.1	7	3.5	3	1.1

***Supplemental Table 3*: Causes and impressions of death among reported deaths to Vaccine Adverse Event Reporting System (VAERS) December 14, 2020–June 14, 2021 following mRNA vaccination**

Commented [RH(34]: Combine 16-24 and 25-34? n=9

ICD-10 Major Group and impression	All reports of death	Reported deaths with death certificate or autopsy
All reported deaths, n	4,472	808
Diseases of the heart	998 (22.3)	376 (46.5)
Aortic dissection, aneurysm or aortitis	13 (0.3)	7 (0.9)
Arrhythmia	42 (0.9)	18 (2.2)
Atherosclerotic cardiovascular or hypertensive cardiovascular disease	129 (2.9)	98 (12.1)
Cardiac arrest	321 (7.2)	79 (9.8)
Cardiomyopathy or hypertrophy	17 (0.4)	12 (1.5)
Heart failure	104 (2.3)	47 (5.8)
Myocardial infarction	247 (5.5)	87 (10.8)
Myocarditis	4 (0.1)	0 (0.0)
Pulmonary embolism	84 (1.9)	17 (2.1)
Other cardiac cause	37 (0.8)	11 (1.4)
COVID-19 disease	419 (9.4)	102 (12.6)
Cerebrovascular diseases	260 (5.8)	53 (6.6)
Other	209 (4.7)	68 (8.4)
Disseminated herpes zoster	2 (0.04)	1 (0.1)
Drug overdose/intoxication	7 (0.2)	5 (0.6)
Failure to thrive	9 (0.2)	9 (1.1)
Gastrointestinal[*]	36 (0.8)	8 (1.0)
Hemorrhage/Hemorrhagic shock	4 (0.1)	2 (0.2)
Metabolic derangement	4 (0.1)	1 (0.1)
Multiorgan failure	28 (0.6)	7 (0.9)
Natural	2 (0.04)	2 (0.2)
Neurologic[†]	28 (0.6)	6 (0.7)
Obesity	2 (0.04)	2 (0.2)
Respiratory failure	63 (1.4)	22 (2.7)
Vaccine related[‡]	4 (0.1)	3 (0.4)
Influenza and pneumonia	135 (3.0)	22 (2.7)
Malignant neoplasms	95 (2.1)	27 (3.3)
Septicemia	95 (2.1)	23 (2.8)
Chronic lower respiratory diseases	57 (1.3)	28 (3.5)
Dementia	50 (1.1)	41 (5.1)
Accidents/unintentional injuries	33 (0.7)	11 (1.4)
Renal disease	33 (0.7)	8 (1.0)
Hematologic disease, other than malignancy	26 (0.6)	7 (0.9)
Intentional self-harm	16 (0.4)	1 (0.1)
Pneumonitis due to solids and liquids	14 (0.3)	6 (0.7)
Chronic liver disease and cirrhosis	11 (0.2)	4 (0.5)
Diabetes mellitus	10 (0.2)	4 (0.5)
Unknown/unclear	2,011 (45.0)	27 (3.3)

[†]Data are n (%) unless otherwise stated.
[*]Gastrointestinal includes gastrointestinal bleeding, bowel obstruction/perforation, mesenteric ischemia, pancreatitis.
[†]Neurologic includes amyotrophic lateral sclerosis, encephalopathy, hydrocephalus, Guillain-Barré syndrome, seizure.
[‡]Vaccine related includes systemic inflammatory response syndrome from vaccine reaction, anaphylaxis post-COVID-19 vaccination

***Supplemental Table* 4: Local and systemic reactions* 0–7 days after vaccination by sex, age, and dose number, reported in v-safe—December 14, 2020–June 14, 2021**

