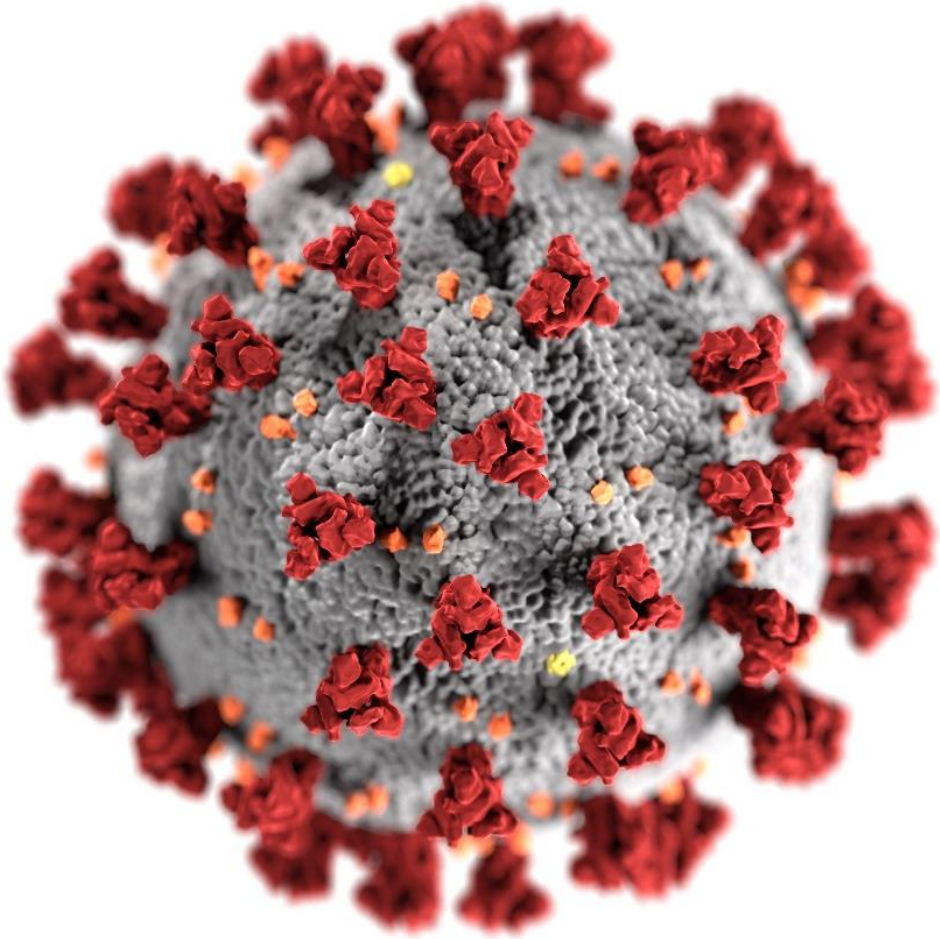
COVID-19 Vaccine safety updates

Advisory Committee on Immunization Practices (ACIP)

June 23, 2021



Tom Shimabukuro, MD, MPH, MBA
Vaccine Safety Team
CDC COVID-19 Vaccine Task Force

cdc.gov/coronavirus

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

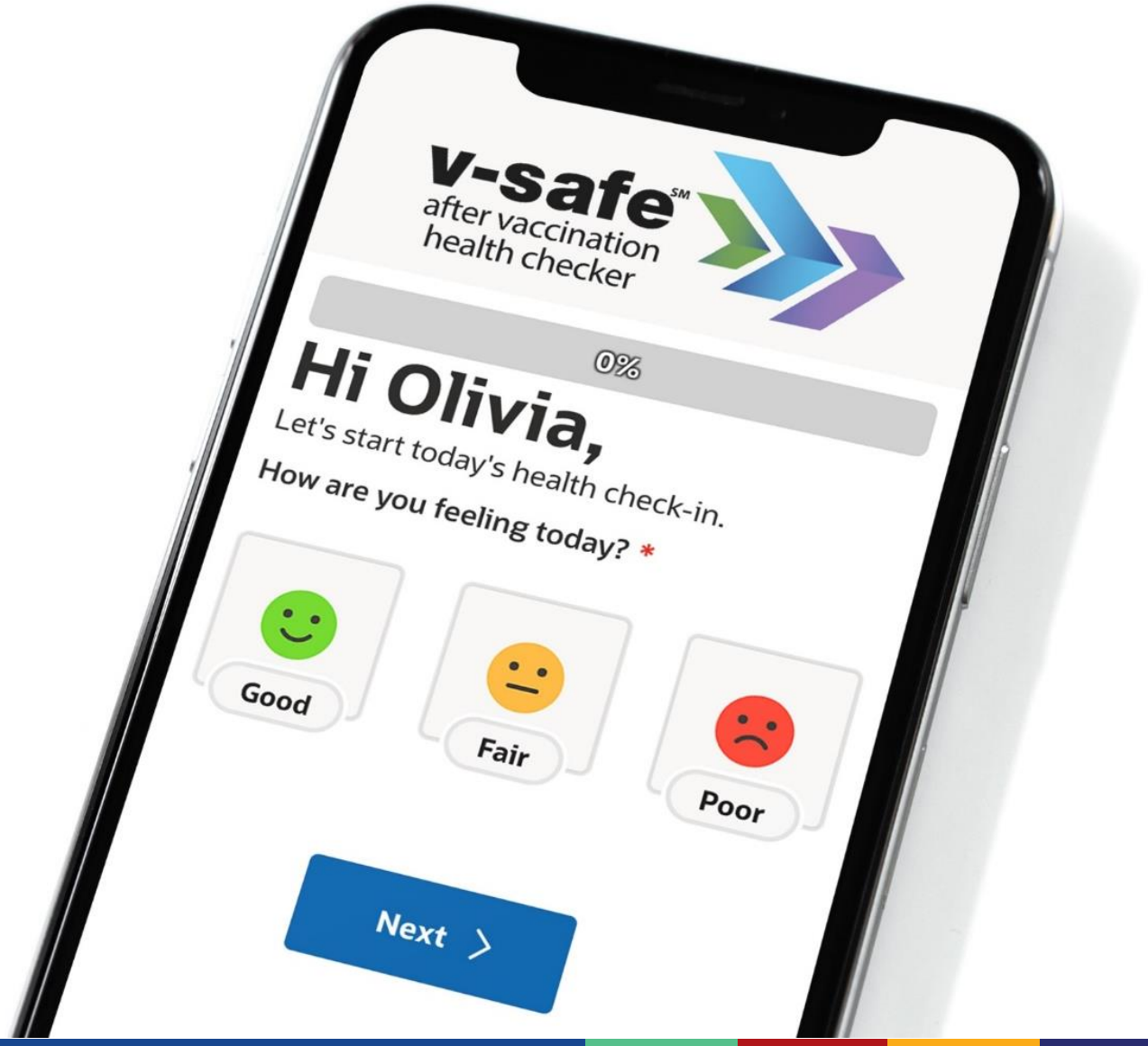
Topics

- Early safety data of Pfizer-BioNTech vaccination in persons aged 12–15 years old
- Myocarditis and pericarditis following mRNA COVID-19 vaccination

