COVID-19 vaccine safety update

Immunization Action Coalition (IAC)
March 4, 2021

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Vaccine Safety Team

Disclaimer

- 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 U.S. Food and Drug Administration (FDA).
- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC or FDA.

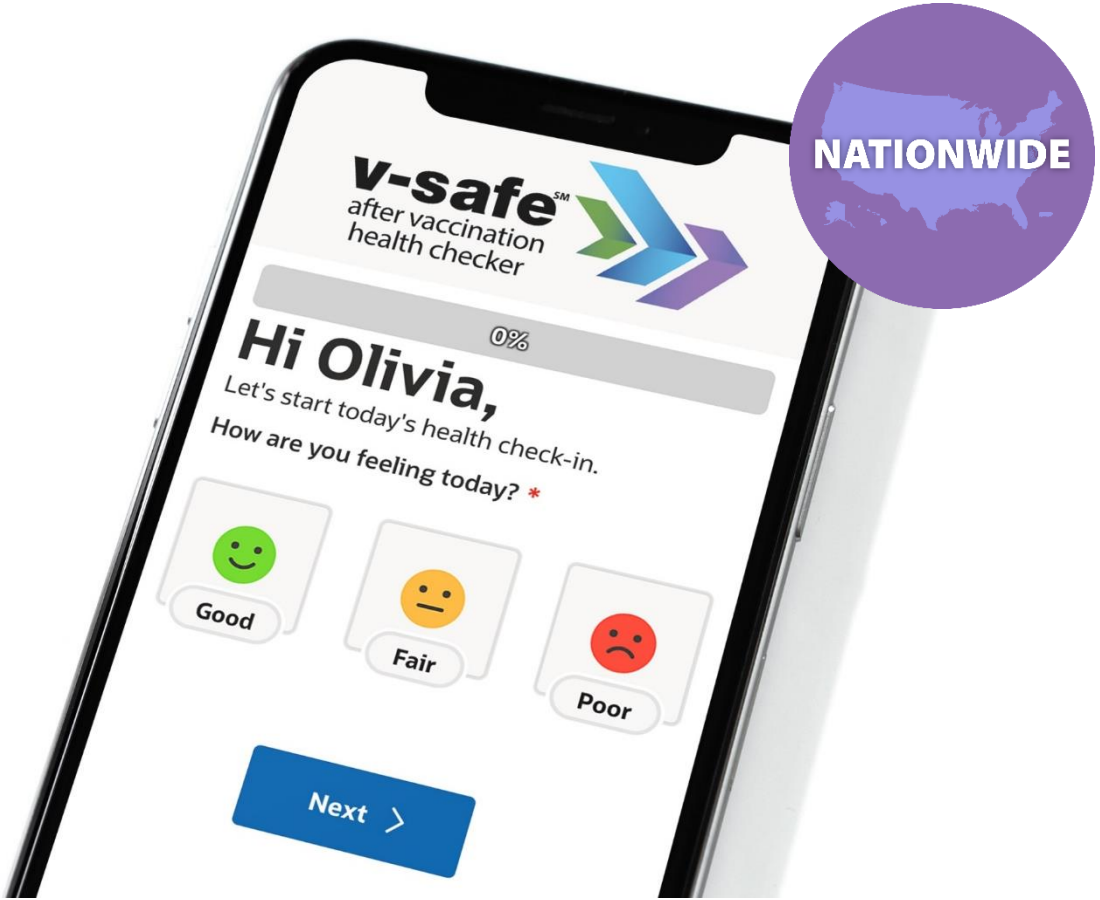
Topics

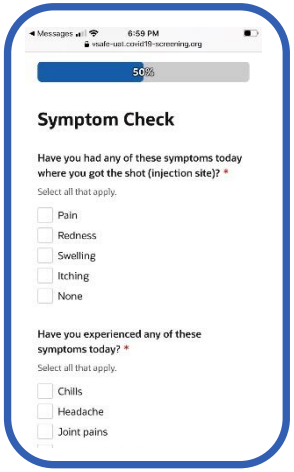
- V-safe update
- Vaccine Adverse Event Reporting System (VAERS) update
- Vaccine Safety Datalink (VSD) update
- Clinical Immunization Safety Assessment (CISA) Project update
- COVID-19 vaccine safety in pregnancy

Smartphone-based active safety monitoring

v-safe[SM]
after vaccination
health checker

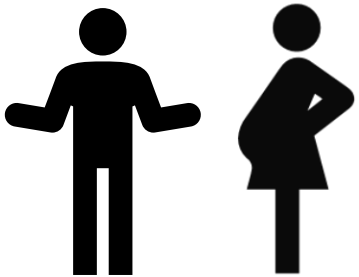
http://cdc.gov/vsafe





1. text message check-ins from CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)

vaccine recipient completes web survey*



Vaccine recipients

v-safe℠ after vaccination health checker

2. clinically important health impact reported

✓ **received medical care**

Call center

3. **V-safe** call center conducts active telephone follow-up on a clinically important event and takes a VAERS report if appropriate

4. pregnancy registry team conducts outreach to assess eligibility for registry and obtain consent for enrollment and follow-up

Call center

* Selected web surveys capture information on pregnancy status

Summary of v-safe data as of February 16, 2021

	Pfizer-BioNTech	Moderna	Total
People receiving 1 or more doses in the United States*	28,374,410	26,738,383	55,220,364
Registrants completing at least 1 v-safe health check-in	1,776,960	2,121,022	3,897,982
Pregnancies reported to v-safe†	16,039	14,455	30,494

* COVID Data Tracker as of Feb 16, 2021 (107,571 doses with manufacturer not identified)
† Self-reported during a **v-safe** health check-in

v-safe[SM] after vaccination health checker

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
February 19, 2021

First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021

Early Release

TABLE 2. Percentage of v-safe enrollees who completed at least one survey (N = 1,602,065) with local and systemic reactions reported for day 0–7 and for day 1 after receiving Pfizer-BioNTech and Moderna COVID-19 vaccines — v-safe,* United States, December 14, 2020–January 13, 2021