	Female		Male		<65 years		≥65 years	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
	(n=4,223,610)	(n=3,640,799)	(n=2,482,633)	(n=1,980,553)	(n=5,210,221)	(n=4,345,643)	(n=1,565,294)	(n=1,328,777)
Any injection site reaction	3,095,194 (73·3)	2,792,488 (76·7)	1,498,108 (60·3)	1,235,278 (62·4)	3,835,618 (73·6)	3,290,266 (75·7)	809,371 (51·7)	778,241 (58·6)
Injection site pain	2,989,733 (70·8)	2,666,734 (73·3)	1,448,440 (58·3)	1,184,914 (59·8)	3,728,795 (71·6)	3,179,024 (73·2)	759,607 (48·5)	711,824 (53·6)
Swelling	539,793 (12·8)	771,962 (21·2)	154,980 (6·2)	194,033 (9·8)	604,868 (11·6)	812,126 (18·7)	98,922 (6·3)	164,820 (12·4)
Redness	283,345 (6·7)	529,175 (14·5)	66,134 (2·7)	104,933 (5·3)	295,413 (5·7)	512,516 (11·8)	58,375 (3·7)	128,223 (9·6)
Itching	299,407 (7·1)	504,016 (13·8)	72,095 (2·9)	95,356 (4·8)	309,607 (5·9)	466,319 (10·7)	66,469 (4·2)	139,314 (10·5)
Any systemic reaction	2,444,362 (57·9)	2,752,592 (75·6)	1,088,296 (43·8)	1,226,561 (61·9)	2,972,931 (57·1)	3,237,621 (74·5)	600,498 (38·4)	781,299 (58·8)
Fatigue	1,624,531 (38·5)	2,221,361 (61·0)	643,206 (25·9)	904,556 (45·7)	1,941,979 (37·3)	2,588,541 (59·6)	353,226 (22·6)	569,758 (42·9)
Headache	1,349,155 (31·9)	1,906,337 (52·4)	460,786 (18·6)	690,138 (34·8)	1,595,091 (30·6)	2,226,046 (51·2)	236,380 (15·1)	397,675 (29·9)
Myalgia	954,469 (22·6)	1,724,474 (47·4)	450,562 (18·1)	726,994 (36·7)	1,219,190 (23·4)	2,085,722 (48·0)	204,146 (13·0)	392,448 (29·5)
Chills	451,583 (10·7)	1,202,364 (33·0)	172,283 (6·9)	459,577 (23·2)	542,285 (10·4)	1,426,710 (32·8)	89,261 (5·7)	253,475 (19·1)
Fever	446,178 (10·6)	1,182,201 (32·5)	187,713 (7·6)	478,912 (24·2)	565,804 (10·9)	1,449,504 (33·4)	76,288 (4·9)	230,073 (17·3)
Joint pain	444,630 (10·5)	1,023,525 (28·1)	188,846 (7·6)	400,963 (20·2)	539,196 (10·3)	1,214,624 (28·0)	102,810 (6·6)	226,303 (17·0)
Nausea	447,766 (10·6)	728,730 (20·0)	106,872 (4·3)	161,455 (8·2)	500,782 (9·6)	794,450 (18·3)	61,491 (3·9)	106,653 (8·0)
Diarrhea	272,890 (6·5)	313,252 (8·6)	106,079 (4·3)	101,107 (5·1)	323,773 (6·2)	352,077 (8·1)	59,803 (3·8)	66,967 (5·0)
Abdominal pain	179,210 (4·2)	283,422 (7·8)	50,991 (2·1)	71,115 (3·6)	203,575 (3·9)	316,165 (7·3)	29,936 (1·9)	42,942 (3·2)
Rash	65,498 (1·6)	79,092 (2·2)	19,193 (0·8)	19,735 (1·0)	70,985 (1·4)	79,913 (1·8)	14,781 (0·9)	19,965 (1·5)
Vomiting	43,998 (1·0)	75,650 (2·1)	10,936 (0·4)	14,915 (0·8)	49,483 (0·9)	81,733 (1·9)	6,227 (0·4)	9,994 (0·8)

Data are n (%).
*Reports of local and systemic reactions are not mutually exclusive.

***Supplemental Table* 5: Most common local and systemic reactions* to mRNA COVID-19 vaccine reported in v-safe, by dose and severity,† 0-7 days after vaccination with BNT162b2 vaccine**