Early safety data of Pfizer-BioNTech vaccination in persons aged 12–15 years old

Smartphone-based active safety monitoring

v-safe[SM]
after vaccination
health checker



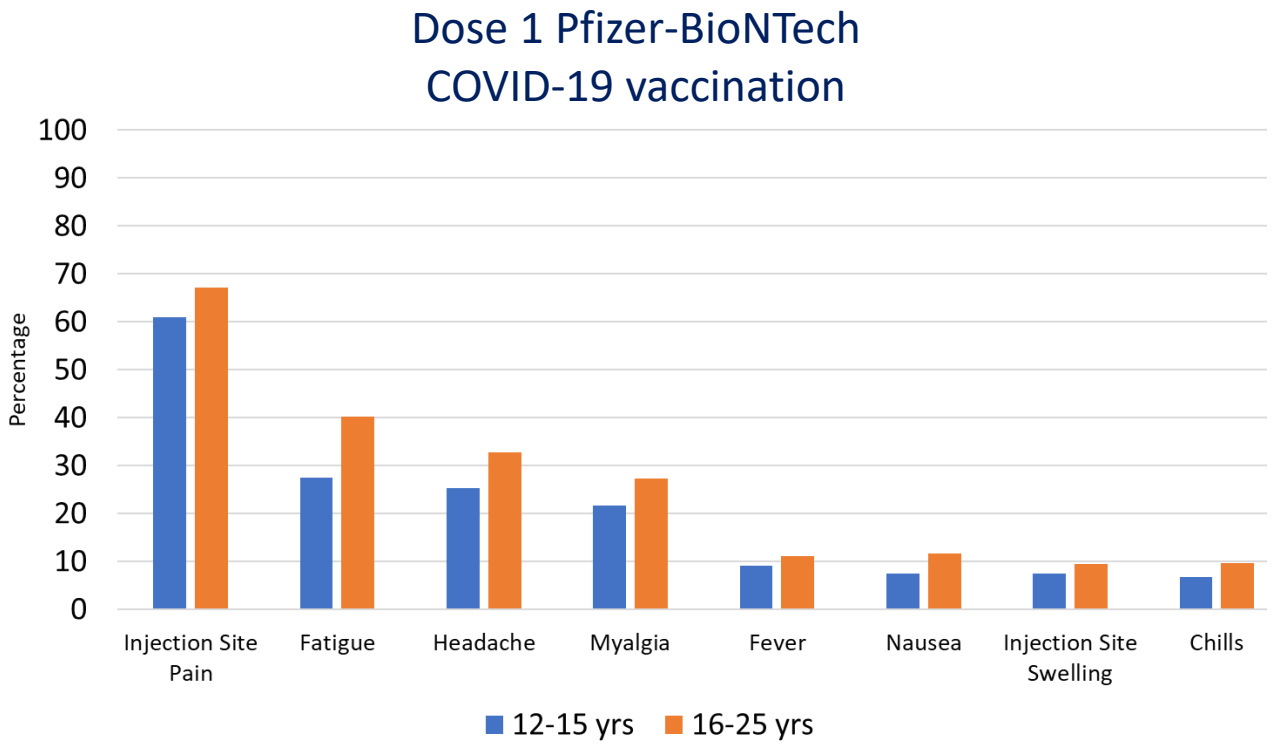
http://cdc.gov/vsafe

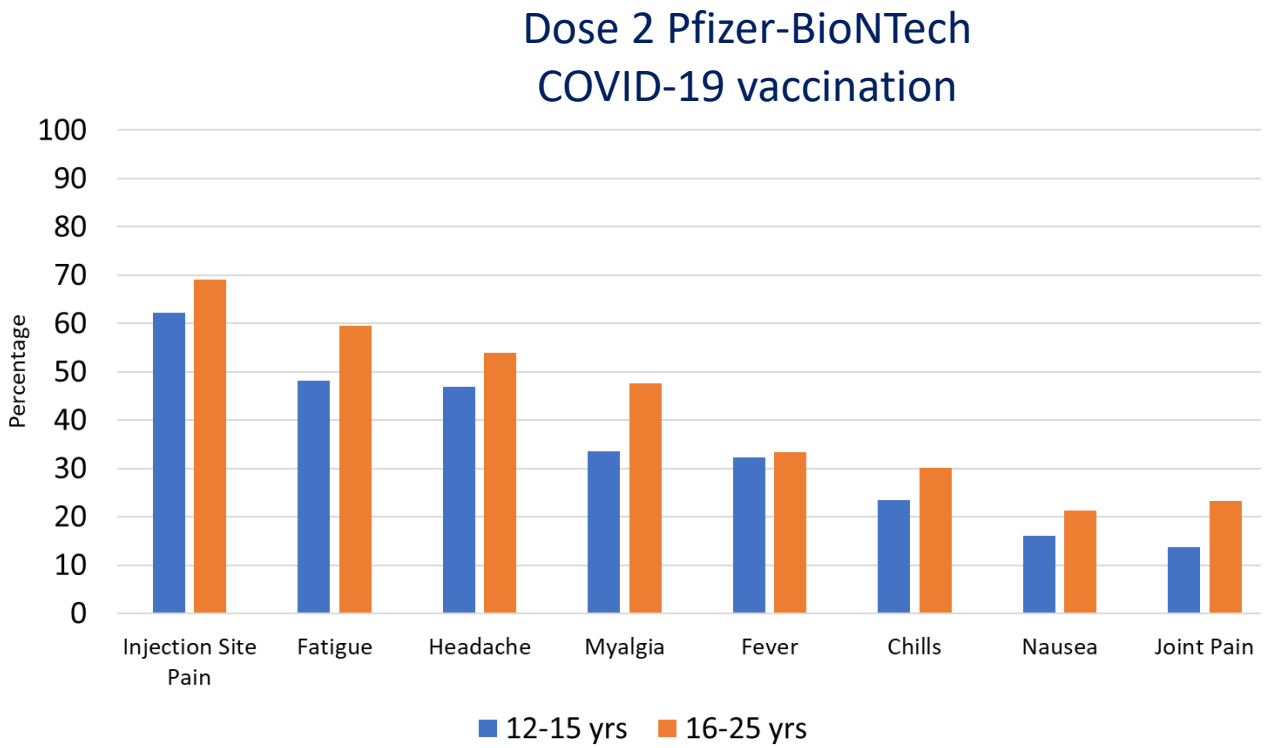
Overview of v-safe monitoring of Pfizer-BioNTech COVID-19 vaccine for younger adolescents

- On May 11, 2021, v-safe age limits expanded to allow registration down to 12 years of age at dose 1
- As of June 13, for persons age 12–15 years after Pfizer-BioNTech COVID-19 vaccination:
  - 57,126 with at least one health check-in during days 0–7 after dose 1
  - 15,988 with at least one health check-in during days 0–7 after dose 2

V-safe: Top solicited reactions reported at least once in days 0–7 after vaccination with Pfizer-BioNTech in 12–15-year-olds vs. 16–25-year-olds*

(data thru Jun 13, 2021)