	Percentage of v-safe enrollees reporting reactions			
	Both vaccines	Pfizer-BioNTech vaccine		Moderna vaccine
Local and systemic reaction	Day 0–7	Dose 1, day 1	Dose 2, day 1	Dose 1, day 1
Injection site pain	70.9	72.9	79.3	78.1
Fatigue	33.5	21.9	53.5	25.1
Headache	29.5	17.5	43.4	19.9
Myalgia	22.9	14.7	47.2	18.3
Chills	11.6	5.5	30.6	8.4
Fever	11.4	5.8	29.2	8.2
Injection site swelling	10.8	6.2	8.6	12.6
Joint pain	10.4	5.3	23.5	7.3
Nausea	8.9	4.2	14.0	5.5

Abbreviation: COVID-19 = coronavirus disease 2019.
* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

* Gee J, Marquez P, Su J, et al. First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021. MMWR Morb Mortal Wkly Rep. ePub: 19 February 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7008e3

v-safe[SM] after vaccination health checker

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

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

Vaccine Adverse Event Reporting System (VAERS)

Strengths

- National data
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

Limitations

- Reporting bias
- Inconsistent data quality and completeness of information
- Lack of unvaccinated comparison group
- Not designed to assess causality

- VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event
- As a hypothesis-generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

U.S. reports to VAERS after COVID-19 vaccines through February 16, 2021*

Vaccine	N	Non-serious AEs (%)	Serious AEs†§ (%)
Moderna	56,567	54,708 (97)	1,859 (3)
Pfizer-BioNTech	48,196	43,974 (91)	4,222 (9)
Total	**104,763**	**98,682 (94)**	**6,081 (6)**

* Total pre-processed reports (reports received and classified as serious or non-serious)

† Based on the Code of Federal Regulations if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly or birth defect

§ Most commonly reported serious adverse events include: death (456 reports of death following Moderna vaccine and 510 following Pfizer-BioNTech vaccine), dyspnoea, pyrexia, SARS-CoV-2 test negative, nausea, headache, dizziness, fatigue, asthenia, pain

Most commonly reported adverse events to VAERS after COVID-19 vaccines through February 16, 2021*

Pfizer-BioNTech

Adverse event†	N (%)
Headache	2,322 (20.0)
Fatigue	1,801 (15.5)
Dizziness	1,659 (14.3)
Pyrexia	1,551 (13.4)
Chills	1,508 (13.0)
Nausea	1,482 (12.8)
Pain	1,464 (12.6)
SARS-CoV-2 Test Positive	1,002 (8.6)
Injection Site Pain	997 (8.6)
Pain in Extremity	923 (8.0)

Moderna

Adverse event†	N (%)
Headache	1,353 (23.4)
Pyrexia	1,093 (18.9)
Chills	1,056 (18.3)
Pain	945 (16.3)
Fatigue	888 (15.4)
Nausea	884 (15.3)
Dizziness	792 (13.7)
Injection Site Pain	671 (11.6)
Pain in Extremity	576 (10.0)
Dyspnoea	487 (8.4)

- No empirical Bayesian data mining alerts (EB05 ≥2) detected for any adverse event-COVID-19 vaccine pairs (most recent weekly results)

* For reports received and processed (coded, redacted, and quality assurance performed)
†Adverse events are not mutually exclusive

Anaphylaxis following mRNA COVID-19 vaccines

Clinical Review & Education

JAMA Insights

Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021

Tom T. Shimabukuro, MD, MPH, MBA; Matthew Cole, MPH; John R. Su, MD, PhD, MPH

Shimabukuro TT, Cole M, Su JR. Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US-December 14, 2020-January 18, 2021. *JAMA*. 2021 Feb 12. doi: 10.1001/jama.2021.1967. Epub ahead of print.

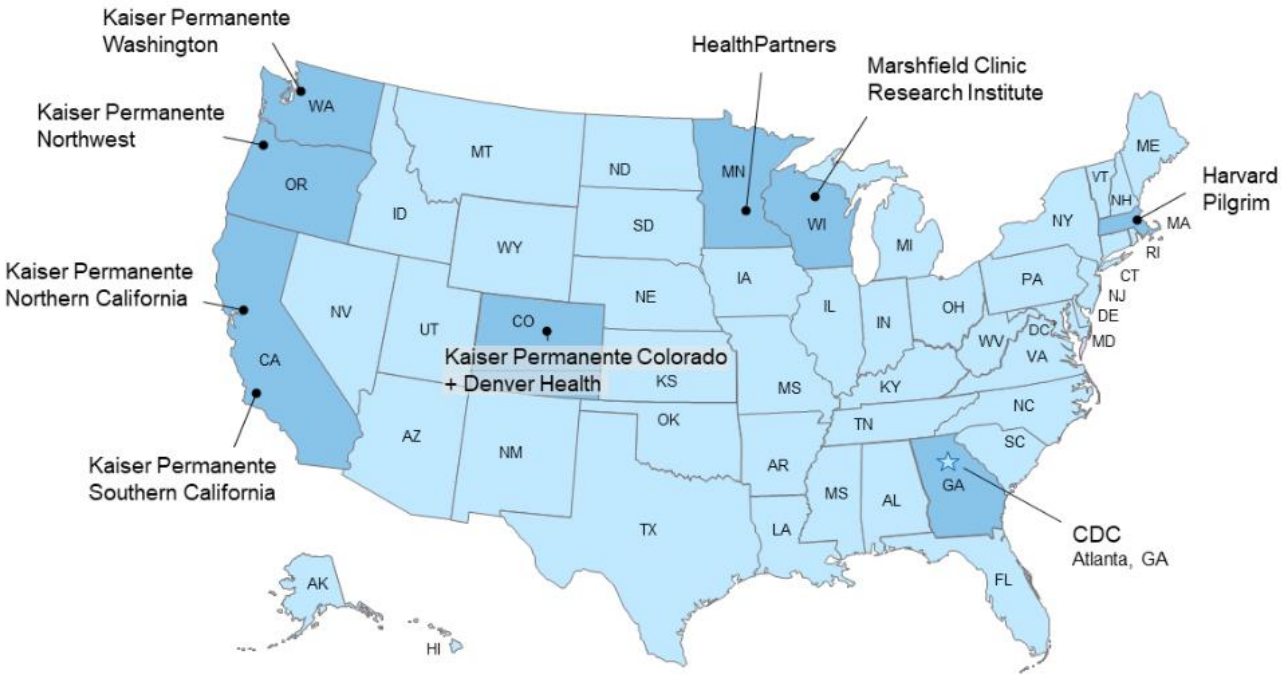
	Pfizer-BioNTech	Moderna
Anaphylaxis reporting rate (cases per million doses administered)	4.7	2.5