		Dose 1				Dose 2			
	Day	All, n	Severe	Moderate	Mild	All, n	Severe	Moderate	Mild
Injection site pain	0	2,272,335	2,533 (0·1)	80,358 (3·5)	599,511 (26·4)	1,766,510	4,359 (0·2)	94,156 (5·3)	503,779 (28·5)
	1	2,545,271	18,827 (0·7)	334,755 (13·2)	1,289,293 (50·7)	2,027,330	48,810 (2·4)	453,726 (22·4)	885,434 (43·7)
	2	2,545,434	4,356 (0·2)	62,838 (2·5)	565,455 (22·2)	2,116,614	10,391 (0·5)	126,741 (6·0)	680,408 (32·1)
	3	2,507,344	2,119 (0·1)	26,602 (1·1)	216,785 (8·6)	2,067,908	3,332 (0·2)	43,037 (2·1)	336,222 (16·3)
	4	2,436,977	1,420 (0·1)	16,710 (0·7)	102,077 (4·2)	2,028,926	1,820 (0·1)	20,548 (1·0)	149,408 (7·4)
	5	2,332,032	1,138 (0·05)	11,965 (0·5)	60,401 (2·6)	2,000,426	1,272 (0·1)	12,719 (0·6)	73,486 (3·7)
	6	2,249,409	909 (0·04)	8,901 (0·4)	40,597 (1·8)	2,000,472	1,106 (0·1)	11,008 (0·6)	46,707 (2·3)
	7	2,198,611	768 (0·03)	7,783 (0·4)	32,967 (1·5)	2,067,201	1,557 (0·1)	14,150 (0·7)	44,322 (2·1)
Fatigue	0	2,272,335	7,280 (0·3)	79,232 (3·5)	193,192 (8·5)	1,766,510	11,293 (0·6)	98,802 (5·6)	185,051 (10·5)
	1	2,545,271	35,734 (1·4)	229,606 (9·0)	326,015 (12·8)	2,027,330	135,581 (6·7)	523,998 (25·8)	373,601 (18·4)
	2	2,545,434	16,936 (0·7)	114,562 (4·5)	211,046 (8·3)	2,116,614	39,668 (1·9)	217,269 (10·3)	308,126 (14·6)
	3	2,507,344	10,636 (0·4)	74,341 (3·0)	145,114 (5·8)	2,067,908	15,361 (0·7)	104,673 (5·1)	193,174 (9·3)
	4	2,436,977	8,275 (0·3)	58,170 (2·4)	109,266 (4·5)	2,028,926	10,280 (0·5)	69,886 (3·4)	133,603 (6·6)
	5	2,332,032	7,062 (0·3)	49,739 (2·1)	88,721 (3·8)	2,000,426	8,089 (0·4)	55,840 (2·8)	103,919 (5·2)
	6	2,249,409	6,428 (0·3)	44,044 (2·0)	76,633 (3·4)	2,000,472	7,200 (0·4)	48,388 (2·4)	86,907 (4·3)
	7	2,198,611	6,027 (0·3)	40,428 (1·8)	67,168 (3·1)	2,067,201	7,528 (0·4)	46,669 (2·3)	78,361 (3·8)
Headache	0	2,272,335	3,394 (0·1)	42,501 (1·9)	167,985 (7·4)	1,766,510	5,217 (0·3)	52,759 (3·0)	144,892 (8·2)
	1	2,545,271	20,011 (0·8)	129,629 (5·1)	265,970 (10·4)	2,027,330	82,393 (4·1)	333,605 (16·5)	381,368 (18·8)
	2	2,545,434	10,458 (0·4)	69,347 (2·7)	162,658 (6·4)	2,116,614	24,063 (1·1)	134,054 (6·3)	249,895 (11·8)
	3	2,507,344	6,670 (0·3)	46,850 (1·9)	110,115 (4·4)	2,067,908	10,356 (0·5)	68,461 (3·3)	148,990 (7·2)
	4	2,436,977	5,552 (0·2)	38,319 (1·6)	85,635 (3·5)	2,028,926	7,238 (0·4)	47,550 (2·3)	103,204 (5·1)
	5	2,332,032	4,911 (0·2)	34,379 (1·5)	72,831 (3·1)	2,000,426	6,154 (0·3)	40,322 (2·0)	82,191 (4·1)
	6	2,249,409	4,733 (0·2)	31,540 (1·4)	64,890 (2·9)	2,000,472	5,467 (0·3)	35,177 (1·8)	69,168 (3·5)
	7	2,198,611	4,381 (0·2)	29,475 (1·3)	58,752 (2·7)	2,067,201	5,372 (0·3)	34,057 (1·6)	63,628 (3·1)
Myalgia	0	2,272,335	1,999 (0·1)	29,601 (1·3)	96,095 (4·2)	1,766,510	4,001 (0·2)	38,960 (2·2)	75,790 (4·3)
	1	2,545,271	18,440 (0·7)	136,939 (5·4)	219,125 (8·6)	2,027,330	101,801 (5·0)	408,637 (20·2)	293,241 (14·5)
	2	2,545,434	7,441 (0·3)	56,954 (2·2)	112,788 (4·4)	2,116,614	23,521 (1·1)	140,700 (6·6)	209,074 (9·9)
	3	2,507,344	4,200 (0·2)	33,605 (1·3)	65,696 (2·6)	2,067,908	6,925 (0·3)	54,206 (2·6)	100,982 (4·9)
	4	2,436,977	3,255 (0·1)	25,814 (1·1)	46,369 (1·9)	2,028,926	4,146 (0·2)	32,786 (1·6)	60,489 (3·0)
	5	2,332,032	2,831 (0·1)	22,598 (1·0)	37,598 (1·6)	2,000,426	3,239 (0·2)	25,326 (1·3)	44,242 (2·2)
	6	2,249,409	2,543 (0·1)	20,904 (0·9)	33,016 (1·5)	2,000,472	2,973 (0·1)	22,422 (1·1)	36,522 (1·8)
	7	2,198,611	2,504 (0·1)	19,474 (0·9)	30,222 (1·4)	2,067,201	3,379 (0·2)	23,046 (1·1)	33,563 (1·6)
Chills	0	2,272,335	879 (0·04)	8,246 (0·4)	34,000 (1·5)	1,766,510	2,091 (0·1)	14,428 (0·8)	38,195 (2·2)
	1	2,545,271	8,558 (0·3)	45,518 (1·8)	78,033 (3·1)	2,027,330	62,884 (3·1)	210,579 (10·4)	207,218 (10·2)
	2	2,545,434	3,371 (0·1)	18,059 (0·7)	36,412 (1·4)	2,116,614	11,744 (0·6)	51,490 (2·4)	76,276 (3·6)
	3	2,507,344	1,462 (0·1)	9,241 (0·4)	19,569 (0·8)	2,067,908	2,582 (0·1)	13,423 (0·6)	25,421 (1·2)
	4	2,436,977	1,051 (0·04)	6,915 (0·3)	13,967 (0·6)	2,028,926	1,336 (0·1)	7,424 (0·4)	14,223 (0·7)
	5	2,332,032	863 (0·04)	5,531 (0·2)	11,284 (0·5)	2,000,426	955 (0·05)	5,423 (0·3)	10,583 (0·5)
	6	2,249,409	779 (0·03)	5,048 (0·2)	9,932 (0·4)	2,000,472	851 (0·04)	4,763 (0·2)	9,029 (0·5)
	7	2,198,611	752 (0·03)	4,645 (0·2)	8,889 (0·4)	2,067,201	1,222 (0·1)	5,515 (0·3)	9,039 (0·4)
Joint pain	0	2,272,335	1,069 (0·05)	11,375 (0·5)	24,689 (1·1)	1,766,510	2,396 (0·1)	18,677 (1·1)	25,699 (1·5)
	1	2,545,271	9,676 (0·4)	61,691 (2·4)	69,532 (2·7)	2,027,330	55,446 (2·7)	225,949 (11·2)	137,601 (6·8)
	2	2,545,434	4,608 (0·2)	31,238 (1·2)	44,072 (1·7)	2,116,614	14,386 (0·7)	80,490 (3·8)	90,461 (4·3)
	3	2,507,344	2,675 (0·1)	19,912 (0·8)	29,313 (1·2)	2,067,908	4,624 (0·2)	32,971 (1·6)	46,467 (2·2)
	4	2,436,977	2,165 (0·1)	15,923 (0·7)	22,386 (0·9)	2,028,926	2,882 (0·1)	20,861 (1·0)	29,916 (1·5)
	5	2,332,032	1,999 (0·1)	13,922 (0·6)	18,869 (0·8)	2,000,426	2,341 (0·1)	16,528 (0·8)	23,366 (1·2)
	6	2,249,409	1,773 (0·1)	13,018 (0·6)	16,874 (0·8)	2,000,472	2,138 (0·1)	15,046 (0·8)	19,649 (1·0)
	7	2,198,611	1,686 (0·1)	12,245 (0·6)	15,605 (0·7)	2,067,201	2,462 (0·1)	15,782 (0·8)	18,678 (0·9)