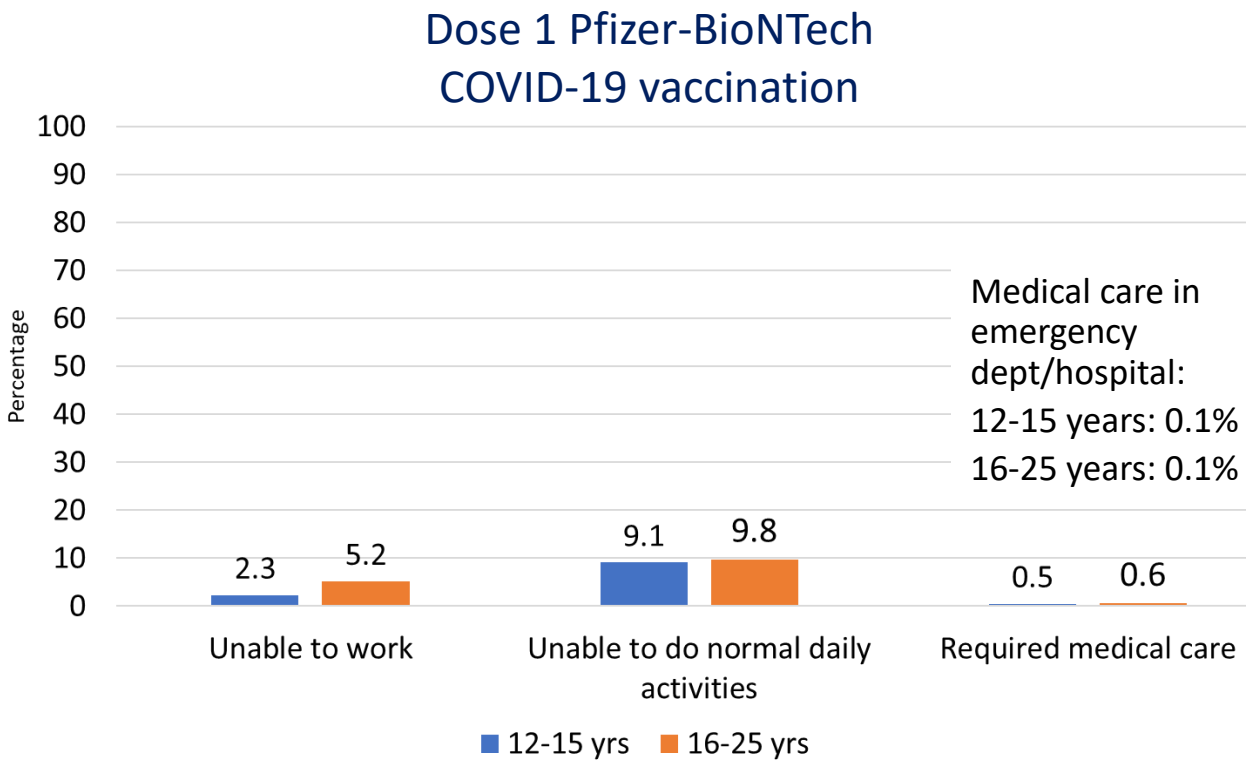


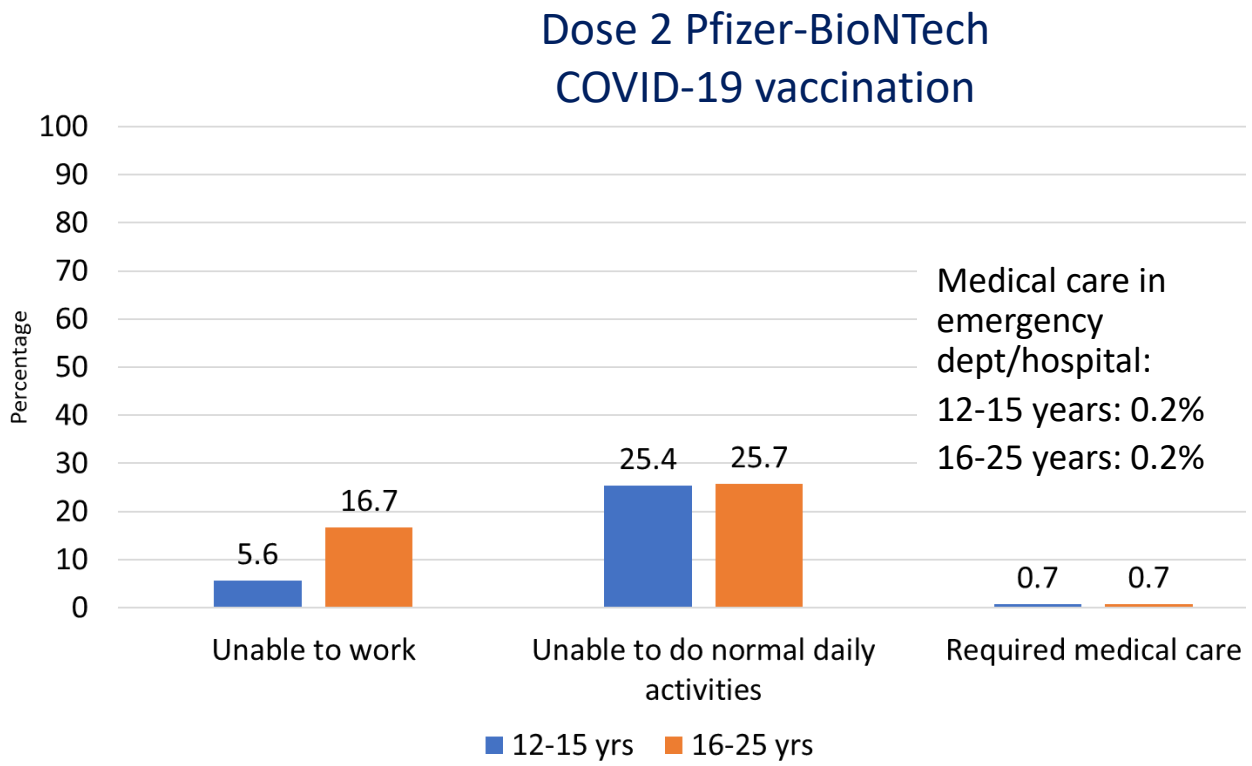


* Includes participants who completed at least one survey in the first week after dose 1 of Pfizer-BioNTech COVID-19 vaccine

V-safe: Health Impact Events reported at least once in days 0-7 after vaccination with Pfizer-BioNTech in 12–15-year-olds vs. 16–25-year-olds*

(data thru Jun 13, 2021)





* Includes participants who completed at least one survey in the first week after dose 1 of Pfizer-BioNTech COVID-19 vaccine

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

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

VAERS

VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

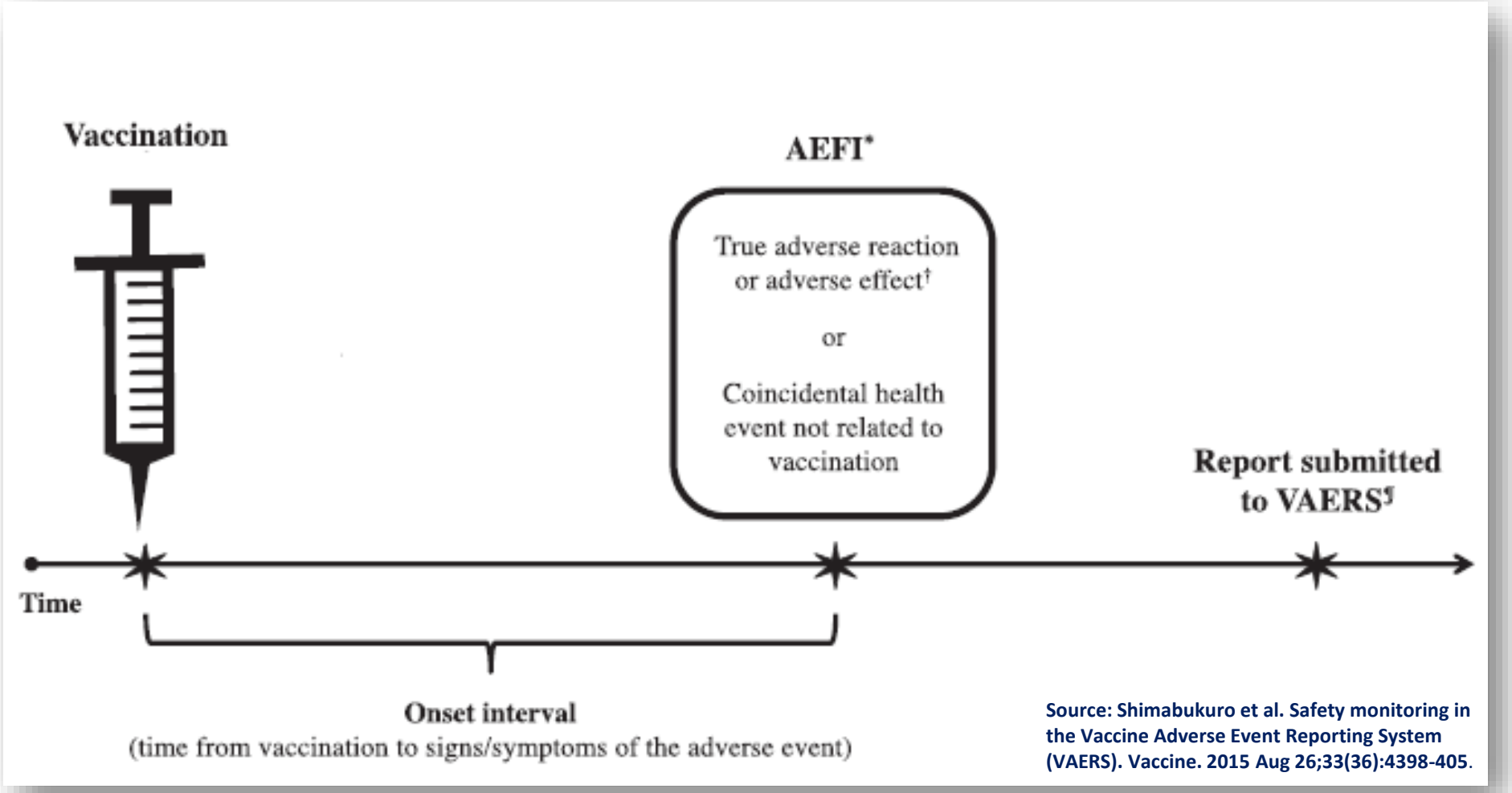
key strengths

- Rapidly detects potential safety problems
- Can detect rare adverse events

key limitations

- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect

What's in VAERS?



Source: Shimabukuro et al. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). Vaccine. 2015 Aug 26;33(36):4398-405.

Does not necessarily mean vaccination caused a health problem

Reports to VAERS after Pfizer-BioNTech COVID-19 vaccination: persons aged 12–15 years vs. 16–25 years* (data thru Jun 11, 2021)

Ages	N	Crude reporting rate (per million doses)	Non-serious adverse events (%)	Serious adverse events‡,§ (%)
12–15 years old	2,540	422	2,396 (94.3)	144 (5.7)
16–25 years old† (for comparison)	12,759	592	11,969 (93.8)	790 (6.2)

- 12–15 years old: ~6.0 million doses administered (May 10 thru June 11, 2021)
- 16–25 years old: ~21.6 million doses administered (December 14, 2020, thru June 11, 2021)

* Data as of June 14, 2021, for reports with vaccination date and receipt date May 10 through June 11, 2021

† Data as of June 14, 2021, for reports with vaccination date and receipt date December 14, 2020, through June 11, 2021

‡ 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

§ Includes 1 report of death in the 12–15-year-old age group and 18 reports of death in the 16–25-year-old age group

Most commonly reported adverse events to VAERS after Pfizer-BioNTech COVID-19 vaccination* (data thru Jun 11, 2021)

12–15 years old* (N= 2,540)

Adverse event‡	n (%)
Dizziness	618 (24.3)
Syncope	446 (17.6)
Nausea	308 (12.1)
Headache	281 (11.1)
Vomiting	221 (8.7)
Pallor	218 (8.6)
Loss of consciousness	217 (8.5)
Pyrexia (fever)	215 (8.5)
Hyperhidrosis	211 (8.3)
Fatigue	182 (7.2)

16–25 years old† (N= 12,759)

(for comparison)

Adverse event‡	n (%)
Dizziness	2,832 (22.2)
Headache	2,197 (17.2)
Nausea	1,955 (15.3)
Pyrexia (fever)	1,948 (15.3)
Fatigue	1,689 (13.2)
Chills	1,609 (12.6)
Pain	1,560 (12.2)
Syncope	1,257 (9.9)
Hyperhidrosis	946 (7.4)
Vomiting	918 (7.2)

- 12–15 years old: ~6.0 million doses administered (May 10 thru Jun 11, 2021)
- 16–25 years old: ~21.6 million doses administered (December 14, 2020, thru Jun 11, 2021)

* Data as of June 14, 2021, for reports with vaccination date and receipt date May 10 through June 11, 2021

† Data as of June 14, 2021, for reports with vaccination date and receipt date December 14, 2020, through June 11, 2021

‡ Adverse events are not mutually exclusive

Myocarditis and pericarditis following mRNA COVID-19 vaccination in the United States