Table. Characteristics of Reported Cases of Anaphylaxis Following Receipt of Pfizer-BioNTech (9 943 247 Doses) and Moderna (7 581 429 Doses) COVID-19 Vaccines—Vaccine Adverse Events Reporting System (VAERS), US, December 14, 2020-January 18, 2021

Characteristics	No. (%) of cases	
	Pfizer-BioNTech (n = 47)	Moderna (n = 19)
Age, median (range), y	39 (27-63)[a]	41 (24-63)
Female sex	44 (94)	19 (100)
Minutes to symptom onset, median (range)	10 (<1-1140 [19 h])[b]	10 (1-45)
Symptom onset, min		
≤15	34 (76)[b]	16 (84)
≤30	40 (89)[b]	17 (89)
Reported history[c]		
Allergies or allergic reactions	36 (77)	16 (84)
Prior anaphylaxis	16 (34)	5 (26)
Vaccine dose		
First	37	17
Second	4	1
Unknown	6	1
Brighton Collaboration case definition level[d]		
1	21 (45)	10 (52)
2	23 (49)	8 (43)
3	3 (6)	1 (5)
Anaphylaxis reporting rate (cases per million doses administered)	4.7	2.5

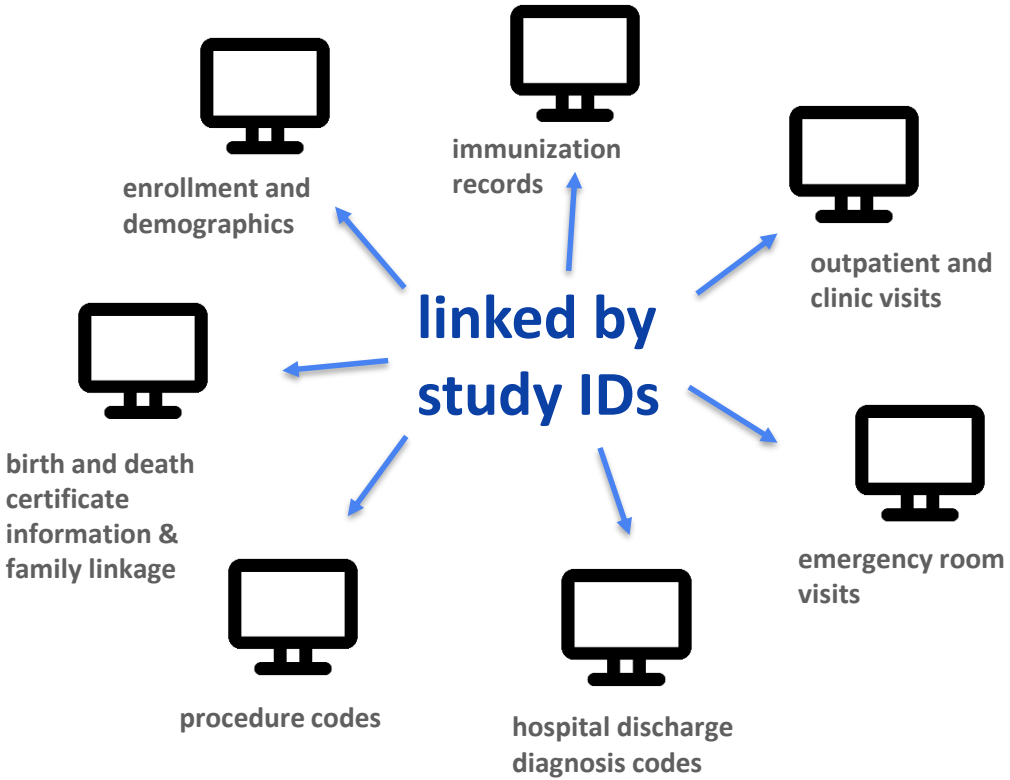
VSD

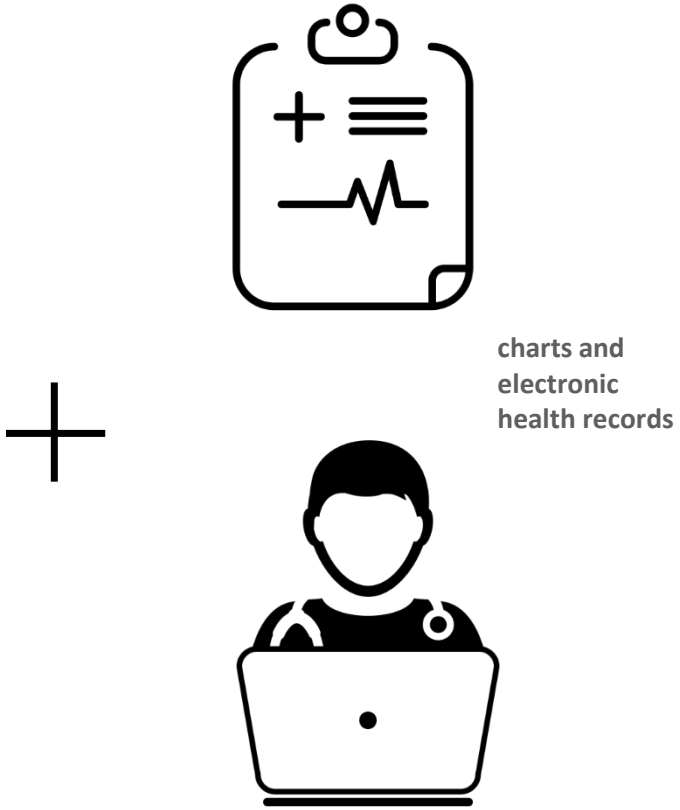
Vaccine Safety Datalink



- **9** participating integrated healthcare organizations
- data on over **12 million** persons per year