Data are n (%) unless otherwise stated.

*Top five reactions determined by reported frequency after second dose of both mRNA COVID-19 vaccines in v-safe, excluding fever because it was not rated mild/moderate/severe. Symptoms are not mutually exclusive. †Mild was defined as "noticeable symptoms but they aren't a problem", moderate was defined as "symptoms that limit normal activities, and severe symptoms", and severe symptoms "make normal daily activities difficult or impossible".

***Supplemental Table* 6: Most common local and systemic reactions* to mRNA COVID-19 vaccine reported in v-safe, by dose and severity,† 0-7 days after vaccination with mRNA-1273 vaccine**

		Dose 1				Dose 2			
	Day	All, n	Severe	Moderate	Mild	All, n	Severe	Moderate	Mild
Injection site pain	0	2,112,380	4,971 (0·2)	113,992 (5·4)	595,108 (28·2)	1,656,723	11,174 (0·7)	155,045 (9·4)	535,260 (32·3)
	1	2,424,231	49,225 (2·0)	512,076 (21·1)	1,214,808 (50·1)	1,937,029	131,379 (6·8)	735,284 (38·0)	713,164 (36·8)
	2	2,474,399	13,723 (0·6)	152,289 (6·2)	932,770 (37·7)	2,035,773	26,351 (1·3)	268,371 (13·2)	890,618 (43·7)
	3	2,459,431	4,778 (0·2)	47,625 (1·9)	370,863 (15·1)	1,993,354	6,469 (0·3)	78,053 (3·9)	525,158 (26·3)
	4	2,390,709	2,881 (0·1)	25,370 (1·1)	148,288 (6·2)	1,960,829	3,393 (0·2)	33,315 (1·7)	239,358 (12·2)
	5	2,285,185	2,087 (0·1)	17,079 (0·7)	77,452 (3·4)	1,939,300	2,493 (0·1)	19,783 (1·0)	109,652 (5·7)
	6	2,196,757	1,512 (0·1)	12,520 (0·6)	50,245 (2·3)	1,949,754	2,496 (0·1)	18,002 (0·9)	61,677 (3·2)
	7	2,157,101	1,595 (0·1)	13,301 (0·6)	45,669 (2·1)	2,019,370	3,443 (0·2)	22,300 (1·1)	49,711 (2·5)
Fatigue	0	2,112,380	7,221 (0·3)	74,690 (3·5)	170,757 (8·1)	1,656,723	13,938 (0·8)	104,699 (6·3)	173,749 (10·5)
	1	2,424,231	54,659 (2·3)	275,510 (11·4)	315,454 (13·0)	1,937,029	240,342 (12·4)	706,424 (36·5)	330,245 (17·0)
	2	2,474,399	23,894 (1·0)	143,988 (5·8)	228,253 (9·2)	2,035,773	60,995 (3·0)	292,539 (14·4)	337,135 (16·6)
	3	2,459,431	11,711 (0·5)	78,023 (3·2)	147,930 (6·0)	1,993,354	19,031 (1·0)	126,765 (6·4)	213,889 (10·7)
	4	2,390,709	8,430 (0·4)	57,900 (2·4)	107,495 (4·5)	1,960,829	11,806 (0·6)	80,578 (4·1)	146,796 (7·5)
	5	2,285,185	7,252 (0·3)	48,602 (2·1)	86,144 (3·8)	1,939,300	9,238 (0·5)	61,449 (3·2)	110,778 (5·7)
	6	2,196,757	6,486 (0·3)	43,439 (2·0)	73,380 (3·3)	1,949,754	8,051 (0·4)	52,161 (2·7)	91,466 (4·7)
	7	2,157,101	6,309 (0·3)	41,022 (1·9)	65,817 (3·1)	2,019,370	8,702 (0·4)	50,008 (2·5)	86,798 (4·0)
Headache	0	2,112,380	3,475 (0·2)	40,930 (1·9)	153,086 (7·2)	1,656,723	6,812 (0·4)	58,638 (3·5)	143,161 (8·6)
	1	2,424,231	33,272 (1·4)	164,590 (6·8)	273,687 (11·3)	1,937,029	154,933 (8·0)	497,171 (25·7)	411,266 (21·2)
	2	2,474,399	15,614 (0·6)	91,066 (3·7)	186,713 (7·5)	2,035,773	39,797 (2·0)	195,074 (9·6)	311,816 (15·3)
	3	2,459,431	7,782 (0·3)	50,386 (2·0)	114,639 (4·7)	1,993,354	13,752 (0·7)	85,153 (4·3)	177,740 (8·9)