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

CDC + FDA

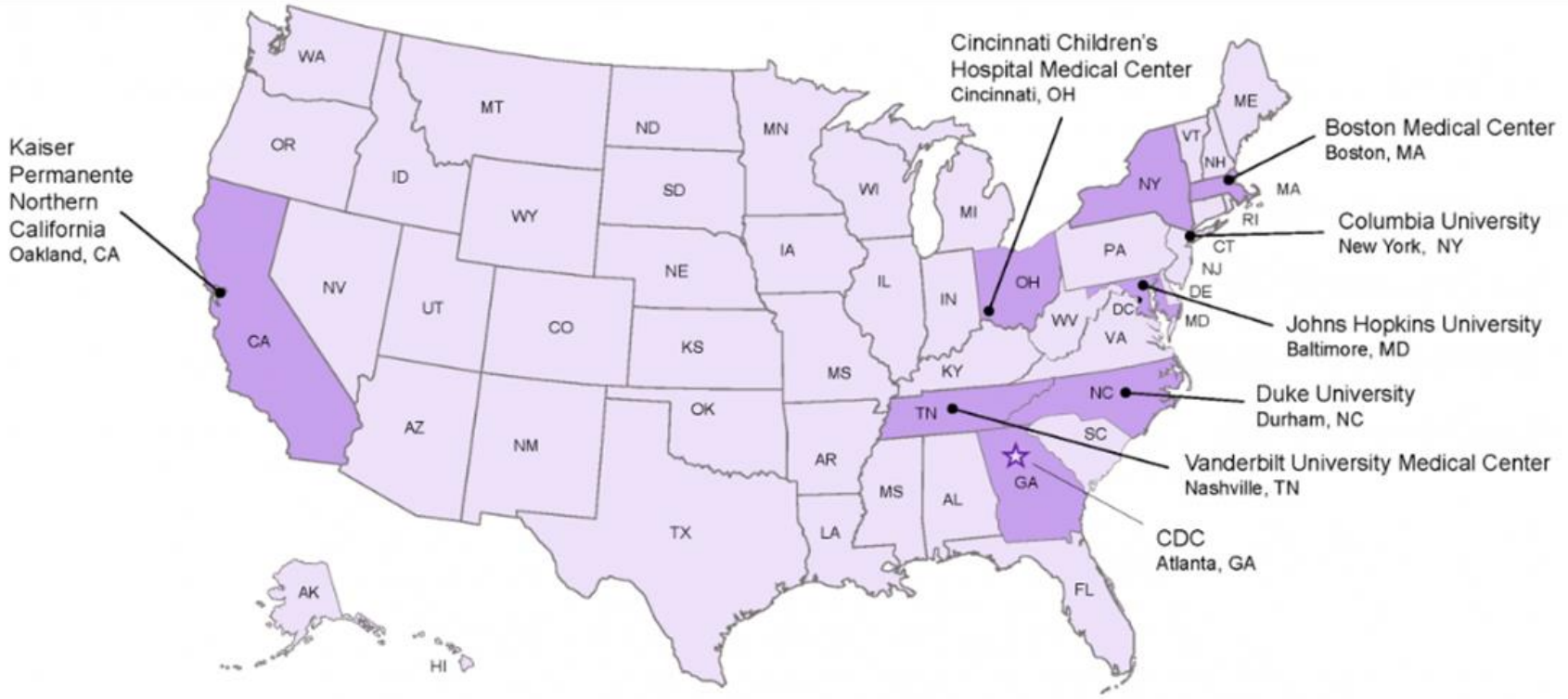
VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

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

Preliminary myocarditis/pericarditis reports to VAERS following mRNA COVID-19 vaccination by dose number
(after ~300 million mRNA doses administered, data thru Jun 11, 2021)

Manufacturer	Reports after dose 1	Reports after dose 2	Reports after unknown dose
Pfizer-BioNTech (n=791)	150	563	78
Moderna (n=435)	117	264	54
Total (N=1,226)	**267**	**827**	**132**

- Includes total preliminary reports identified through VAERS database searches for reports with myocarditis/pericarditis MedDRA* codes and pre-screened VAERS reports with signs and symptoms consistent with myocarditis/pericarditis
  - Follow-up, medical record review, application of CDC working case definition, and adjudication is ongoing or pending

* Medical Dictionary for Regulatory Activities https://www.meddra.org/

Characteristics of preliminary* myocarditis/pericarditis reports to VAERS following mRNA COVID-19 vaccination (data thru Jun 11, 2021)

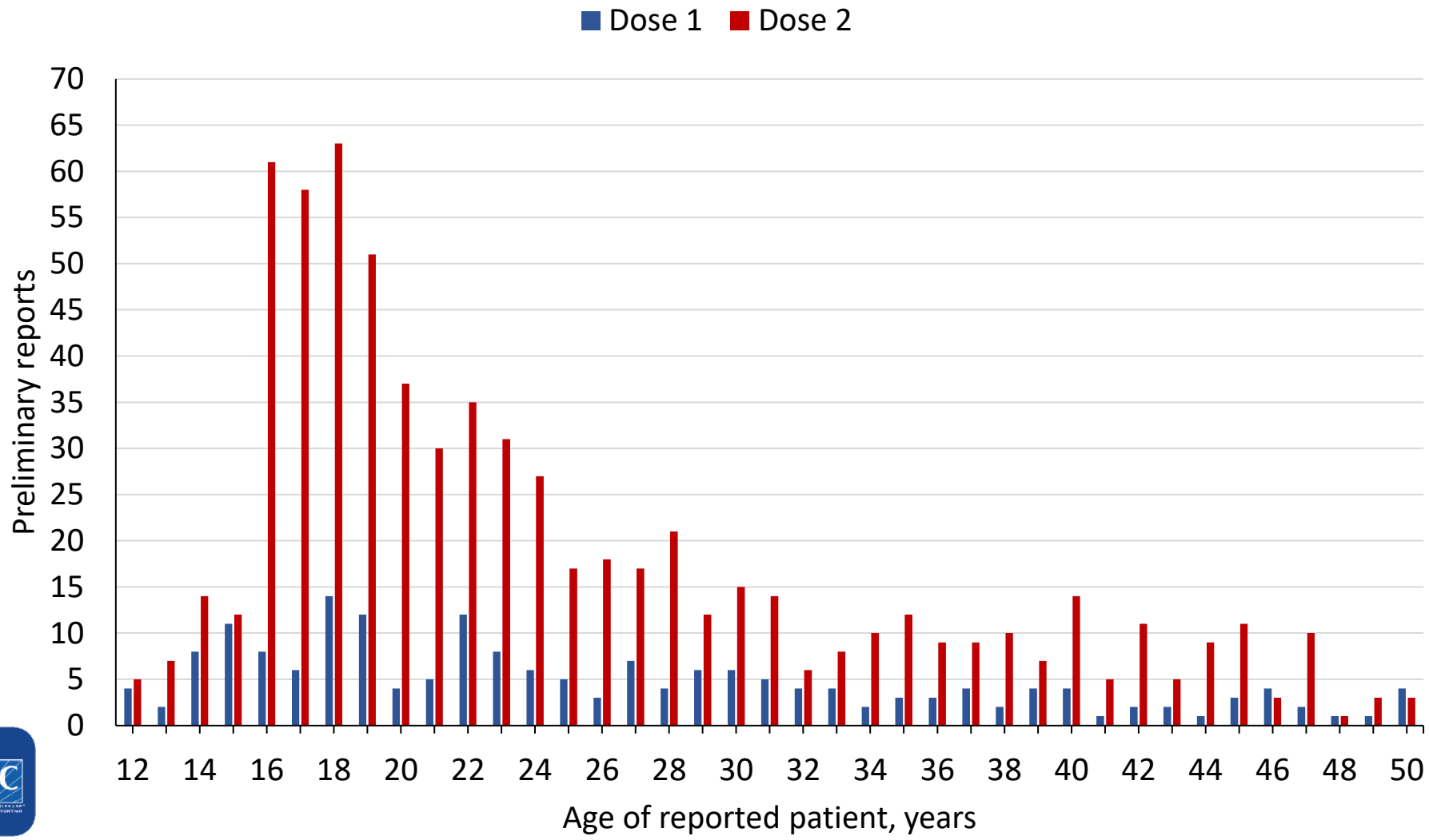
Characteristics	Dose 1 (n=267)	Dose 2 (n=827)
Median age, years (range)	30 (12–94)	24 (12–87)
Median time to symptom onset, days (range)	4 (0–61)†	3 (0–98)†
Sex (%)		
Male	176 (66%)	655 (79%)
Female	88 (33%)	165 (20%)
Not reported/not available	3 (1%)	7 (1%)

* Includes total reports identified through VAERS database searches for reports with myocarditis/pericarditis MedDRA codes and pre-screened VAERS reports with signs and symptoms consistent with myocarditis/pericarditis (and with dose number documented); Follow-up, medical record review, application of CDC working case definition, and adjudication is ongoing or pending

† One report of 179-day onset after dose 1; one report of 151-day onset after dose 2 – included in counts, but not in range

Preliminary reports of myocarditis/pericarditis to VAERS after mRNA COVID-19 vaccination by age and dose number*