Types of information in VSD





Images created by Wilson Joseph, Megan Mitchell, Ananth, and Iga from the noun project

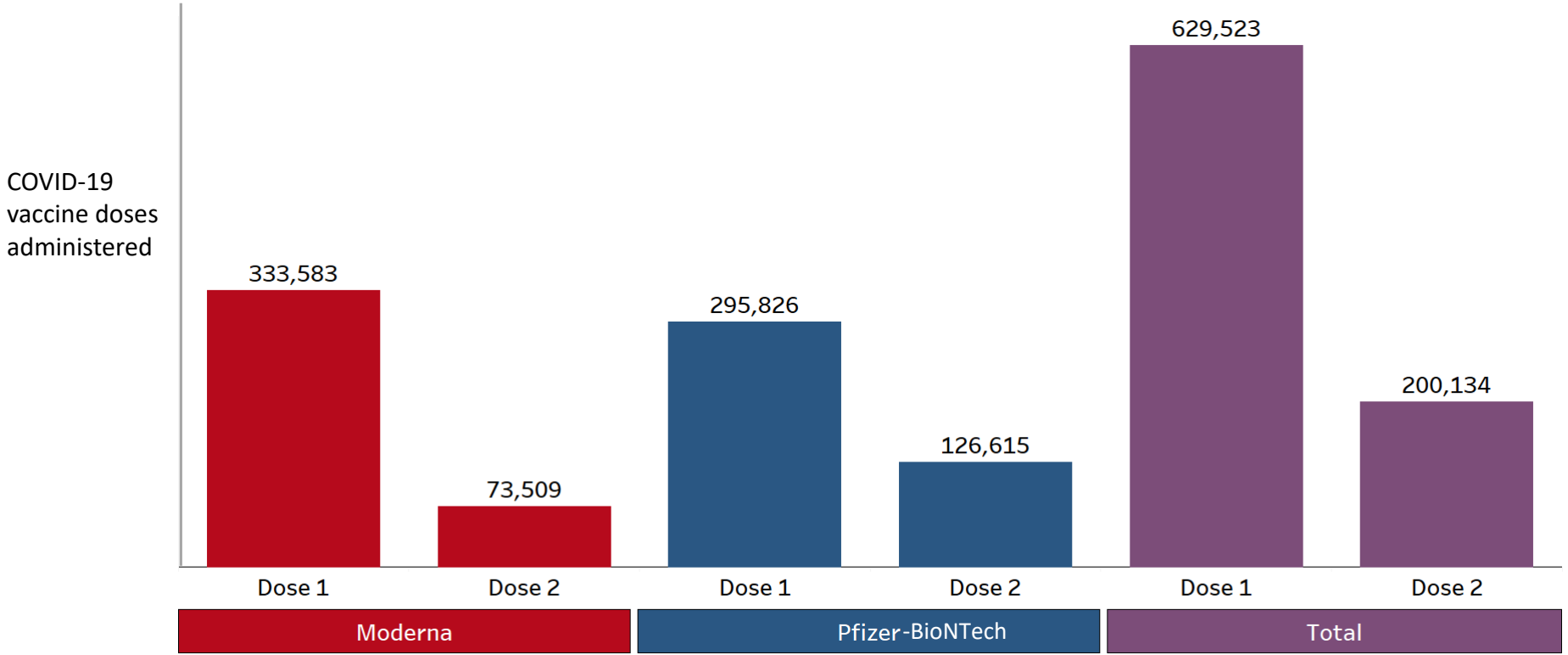
VSD Rapid Cycle Analysis (RCA) for COVID-19 vaccines

- Data are refreshed weekly
- Outcomes monitored are pre-specified (i.e., identified in advance)
- Includes methods to adjust for sequential testing
- A surveillance activity, not the same as an epidemiologic study
- Designed to detect statistically significant associations and statistical signals (values above specified statistical thresholds)
- When a statistically significant association or signal occurs, assessment involves a series of checks and evaluations
- Chart-confirmation of diagnoses to confirm or exclude cases as true incident cases is a key part of statistical signal assessment

VSD RCA for COVID-19 vaccines

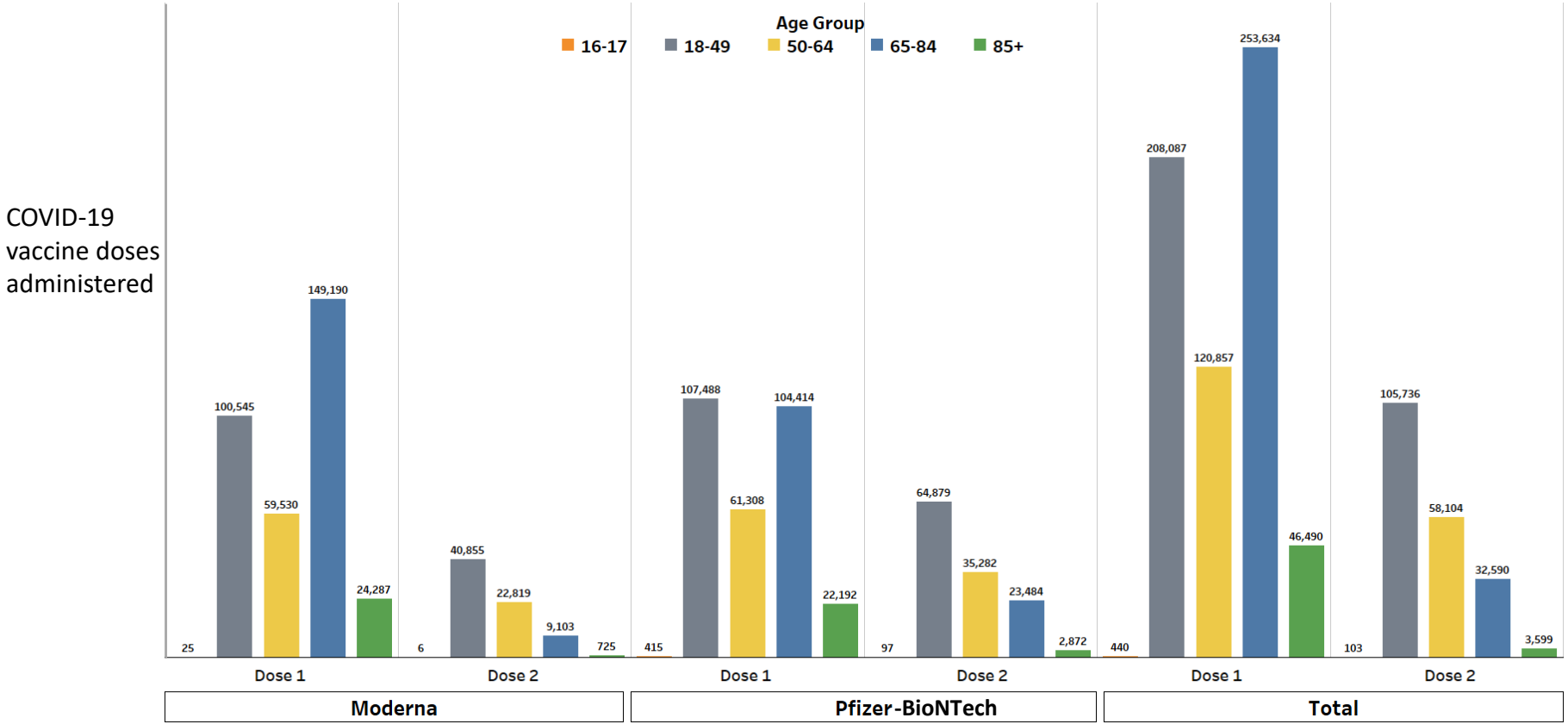
- Analyses
  - Unvaccinated concurrent comparators (currently being conducted)
  - Vaccinated concurrent comparators (currently being conducted)
  - Self-controlled risk interval (planned)
  - Historical comparators (planned)