	4	2,390,709	5,818 (0·2)	38,567 (1·6)	86,140 (3·6)	1,960,829	8,903 (0·5)	56,974 (2·9)	120,773 (6·2)
	5	2,285,185	5,316 (0·2)	34,399 (1·5)	72,082 (3·2)	1,939,300	7,429 (0·4)	46,575 (2·4)	93,323 (4·8)
	6	2,196,757	4,732 (0·2)	31,891 (1·5)	63,922 (2·9)	1,949,754	6,576 (0·3)	40,092 (2·1)	77,243 (4·0)
	7	2,157,101	4,585 (0·2)	30,705 (1·4)	59,396 (2·8)	2,019,370	6,705 (0·3)	37,634 (1·9)	68,333 (3·4)
Myalgia	0	2,112,380	3,011 (0·1)	35,724 (1·7)	95,048 (4·5)	1,656,723	7,757 (0·5)	54,566 (3·3)	82,160 (5·0)
	1	2,424,231	38,950 (1·6)	197,871 (8·2)	226,700 (9·4)	1,937,029	198,988 (10·3)	610,812 (31·5)	292,422 (15·1)
	2	2,474,399	13,531 (0·5)	86,102 (3·5)	150,896 (6·1)	2,035,773	39,990 (2·0)	203,682 (10·0)	251,594 (12·4)
	3	2,459,431	5,264 (0·2)	38,086 (1·6)	74,647 (3·0)	1,993,354	9,143 (0·5)	65,042 (3·3)	114,111 (5·7)
	4	2,390,709	3,627 (0·2)	26,656 (1·1)	47,845 (2·0)	1,960,829	5,041 (0·3)	36,805 (1·9)	65,072 (3·3)
	5	2,285,185	2,989 (0·1)	22,955 (1·0)	37,471 (1·6)	1,939,300	3,796 (0·2)	27,445 (1·4)	45,771 (2·4)
	6	2,196,757	2,667 (0·1)	21,040 (1·0)	33,060 (1·5)	1,949,754	3,592 (0·2)	24,073 (1·2)	37,073 (1·9)
	7	2,157,101	2,731 (0·1)	20,799 (1·0)	31,659 (1·5)	2,019,370	4,415 (0·2)	25,026 (1·2)	33,652 (1·7)
Chills	0	2,112,380	1,395 (0·1)	10,125 (0·5)	35,178 (1·7)	1,656,723	4,685 (0·3)	23,091 (1·4)	45,194 (2·7)
	1	2,424,231	23,553 (1·0)	84,997 (3·5)	101,682 (4·2)	1,937,029	137,685 (7·1)	402,336 (20·8)	291,400 (15·0)
	2	2,474,399	7,601 (0·3)	33,238 (1·3)	52,246 (2·1)	2,035,773	23,939 (1·2)	90,569 (4·5)	113,067 (5·6)
	3	2,459,431	2,358 (0·1)	11,569 (0·5)	21,723 (0·9)	1,993,354	4,164 (0·2)	18,349 (0·9)	31,919 (1·6)
	4	2,390,709	1,374 (0·1)	7,398 (0·3)	14,470 (0·6)	1,960,829	2,100 (0·1)	9,271 (0·5)	16,372 (0·8)
	5	2,285,185	1,022 (0·04)	5,986 (0·3)	11,645 (0·5)	1,939,300	1,547 (0·1)	6,581 (0·3)	11,521 (0·6)
	6	2,196,757	838 (0·04)	5,231 (0·2)	10,167 (0·5)	1,949,754	1,500 (0·1)	6,158 (0·3)	9,622 (0·5)
	7	2,157,101	891 (0·04)	5,094 (0·2)	9,317 (0·4)	2,019,370	2,376 (0·1)	7,405 (0·4)	9,915 (0·5)
Joint pain	0	2,112,380	1,448 (0·1)	13,228 (0·6)	24,666 (1·2)	1,656,723	4,387 (0·3)	26,725 (1·6)	29,864 (1·8)
	1	2,424,231	20,384 (0·8)	92,808 (3·8)	79,034 (3·3)	1,937,029	115,152 (5·9)	375,004 (19·4)	163,832 (8·5)
	2	2,474,399	8,102 (0·3)	46,926 (1·9)	57,163 (2·3)	2,035,773	25,592 (1·3)	123,386 (6·1)	116,891 (5·7)
	3	2,459,431	3,509 (0·1)	23,226 (0·9)	33,006 (1·3)	1,993,354	6,277 (0·3)	41,550 (2·1)	55,855 (2·8)
	4	2,390,709	2,400 (0·1)	16,852 (0·7)	23,553 (1·0)	1,960,829	3,601 (0·2)	24,570 (1·3)	34,118 (1·7)
	5	2,285,185	2,010 (0·1)	14,447 (0·6)	19,143 (0·8)	1,939,300	2,831 (0·1)	18,829 (1·0)	25,132 (1·3)
	6	2,196,757	1,821 (0·1)	13,250 (0·6)	16,821 (0·8)	1,949,754	2,582 (0·1)	16,587 (0·9)	21,152 (1·1)
	7	2,157,101	1,874 (0·1)	13,157 (0·6)	16,230 (0·8)	2,019,370	3,240 (0·2)	17,390 (0·9)	19,800 (1·0)