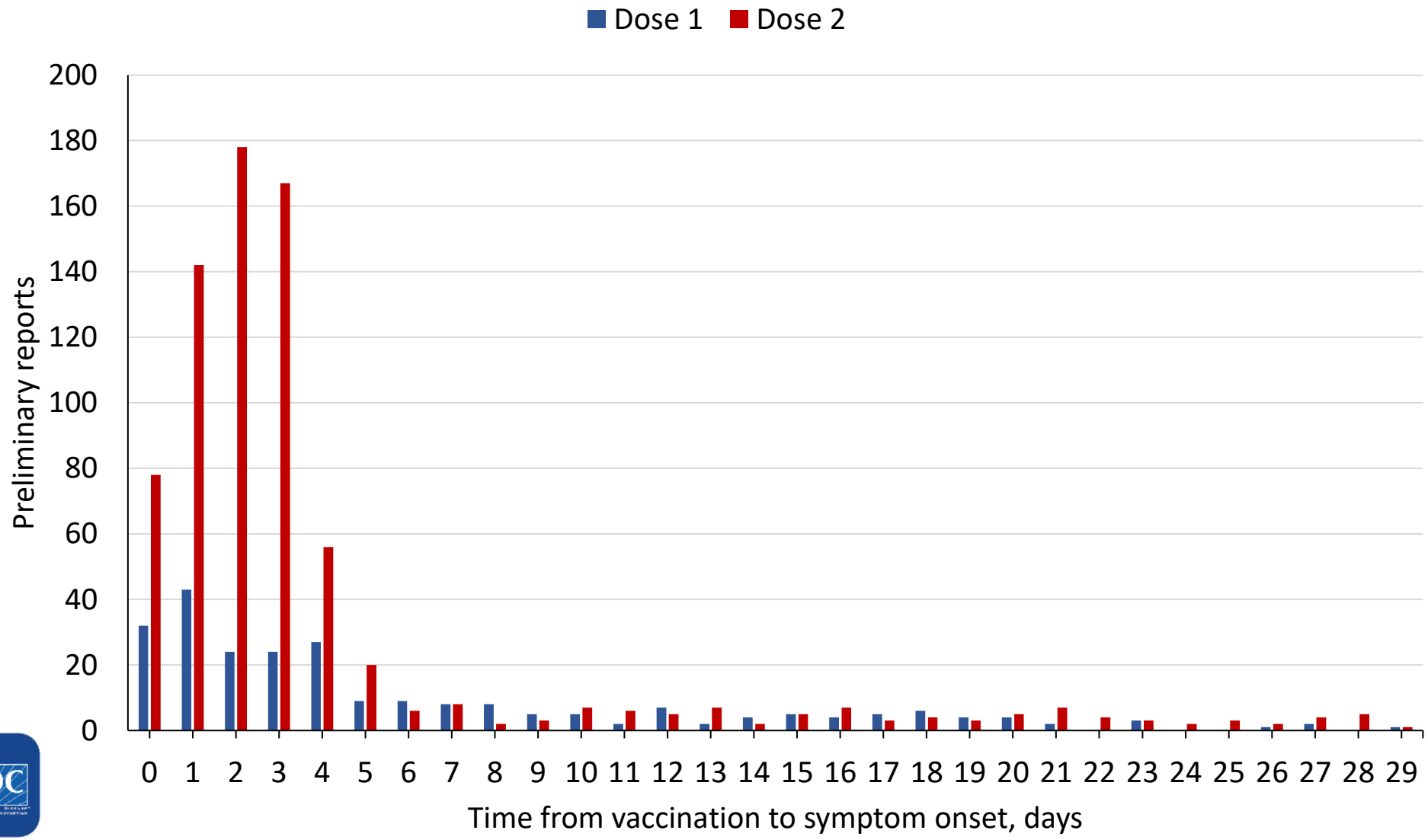
(as of Jun 11, 2021)



* Age truncated at >50yr: Reports of persons >50yr of age include 70 after Dose 1, 119 after Dose 2

Preliminary reports of myocarditis/pericarditis to VAERS after mRNA COVID-19 vaccination by dose number and time to symptom onset*

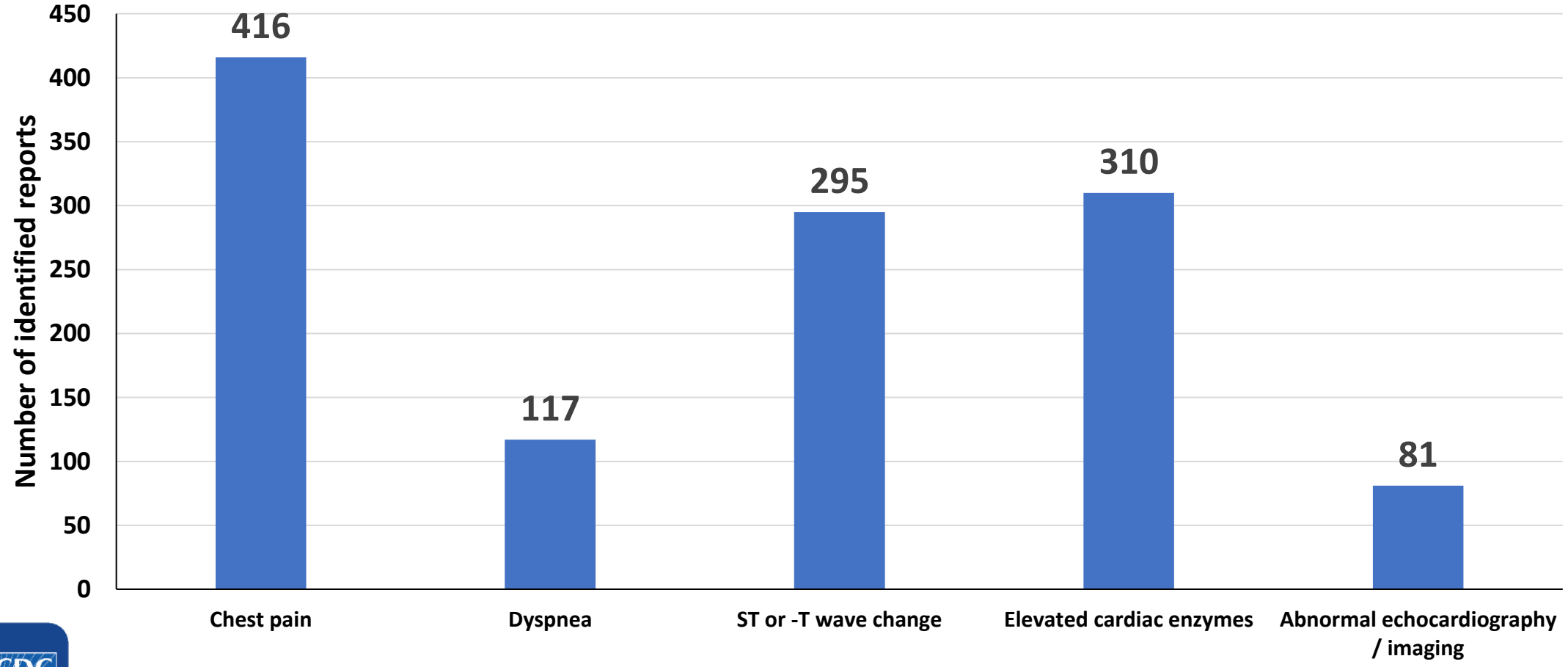
(as of Jun 11, 2021)



* Reports of time to symptom onset truncated at >29 days: Includes 5 reports after Dose 1, 56 after Dose 2

Symptoms and diagnostic findings of preliminary myocarditis/pericarditis reports after mRNA COVID-19 vaccination under review, limited to ≤29 years old (N=484)

(data thru Jun 11, 2021)



Care and outcomes of preliminary myocarditis/pericarditis cases reported to VAERS after mRNA COVID-19 vaccination in persons ≤29 years old (N=484) (data thru Jun 11, 2021)

484 total preliminary reports

- **323** have met CDC working case definition of myocarditis or pericarditis (or both)
- 148 are under review

Of 323 meeting case definition:

- 309 were hospitalized
  - 295 discharged
    - **218 (79%) known to have recovered from symptoms at time of report**
  - 9 still hospitalized (2 in ICU)
  - 5 without outcome data
- 14 were not hospitalized (seen in emergency dept., urgent care, outpatient clinic, not specified)

CDC working case definition for acute myocarditis

Acute Myocarditis

Clinical myocarditis

Probable Case

Presence of ≥ 1 new or worsening of the following clinical symptoms:

- chest pain/pressure/discomfort
- dyspnea/shortness of breath/pain with breathing
- palpitations
- syncope

OR, infants and children <12 years of age may instead present with ≥ 2 of:

- irritability
- vomiting
- poor feeding
- tachypnea
- lethargy

AND

≥ 1 new finding of:

- troponin level above upper limit of normal (any type of troponin)
- abnormal electrocardiogram (ECG or EKG) or rhythm monitoring findings consistent with myocarditis*
- abnormal cardiac function or wall motion abnormalities on echocardiogram
- cMRI findings consistent with myocarditis†

AND

- No other identifiable cause of the symptoms and findings

Confirmed Case

Presence of ≥ 1 new or worsening of the following clinical symptoms:

- chest pain/pressure/discomfort
- dyspnea/shortness of breath/pain with breathing
- palpitations
- syncope