VSD COVID-19 vaccine doses administered by manufacturer through February 13, 2021*



* Source: VSD participating integrated healthcare organizations; total includes a small number of unknow vaccine type

VSD COVID-19 vaccine doses administered by manufacturer, age group, and dose number through February 13, 2021*



* Source: VSD participating integrated healthcare organizations; total includes a small number of unknow vaccine type

Preliminary results of the VSD **unvaccinated concurrent comparator** analysis for COVID-19 vaccine safety after either dose of any mRNA vaccine as of February 13, 2021

VSD Rapid Cycle Analysis prespecified outcomes for COVID-19 vaccines	Concurrent comparator analysis	Risk interval	Events in vaccinated	Adjusted expected events in risk interval
Acute disseminated encephalomyelitis	Unvaccinated	1-21 days	0	0
Acute myocardial infarction	Unvaccinated	1-21 days	23	26.0
Acute respiratory distress syndrome	Unvaccinated	N/A	0	N/A
Anaphylaxis	Unvaccinated	0-1 days	20	N/A
Appendicitis	Unvaccinated	1-21 days	31	23.6
Bell's palsy	Unvaccinated	1-21 days	21	20.3
Convulsions/seizures	Unvaccinated	1-21 days	10	9.6
Disseminated intravascular coagulation	Unvaccinated	1-21 days	1	1.1
Encephalitis/myelitis/encephalomyelitis	Unvaccinated	1-21 days	1	.1
Guillain-Barré syndrome	Unvaccinated	1-21 days	1	.6
Thrombotic thrombocytopenic purpura	Unvaccinated	1-21 days	0	0
Immune thrombocytopenia	Unvaccinated	1-21 days	1	1
Kawasaki disease	Unvaccinated	1-21 days	0	0
MIS-C and MIS-A	Unvaccinated	N/A	0	N/A
Myocarditis/pericarditis	Unvaccinated	1-21 days	2	2.1
Narcolepsy and cataplexy	Unvaccinated	N/A	2	N/A
Stroke, hemorrhagic	Unvaccinated	1-21 days	8	10
Stroke, ischemic	Unvaccinated	1-21 days	41	38.8
Transverse myelitis	Unvaccinated	1-21 days	0	0
Venous thromboembolism	Unvaccinated	1-21 days	26	26.3
Pulmonary embolism (subset of VTE)	Unvaccinated	1-21 days	20	21.0

- No statistically significant increased risks detected for any prespecified outcomes

Preliminary results of the VSD **sequential vaccinated concurrent comparator** analysis for COVID-19 vaccine safety after either dose of any mRNA vaccine as of February 13, 2021

- No statistical signals detected

VSD Rapid Cycle Analysis prespecified outcomes for COVID-19 vaccines*	Concurrent comparator analysis	Risk interval	Events in risk Interval	Adjusted expected events in risk interval	Statistical signal (Y/N)
Acute myocardial infarction	Vaccinated	1-21 days	21	30.8	N
Appendicitis	Vaccinated	1-21 days	25	53.5	N
Bell's palsy	Vaccinated	1-21 days	17	23.1	N
Convulsions/seizures	Vaccinated	1-21 days	10	9.4	N
Disseminated intravascular coagulation	Vaccinated	1-21 days	1	0	N
Immune thrombocytopenia	Vaccinated	1-21 days	1	0	N
Myocarditis/pericarditis	Vaccinated	1-21 days	2	0	N
Stroke, hemorrhagic	Vaccinated	1-21 days	7	0	N
Stroke, ischemic	Vaccinated	1-21 days	37	43.5	N
Venous thromboembolism	Vaccinated	1-21 days	23	12.4	N
Pulmonary embolism (subset of VTE)	Vaccinated	1-21 days	19	0	N