Data are n (%) unless otherwise stated.

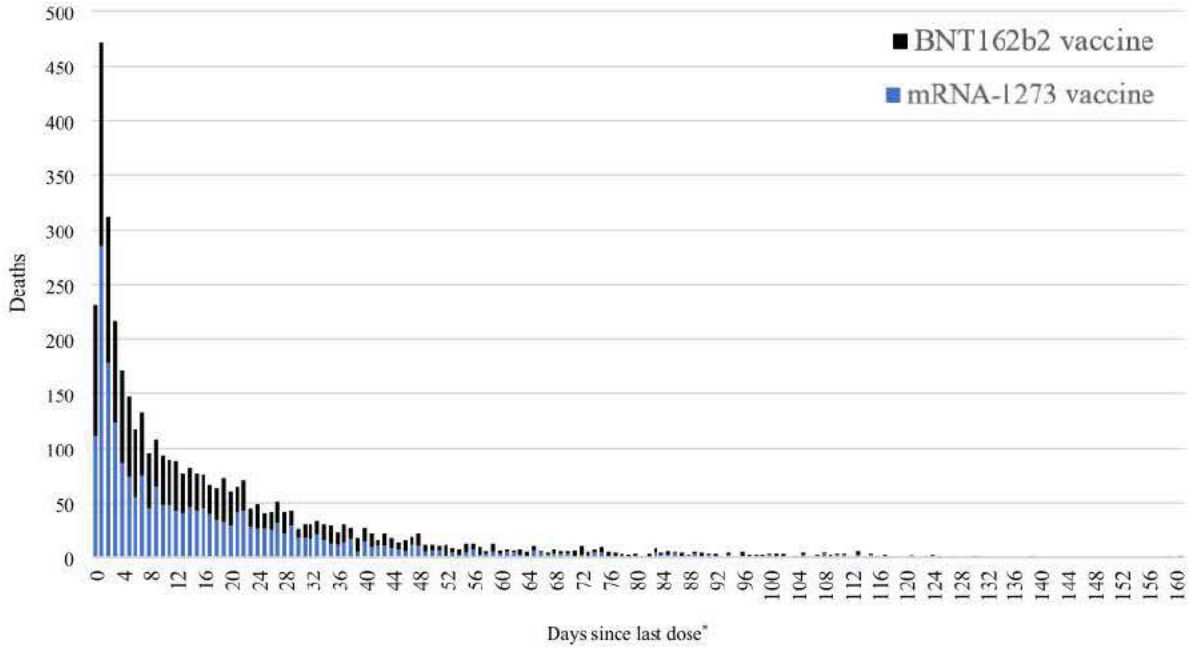
*Top five reactions determined by reported frequency after second dose of both mRNA COVID-19 vaccines in v-safe, excluding fever because it was not rated mild/moderate/severe. Symptoms are not mutually exclusive. †Mild was defined as "noticeable symptoms but they aren't a problem", moderate was defined as "symptoms that limit normal activities, and severe symptoms", and severe symptoms "make normal daily activities difficult or impossible".