OR, infants and children <12 years of age may instead present with ≥ 2 of:

- irritability
- vomiting
- poor feeding
- tachypnea
- lethargy

AND

- Histopathologic confirmation of myocarditis§

OR

- Troponin level above upper limit of normal (any type of troponin), **AND**
- cMRI findings consistent with myocarditis†

AND

- No other identifiable cause of the symptoms and findings

---

*To meet the ECG or rhythm monitoring criterion, must include at least one of:

- ST-segment or T-wave abnormalities
- Paroxysmal or sustained atrial, supraventricular, or ventricular arrhythmias
- AV nodal conduction delays or intraventricular conduction defects

†Using either the original or the revised Lake Louise criteria (Ferreira et al. *J Am Coll Cardiol.* 2018;72:3158-76)
§Using the Dallas criteria (Aretz et al. *Am J Cardiovasc Pathol.* 1987;1:3-14)

Notes:
1. Autopsy cases may be classified as confirmed clinical myocarditis on the basis of meeting histopathologic criteria if no other identifiable cause
2. Cases with individuals who lack the listed symptoms but who meet other criteria may be classified as subclinical myocarditis (probable or confirmed)

CDC working case definition for acute pericarditis

Acute Pericarditis

Presence of ≥2 new or worsening of the following clinical features:

- acute chest pain*
- pericardial rub on exam,
- new ST-elevation or PR-depression on EKG, or
- new or worsening pericardial effusion on echocardiogram or MRI

*typically described as pain made worse by lying down, deep inspiration, or cough and relieved by sitting up or leaning forward, although other types of chest pain may occur.

Notes:

1. Autopsy cases may be classified as pericarditis on basis of meeting histopathologic criteria of the pericardium

Myopericarditis

This term may be used for patients who meet criteria for both myocarditis and pericarditis.

Preliminary myocarditis/pericarditis reports to VAERS following dose 1 mRNA COVID-19 vaccination, Exp. vs. Obs. using 21-day risk window (data thru Jun 11, 2021)

Age groups	Females			Male		
	Doses admin	Expected*,†	Observed*	Doses admin	Expected*,†	Observed*
12–17 yrs	3,777,097	1–13	4	3,569,239	2–21	**32**
18–24 yrs	6,830,706	2–23	9	5,863,268	3–34	**47**
25–29 yrs	5,198,356	2–18	3	4,685,036	3–27	18
30–39 yrs	11,505,068	7–66	15	10,391,499	6–60	17
40–49 yrs	11,996,507	7–69	9	10,513,258	6–60	8
50–64 yrs	21,957,007	13–126	22	19,270,825	11–111	18
65+ yrs	24,795,212	14–143	13	20,473,779	12–118	15
Not reported	—	—	2	—	—	4

* Assumes a 21-day post-vaccination observation window (i.e., symptom onset from day of vaccination through Day 20 after vaccination)

† Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8. Expected counts among females 12–29 years adjusted for lower prevalence relative to males by factor of 1.7 (Fairweather, D. et al, *Curr Probl Cardiol.* 2013;38(1):7-46).

Preliminary myocarditis/pericarditis reports to VAERS following dose 1 mRNA COVID-19 vaccination, Exp. vs. Obs. using 7-day risk window (data thru Jun 11, 2021)

Age groups	Females			Males		
	Doses admin	Expected*,†	Observed*	Doses admin	Expected*,†	Observed*
12–17 yrs	3,777,097	0–4	3	3,569,239	1–7	**27**
18–24 yrs	6,830,706	1–8	6	5,863,268	1–11	**41**
25–29 yrs	5,198,356	1–6	2	4,685,036	1–9	**14**
30–39 yrs	11,505,068	1–13	8	10,391,499	2–20	14
40–49 yrs	11,996,507	1–14	1	10,513,258	2–20	5
50–64 yrs	21,957,007	2–25	16	19,270,825	4–37	10
65+ yrs	24,795,212	2–25	8	20,473,779	4–39	8
Not reported	—	—	2	—	—	2

* Assumes a 7-day post-vaccination observation window (i.e., symptom onset from day of vaccination through Day 6 after vaccination)

† Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8. Expected counts among females 12–29 years adjusted for lower prevalence relative to males by factor of 1.7 (Fairweather, D. et al, *Curr Probl Cardiol.* 2013;38(1):7-46).

Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA COVID-19 vaccination, Exp. vs. Obs. using 21-day risk window (data thru Jun 11, 2021)

Age groups	Females			Males		
	Doses admin	Expected*,†	Observed*	Doses admin	Expected*,†	Observed*
12–17 yrs	2,189,726	1–7	**20**	2,039,871	1–12	**132**
18–24 yrs	5,237,262	2–18	**27**	4,337,287	2–25	**233**
25–29 yrs	4,151,975	1–15	11	3,625,574	2–21	**69**
30–39 yrs	9,356,296	5–54	14	8,311,301	5–48	**71**
40–49 yrs	9,927,773	6–57	23	8,577,766	5–49	40
50–64 yrs	18,696,450	11–108	25	16,255,927	9–94	34
65+ yrs	21,708,975	12–125	17	18,041,547	10–104	16
Not reported	—	—	1	—	—	9

* Assumes a 21-day post-vaccination observation window (i.e., symptom onset from day of vaccination through Day 20 after vaccination)

† Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8. Expected counts among females 12–29 years adjusted for lower prevalence relative to males by factor of 1.7 (Fairweather, D. et al, *Curr Probl Cardiol.* 2013;38(1):7-46).

Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. using 7-day risk window (data thru Jun 11, 2021)

Age groups	Females			Males		
	Doses admin	Expected*,†	Observed*	Doses admin	Expected*,†	Observed*
12–17 yrs	2,189,726	0–2	**19**	2,039,871	0–4	**128**
18–24 yrs	5,237,262	1–6	**23**	4,337,287	1–8	**219**
25–29 yrs	4,151,975	0–5	**7**	3,625,574	1–7	**59**
30–39 yrs	9,356,296	2–18	11	8,311,301	2–16	**61**
40–49 yrs	9,927,773	2–19	18	8,577,766	2–16	**34**
50–64 yrs	18,696,450	4–36	18	16,255,927	3–31	18
65+ yrs	21,708,975	4–42	10	18,041,547	3–35	11
Not reported	—	—	1	—	—	8

* Assumes a 7-day post-vaccination observation window (i.e., symptom onset from day of vaccination through Day 6 after vaccination)

† Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8. Expected counts among females 12–29 years adjusted for lower prevalence relative to males by factor of 1.7 (Fairweather, D. et al, *Curr Probl Cardiol.* 2013;38(1):7-46).

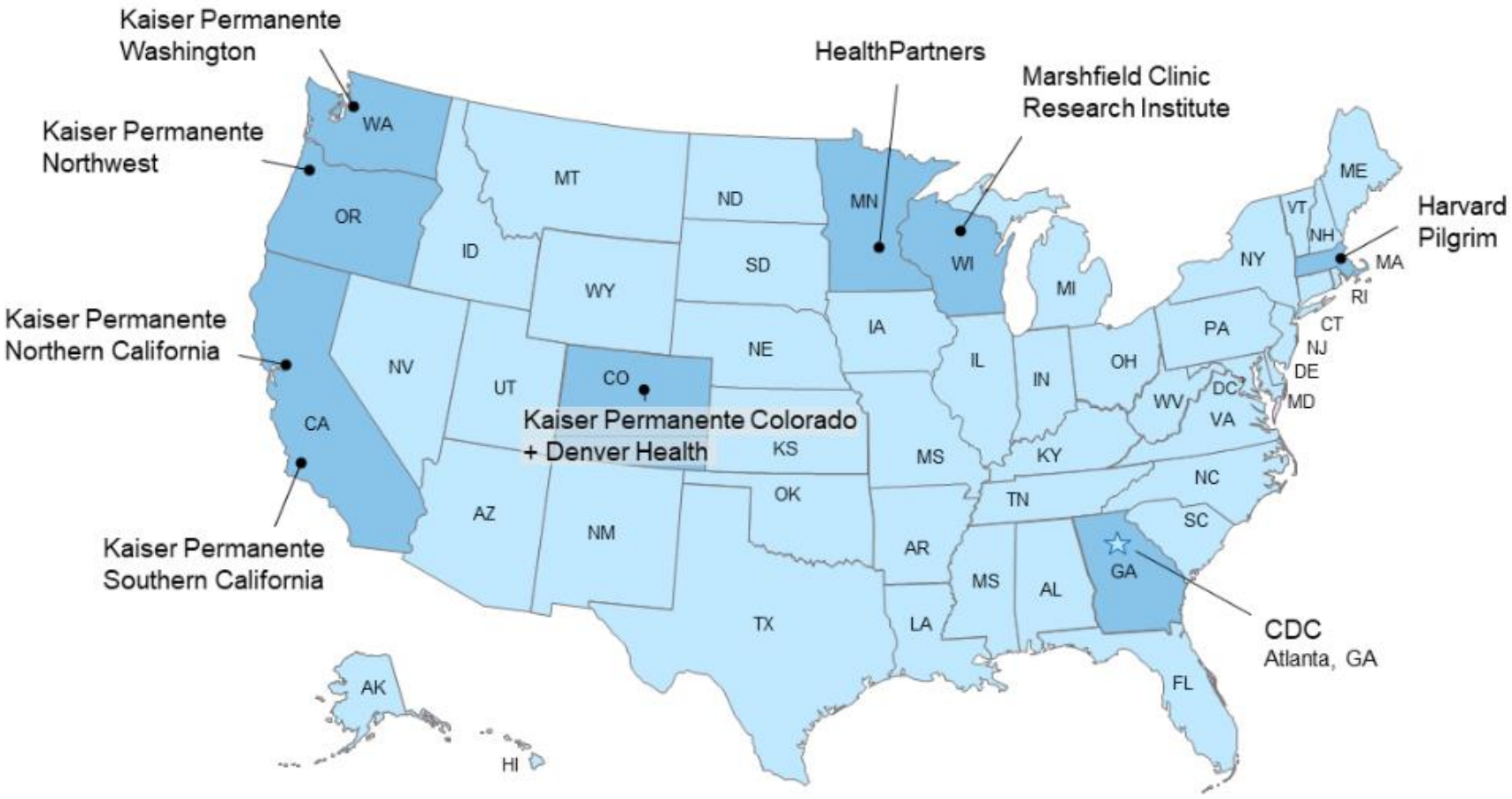
Preliminary myocarditis/pericarditis crude reporting rates to VAERS following mRNA COVID-19 vaccination (data thru Jun 11, 2021)