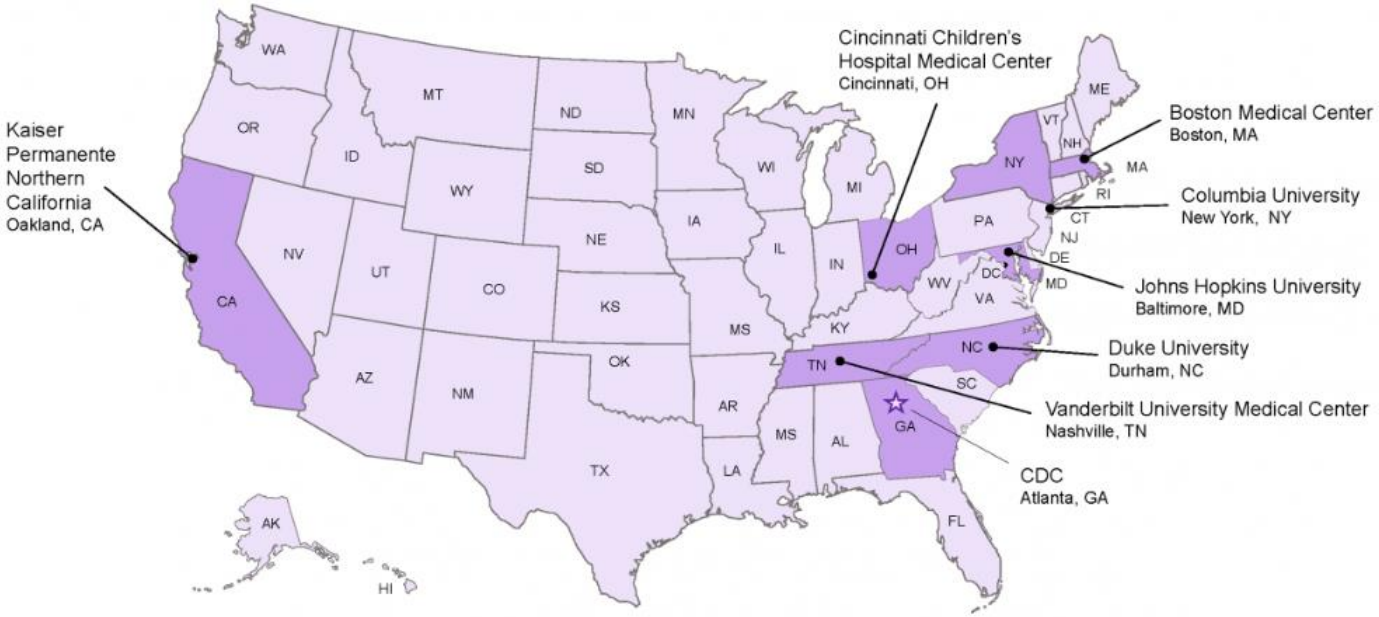
* Only includes outcomes with events in the risk window

VSD RCA next steps – next analyses

- Dose-specific analyses
- Product-specific analyses
- Analyses for two risk intervals 1-21 and 1-42 days
- Historical comparator analysis

CISA

Clinical Immunization Safety Assessment (CISA) Project



7 participating medical research centers with vaccine safety experts

- clinical consult services†
- clinical research

†More information about clinical consults available at http://www.cdc.gov/vaccinesafety/Activities/CISA.html

CISA Project COVIDvax

- Extension of CDC's CISA* Project's clinical consultation service for U.S. healthcare providers and health departments for complex COVID-19 vaccine safety questions/issues that are†
  - (1) about an individual patient(s) residing in the United States
  - (2) not readily addressed by CDC or ACIP guidelines
- Vaccine safety subject matter expertise in multiple specialties (e.g., infectious diseases, allergy/immunology, neurology, OB/GYN, pediatrics, geriatrics)
- Requests for a CISA consult about COVID-19 vaccine safety:
  - Contact CDC-INFO: 800-CDC-INFO (800-232-4636) or webform
  - Indicate the request is for a "CDC CISA"* consult (no patient identifiers)

* https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html
† Advice from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management

CISA Project contributions

- Responded to 331 clinical inquiries or consultation requests about COVID-19 vaccine safety (December 14, 2020 through February 20, 2021)
  - Received from 43 states
  - >90% from healthcare providers or health departments
  - Most common topics include anaphylaxis/allergic reactions and nervous system disorders*
- Assisted state health departments with evaluation of complex medical issues pertaining to COVID-19 vaccines safety
- Established CISA Project workgroup with allergy/immunology specialists
  - Provided expert input on anaphylaxis and other allergic reactions to inform clinical considerations for use of COVID-19 vaccines
  - Ongoing work to investigate possible mechanism for anaphylaxis after COVID-19 vaccine, in collaboration with FDA, NIH and other partners

* Includes inquiries about adverse events and for clinical guidance without adverse event

COVID-19 vaccine safety in pregnancy

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	Pfizer-BioNTech	Moderna	Total
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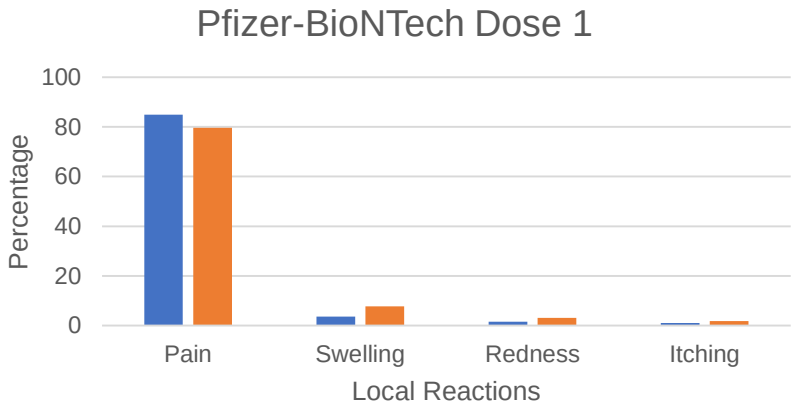
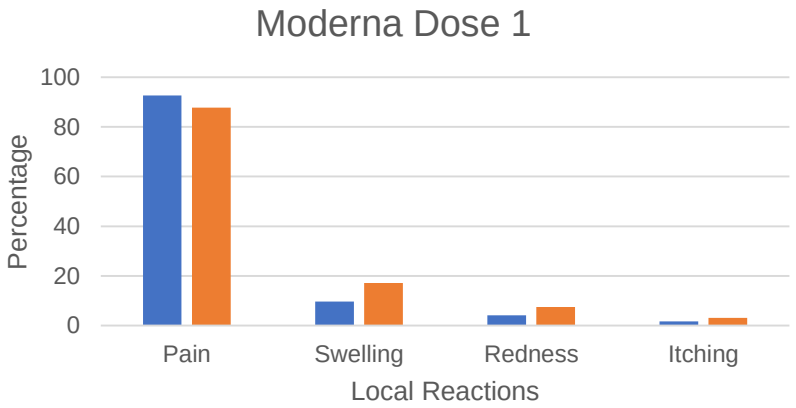
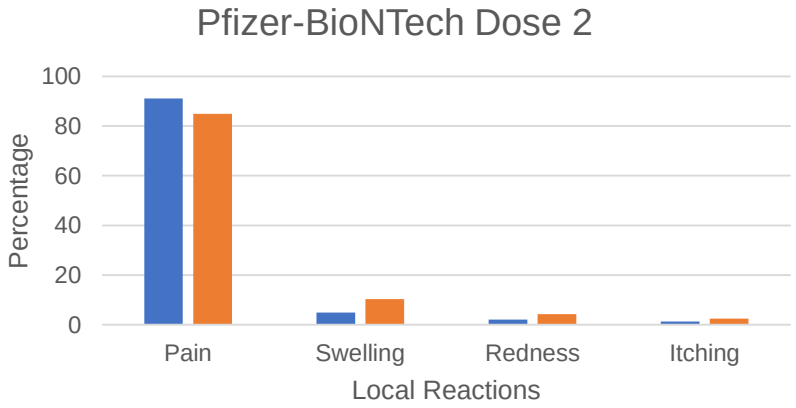
V-safe: Day 1 post-vaccination local reactions in pregnant and non-pregnant women aged 16-54 years*