***Supplemental Table* 7: Reported health impact* 0-7 days after vaccination by mRNA COVID-19 vaccine manufacturer, dose, and sex reported in v-safe—December 14, 2020–June 14, 2021**

	BNT162b2 vaccine						mRNA-1273 vaccine					
	Dose 1 (n=3,455,778)			Dose 2 (n=2,920,526)			Dose 1 (n=3,319,737)			Dose 2 (n=2,753,894)		
Sex/day	Unable to do normal activity	Unable to work	Reported medical care	Unable to do normal activity	Unable to work	Reported medical care	Unable to do normal activity	Unable to work	Reported medical care	Unable to do normal activity	Unable to work	Reported medical care
Female												
Day 0	29,039 (2·1)	11,480 (0·8)	2,486 (0·2)	38,593 (3·5)	18,411 (1·7)	1,567 (0·1)	30,334 (2·4)	10,888 (0·8)	2,099 (0·2)	48,485 (4·6)	22,274 (2·1)	1,471 (0·1)
Day 1	105,123 (6·6)	41,398 (2·6)	2,810 (0·2)	324,559 (24·9)	178,817 (13·7)	3,276 (0·3)	151,710 (10·0)	60,161 (4·0)	3,370 (0·2)	522,192 (41·4)	296,178 (23·5)	4,470 (0·4)
Day 2	53,456 (3·4)	22,016 (1·4)	2,912 (0·2)	121,302 (8·9)	67,628 (5·0)	3,335 (0·2)	74,193 (4·8)	31,936 (2·1)	3,432 (0·2)	188,421 (14·2)	107,761 (8·1)	3,767 (0·3)
Day 3	35,994 (2·3)	13,399 (0·9)	3,387 (0·2)	55,917 (4·2)	24,334 (1·8)	3,695 (0·3)	40,305 (2·6)	15,496 (1·0)	3,345 (0·2)	73,844 (5·7)	32,292 (2·5)	4,052 (0·3)
Day 4	28,877 (1·9)	10,799 (0·7)	3,572 (0·2)	36,450 (2·8)	14,154 (1·1)	3,377 (0·3)	29,880 (2·0)	10,773 (0·7)	3,351 (0·2)	43,833 (3·4)	16,702 (1·3)	3,541 (0·3)
Day 5	24,765 (1·7)	9,468 (0·6)	3,548 (0·2)	29,069 (2·3)	10,747 (0·8)	3,125 (0·2)	25,056 (1·7)	9,512 (0·7)	3,467 (0·2)	32,958 (2·6)	12,195 (1·0)	3,065 (0·2)
Day 6	22,401 (1·6)	9,187 (0·7)	3,621 (0·3)	25,167 (2·0)	9,669 (0·8)	3,157 (0·2)	22,502 (1·6)	9,271 (0·7)	3,733 (0·3)	28,146 (2·2)	10,840 (0·9)	3,133 (0·2)
Day 7	20,820 (1·5)	8,801 (0·6)	3,811 (0·3)	24,955 (1·9)	10,066 (0·8)	3,419 (0·3)	21,804 (1·6)	9,242 (0·7)	4,483 (0·3)	28,538 (2·2)	12,066 (0·9)	3,272 (0·3)
Male												
Day 0	8,905 (1·0)	5,711 (0·7)	569 (0·1)	11,137 (1·7)	8,208 (1·3)	380 (0·1)	8,954 (1·1)	5,339 (0·7)	479 (0·1)	13,450 (2·3)	8,955 (1·5)	337 (0·1)
Day 1	30,240 (3·2)	15,781 (1·8)	656 (0·1)	93,820 (13·3)	66,375 (9·4)	820 (0·1)	46,535 (5·3)	24,313 (2·8)	955 (0·1)	167,957 (25·6)	110,868 (16·9)	1,104 (0·2)
Day 2	13,698 (1·5)	7,846 (0·8)	767 (0·1)	29,528 (4·0)	21,766 (3·0)	768 (0·1)	21,696 (2·4)	12,307 (1·4)	836 (0·1)	47,601 (6·9)	33,333 (4·9)	785 (0·1)
Day 3	8,925 (1·0)	4,669 (0·5)	827 (0·1)	12,163 (1·7)	7,101 (1·0)	788 (0·1)	10,625 (1·2)	5,218 (0·6)	865 (0·1)	15,542 (2·3)	8,550 (1·3)	784 (0·1)
Day 4	7,267 (0·8)	3,667 (0·4)	967 (0·1)	7,978 (1·1)	4,250 (0·6)	843 (0·1)	7,670 (0·9)	3,801 (0·4)	867 (0·1)	9,428 (1·4)	4,613 (0·7)	754 (0·1)
Day 5	6,180 (0·7)	3,207 (0·4)	981 (0·1)	6,319 (0·9)	3,224 (0·5)	901 (0·1)	6,516 (0·8)	3,376 (0·4)	932 (0·1)	7,156 (1·1)	3,425 (0·5)	785 (0·1)
Day 6	5,696 (0·7)	3,019 (0·4)	1,022 (0·1)	5,790 (0·8)	2,902 (0·4)	868 (0·1)	5,829 (0·7)	3,107 (0·4)	1,035 (0·1)	6,433 (1·0)	3,146 (0·5)	793 (0·1)
Day 7	5,324 (0·7)	2,937 (0·4)	1,050 (0·1)	5,873 (0·8)	3,147 (0·4)	975 (0·1)	5,443 (0·7)	3,047 (0·4)	1,094 (0·1)	6,651 (0·9)	3,547 (0·5)	886 (0·1)