	Overall reporting rate per million doses			Reporting rate in females per million doses			Reporting rate in males per million doses		
Age groups	All doses	Dose 1	Dose 2	All doses	Dose 1	Dose 2	All doses	Dose 1	Dose 2
12-17 yrs	18.1	5.3	37.0	4.2	1.1	9.1	32.4	9.8	66.7
18-24 yrs	15.9	4.8	28.4	3.6	1.5	5.5	30.7	8.7	56.3
25-29 yrs	6.7	2.5	10.8	2.0	0.8	2.6	12.2	4.5	20.4
30-39 yrs	4.2	1.7	5.6	1.8	1.4	1.8	6.9	2.0	10.0
40-49 yrs	2.7	0.9	3.8	2.0	0.9	2.8	3.5	1.0	5.1
50-64 yrs	1.7	1.0	2.0	1.6	1.0	1.8	1.9	1.0	2.3
65+ yrs	1.1	0.7	1.3	1.1	0.6	1.2	1.2	0.7	1.4

- Myocarditis/pericarditis reports per million mRNA vaccine doses administered by sex and dose number with no restrictions on post-vaccination observation time

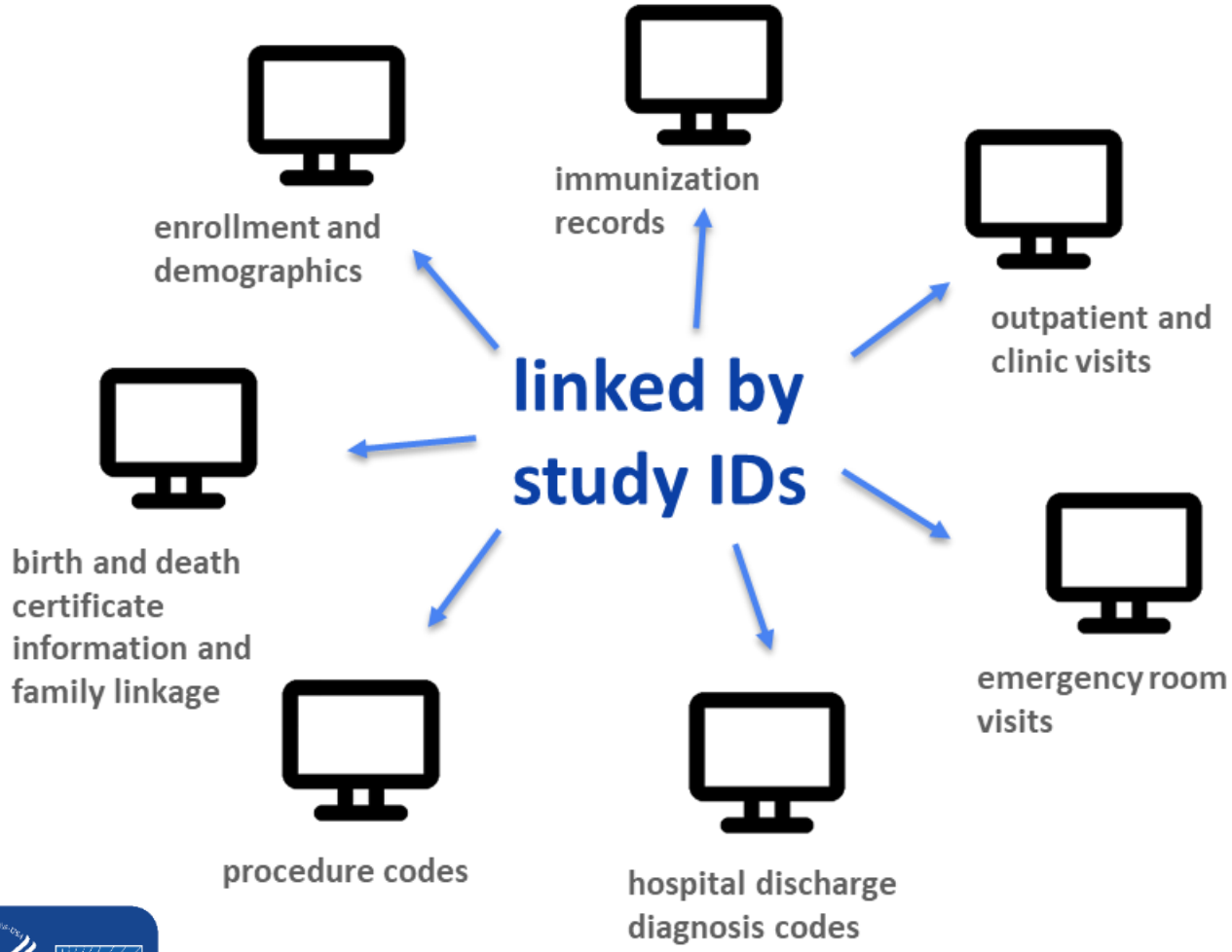
VSD

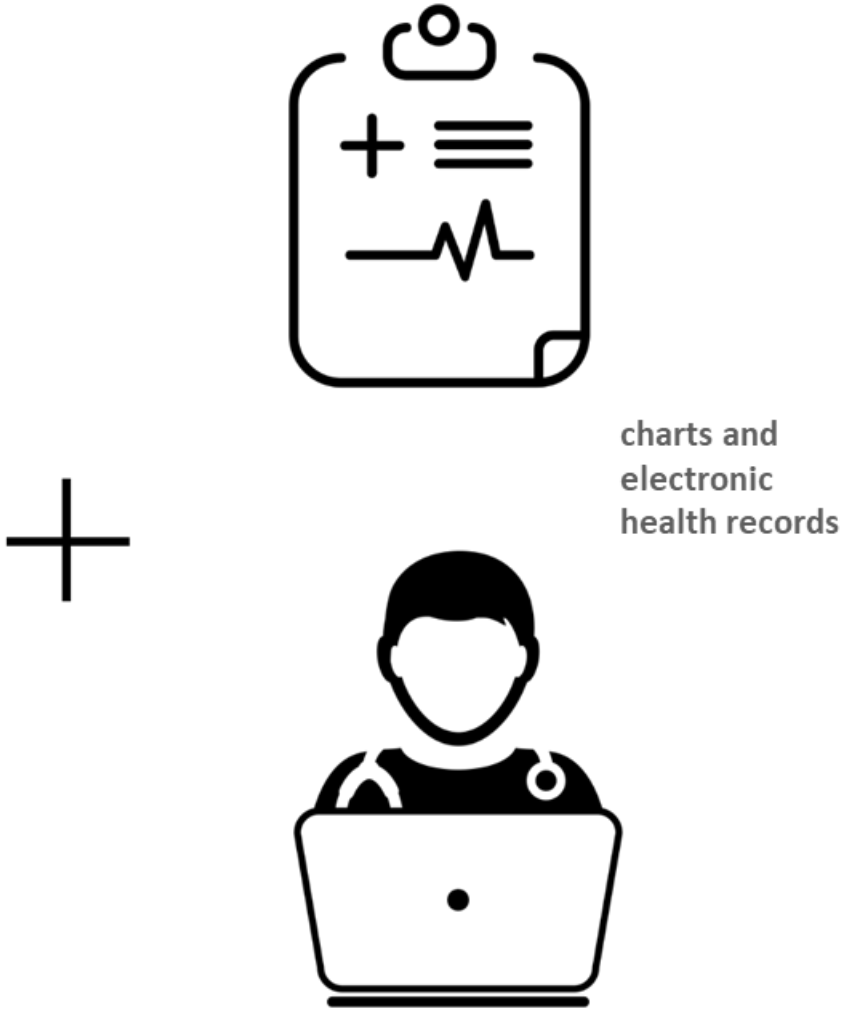
Vaccine Safety Datalink



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

Types of information in VSD



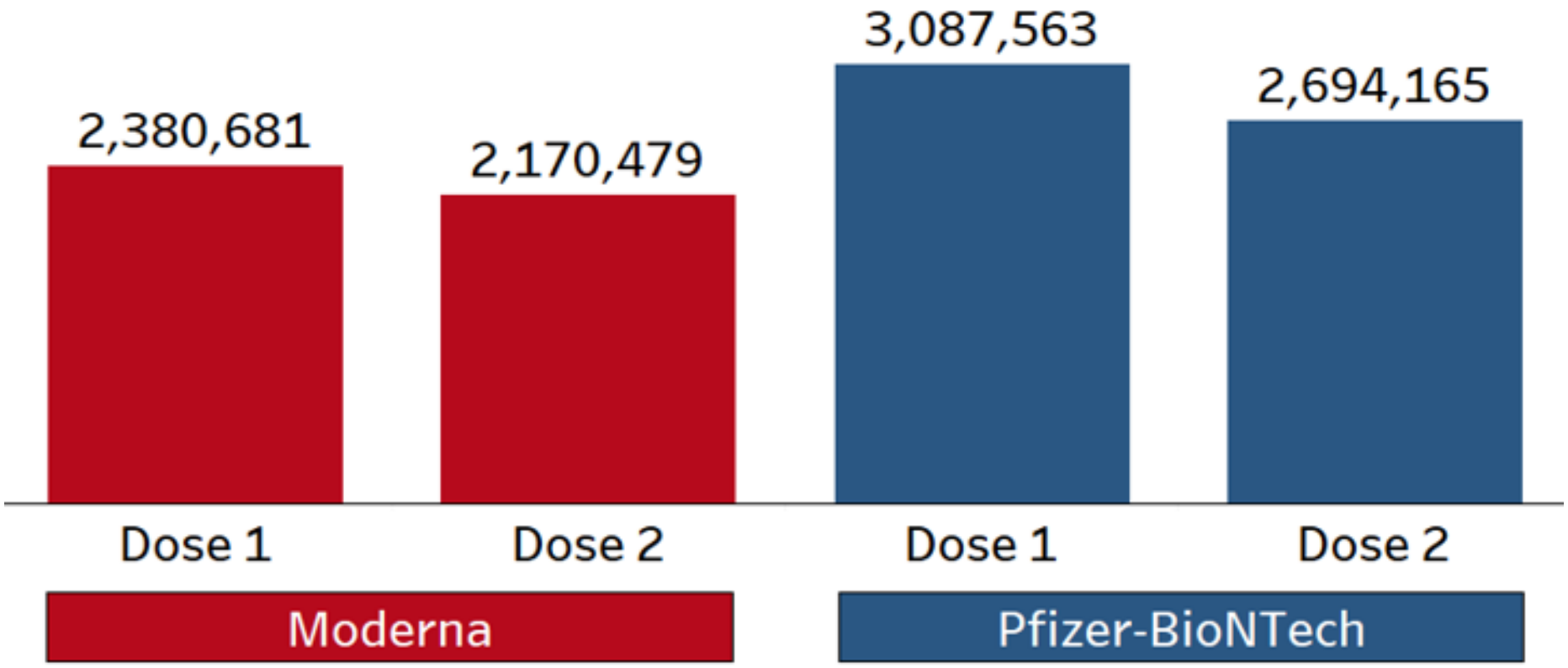


Images created by Wilson Joseph, Megan Mitchell, Ananth, and Iga from the noun project

VSD Rapid Cycle Analysis (RCA) safety monitoring

- Near real-time sequential (i.e., weekly) monitoring as data become available
- Monitors a limited set of prespecified vaccine safety outcomes
- A public health surveillance activity, not the same as an epidemiologic study
- Designed to detect statistically significant associations and statistical signals (values above specified statistical thresholds), which do not necessarily indicate a safety problem