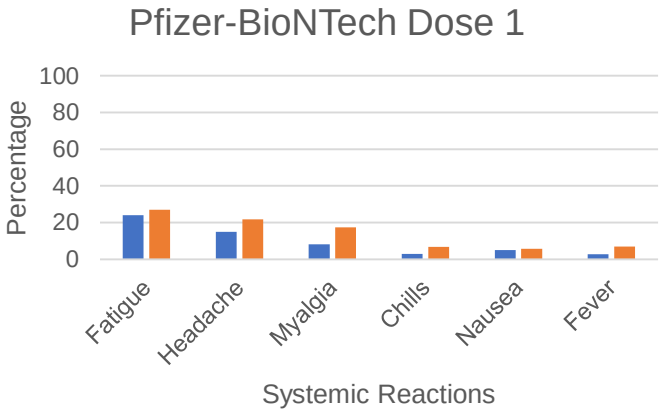


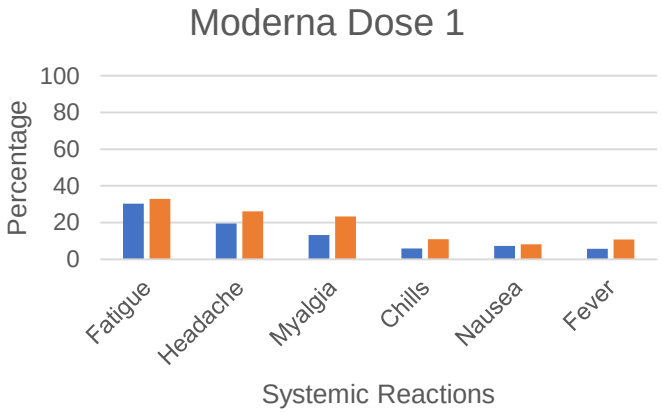
Pregnant (self-report)
Not pregnant

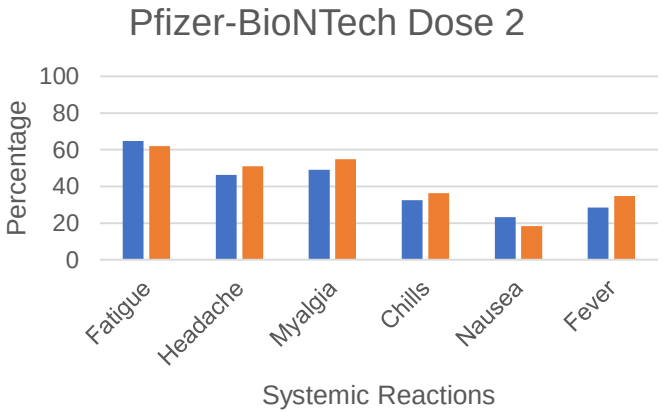
v-safe℠
after vaccination
health checker

* Source: CDC unpublished **v-safe** data through January 13, 2021

V-safe: Day 1 post-vaccination systemic reactions in pregnant and non-pregnant women aged 16-54 years*







Pregnant (self-report)
Not pregnant

v-safe℠
after vaccination
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* Source: CDC unpublished **v-safe** data through January 13, 2021

V-safe pregnancy registry

- **V-safe** participants who report pregnancy following COVID-19 vaccination are actively contacted to enroll in pregnancy registry*
- Participants are contacted once per trimester, after delivery, and when the infant is 3 months old†
- Outcomes of interest include miscarriage and still birth, pregnancy complications, maternal intensive care unit admission, adverse birth outcomes, neonatal death, infant hospitalizations, and birth defects

* Must be registered in **v-safe** and have been pregnant at the time of COVID-19 vaccine receipt or within 30 days of vaccination; enrollment may discontinue when sufficient enrollment numbers are achieved

† Phone surveys are conducted along with maternal and infant medical record review

V-safe pregnancy registry enrollment as of February 19, 2021

Registry participants to date (N = 1,949)	
Enrolled	1,815
Not eligible*	103
Refused/declined†	31

- In the enrolled population, there have been 275 completed pregnancies, including 232 live births
  - Other outcomes include miscarriage, stillbirth, ectopic/tubal, other

* Eligibility assessment determines whether vaccination was during pregnancy or within 30 days of last menstrual period

† Refused indicates those for whom eligibility could not be fully assessed because participant chose not to engage with pregnancy registry team; declined indicates those who were eligible to participate but chose not to enroll

V-safe pregnancy registry outcomes of interest in COVID-19 vaccinated pregnant women as of February 18, 2021*