Data are n (%)†.
*Reports of health impacts are not mutually exclusive.
†Percent corresponds to number of respondents by sex and day.

***Supplemental Figure* 1: Number of reports of death per day following vaccination, by manufacturer, to Vaccine Adverse Event Reporting System (VAERS)—December 14, 2020–June 14, 2021**

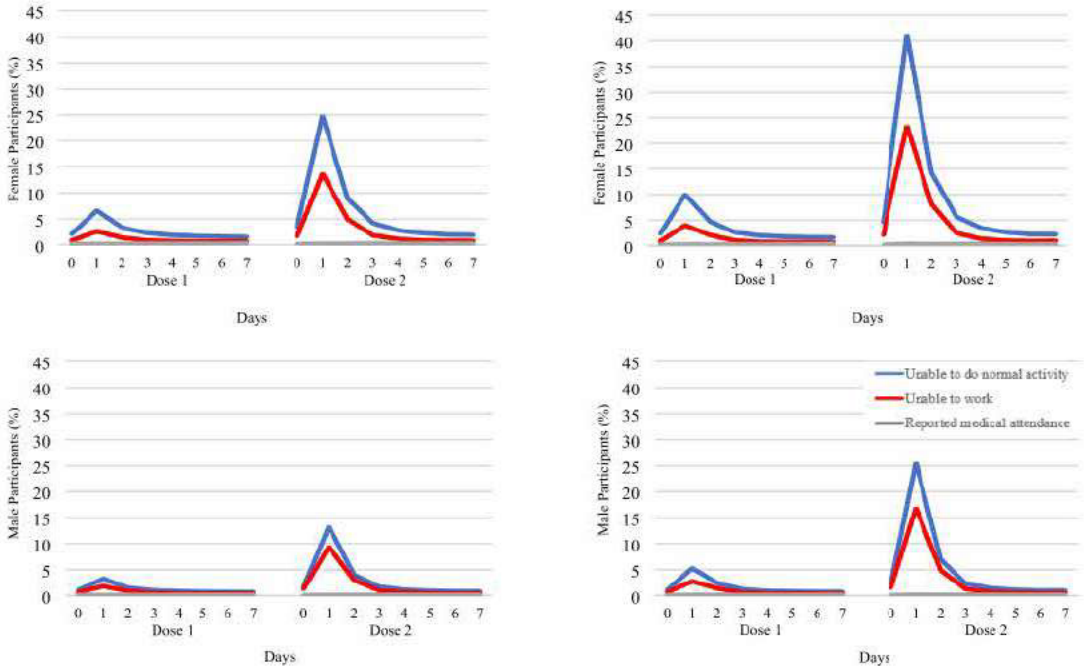


*x-axis reports through 161 days since last dose.

Commented [BR(35]: Editorial suggestion:
This wording sounds awkward and confusing. Please revise for clarity. Consider something like "Number of reports by day of onset" .....

Commented [RH(36R36]: Thanks. done

***Supplemental Figure* 2: Reported health impact 0-7 days after mRNA COVID-19 vaccination by manufacturer, type of impact, and sex reported in v-safe—December 14, 2020–June 14, 2021**



Top left: Female participants reporting health impact after receiving BNT162b2 vaccine. *Top right:* Female participants reporting health impact after receiving mRNA-1273 vaccine. *Bottom left:* Male participants reporting health impact after receiving BNT162b2 vaccine. *Bottom right*: Male participants reporting health impact after receiving mRNA-1273 vaccine.