Outcomes	Background rates*	V-safe pregnancy registry overall
Pregnancy outcome		
Miscarriage (<20 weeks)	26%	15%†
Stillbirth (≥ 20 weeks)	0.6%	1%
Pregnancy complications		
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension§	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
Neonatal		
Preterm birth	10.1%	10%
Congenital anomalies‡	3%	4%
Small for gestational age^	3-7%	4%
Neonatal death	0.38%	0%

* Sources listed on slide 33; † 93% of these were pregnancy losses <13 weeks of age; § Pre-eclampsia or gestational hypertension diagnosed during pregnancy and/or during delivery; ‡ Congenital anomalies (overall) diagnosed after delivery only; ^ Birthweight below the 10th percentile for gestational age and sex using INTERGROWTH-21st Century growth standards

Sources for pregnancy outcomes and complications and neonatal outcomes background rates

- Miscarriage: https://www.ncbi.nlm.nih.gov/books/NBK532992/
- Stillbirth: https://www.cdc.gov/nchs/data/nvsr/nvsr69/nvsr69-04-508.pdf
- Gestational diabetes: https://dmsjournal.biomedcentral.com/articles/10.1186/s13098-019-0406-1, https://www.cdc.gov/pcd/issues/2018/18_0094.htm#:~:text=An%20estimated%201%25%20to%2014,without%20gestational%20diabetes%20(4)
- Preeclampsia or gestational hypertension: https://www.frontiersin.org/articles/10.3389/fcvm.2020.00059/full, https://pubmed.ncbi.nlm.nih.gov/32381164/
- Eclampsia: CDC Wonder
- Intrauterine growth restriction: https://pubmed.ncbi.nlm.nih.gov/19404231/
- Preterm birth: NCHS/Peristats
- Congenital anomalies: https://www.cdc.gov/ncbddd/birthdefects/data.html
- Small for gestational age (this has it up to 11%): https://www.ncbi.nlm.nih.gov/books/NBK563247/
- Neonatal death: NCHS/Peristats

Characteristics of COVID-19 vaccine pregnancy reports to VAERS through February 16, 2021* (N=154)

Characteristic	
Maternal age in years, median (range)	33 (16–51)
Gestational age in weeks at time of vaccination when reported, median (range)	13 (2–38)
Trimester of pregnancy at time of vaccination	**n (%)**
First (0-13 weeks)	60/118 (51)
Second (14-27 weeks)	36/118 (31)
Third (28+ weeks)	22/118 (19)
Vaccine	
Pfizer-BioNTech	97 (63)
Moderna	56 (36)
Unreported	1 (0.6)

* Reports received and processed through February 16, 2021

Adverse events in pregnant women following COVID-19 vaccine reported to VAERS through February 16, 2021* (N=154)

Adverse events	N (%)
Pregnancy/neonatal specific conditions	**42 (27)**
Spontaneous abortion/miscarriage†	29
Premature rupture of membranes	3
Fetal hydrops	2
Neonatal death in 22-week preterm birth	1
Premature delivery	1
Gestational diabetes	1
Vaginal bleeding	1
Stillbirth	1
Shortened cervix	1
Leakage amniotic fluid	1
Calcified placenta	1
Non-pregnancy specific adverse events (top 10) Headache (31), fatigue (29), chills (21), pain in extremity (17), nausea (15), dizziness (14), pain (14), pyrexia (13), injection site pain (13), injection site erythema (10)	**112 (73)**

* Reports received and processed through February 16, 2021

† Frequency of clinically recognized early pregnancy loss for women aged 20–30 years, 9–17%; age 30, 20%; age 40, 40%; age 45, 80%. ACOG Practice Bulletin No. 200: Early Pregnancy Loss. Obstet Gynecol. 2018132(5):e197-e207

Other CDC COVID-19 maternal vaccination safety activities

- Vaccine Safety Datalink (VSD)
  - COVID-19 vaccination coverage in pregnant women
  - Risk of miscarriage and stillbirth following COVID-19 vaccination
  - Safety in pregnancy
    - Acute adverse events in pregnancy, longer-term safety assessment of acute adverse events, pregnancy complications and birth outcomes, and infant follow-up for the first year of life
- Clinical Immunization Safety Assessment (CISA) Project
  - Prospective observational cohort study
    - Adverse pregnancy and birth outcomes, serious adverse events, local and systemic reactogenicity, infant health outcomes for first 3 months of life

Maternal vaccination safety summary

- Pregnant women were not specifically included in pre-authorization clinical trials of COVID-19 vaccines
  - Post-authorization safety monitoring and research are the primary ways to obtain safety data on COVID-19 vaccination during pregnancy
- Substantial numbers of self-reported pregnant persons (>30,000) have registered in **v-safe**
- The reactogenicity profile and adverse events observed among pregnant women in **v-safe** did not indicate any safety problem
- Most (73%) reports to VAERS among pregnant women involved non-pregnancy-specific adverse events (e.g., local and systemic reactions)
- Miscarriage was the most frequently reported pregnancy-specific adverse event to VAERS; numbers are within the known background rates based on presumed COVID-19 vaccine doses administered to pregnant women

Closing thoughts on COVID-19 vaccine safety (Feb 2021)

- 75 million COVID-19 vaccine doses have been administered in the United States through February 28
- Reactogenicity profiles of mRNA vaccines in **v-safe** monitoring are consistent with what was observed in clinical trials, and systemic and local reactions are most commonly reported to VAERS
- Anaphylaxis following both vaccines has been reported to VAERS, though rarely
- No other safety signals for serious adverse events have been detected in VAERS
- No safety concerns have been identified among VSD Rapid Cycle Analysis prespecified outcomes as of February 13
- No unexpected pregnancy or infant outcomes have been observed related to COVID-19 vaccination during pregnancy
- Safety monitoring in pregnant women is ongoing and planned in **v-safe**, VAERS, VSD, and CISA

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COVID-19 Vaccine Task Force

COVID-19 Vaccine Task Force, Vaccine Safety Team

Immunization Safety Office

Division of Healthcare Quality Promotion

National Center on Birth Defects and Developmental Disabilities

Division of Reproductive Health

Vaccine Safety Datalink

Clinical Immunization Safety Assessment Project

V-safe Team

U.S. Food and Drug Administration

Office of Biostatistics and Epidemiology

Questions