- Statistical signals detected through RCA require further evaluation

COVID-19 vaccine doses administered in the VSD
(thru Jun 12, 2021)



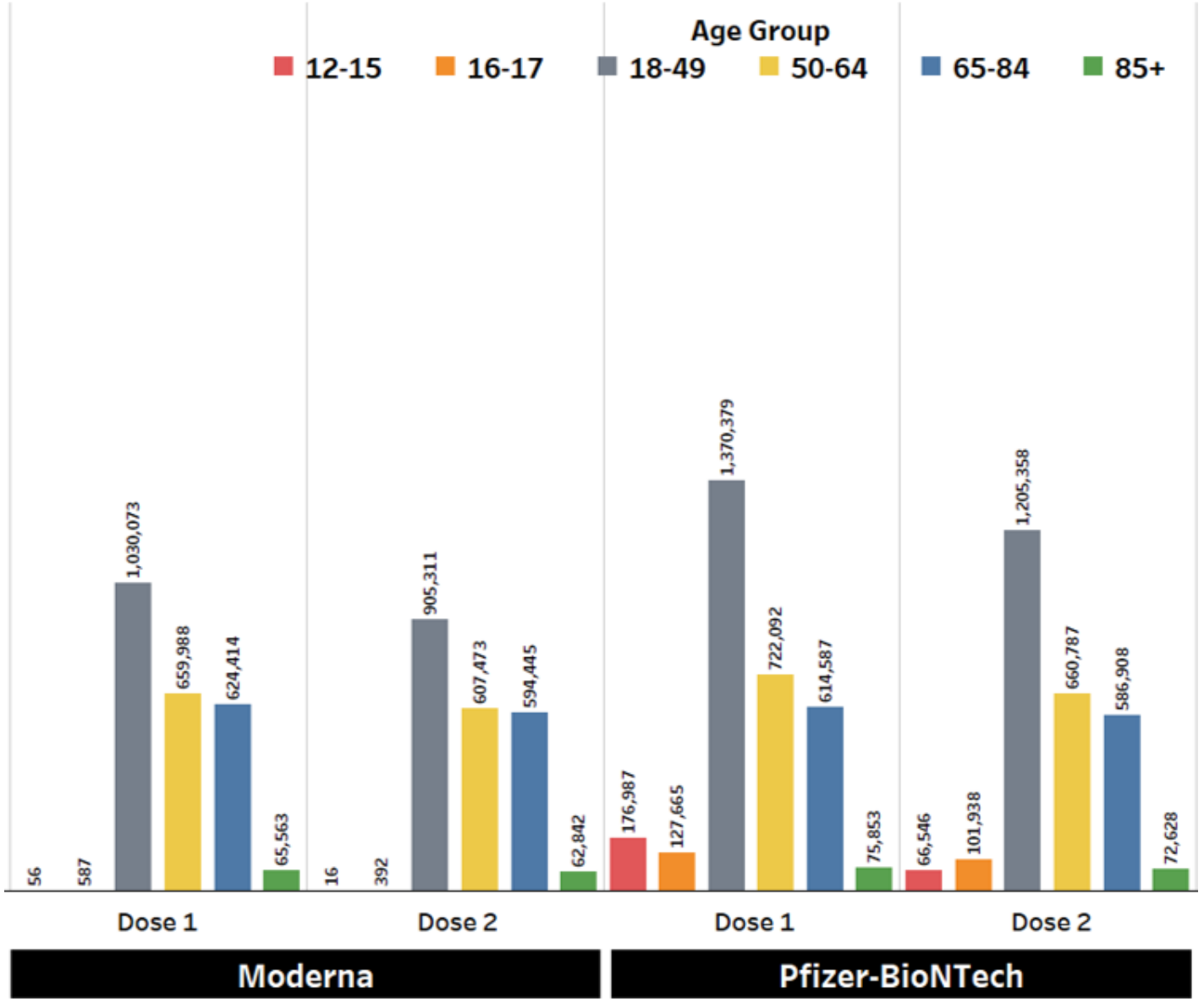
4,551,160
total doses

5,781,728
total doses

COVID-19 vaccine doses administered by age group in the VSD
(thru Jun 12, 2021)

Pfizer-BioNTech doses

- 12–15-year-olds
  - 176,987 first doses
  - 66,546 second doses
- 16–17-year-olds
  - 127,665 first doses
  - 101,938 second doses



VSD Rapid Cycle Analysis: Outcome events in the 21-day risk interval after either dose of any mRNA vaccine compared with outcome events in vaccinated comparators on the same calendar days

(thru Jun 12, 2021)

Pre-specified outcome event	Events in risk interval	Adj Rate Ratio*	95% CI	Signal
Acute disseminated encephalomyelitis	2	.	0.07 - ne	no
Acute myocardial infarction	578	0.99	0.85 - 1.15	no
Appendicitis	691	0.80	0.70 - 0.90	no
Bell's palsy	493	0.97	0.83 - 1.15	no
Cerebral venous sinus thrombosis	5	1.15	0.23 - 6.67	no
Disseminated intravascular coagulation	28	0.65	0.35 - 1.20	no
Encephalitis / myelitis / encephalomyelitis	15	0.94	0.35 - 2.77	no
Guillain-Barré syndrome	8	0.57	0.16 - 2.15	no
Stroke, hemorrhagic	227	0.81	0.64 - 1.03	no
Stroke, ischemic	1009	0.98	0.87 - 1.10	no
Immune thrombocytopenia	45	1.03	0.59 - 1.85	no
Kawasaki disease	0	0.00	0.00 - 2.60	no
Myocarditis / pericarditis	75	1.07	0.70 - 1.67	**no**
Seizures	266	1.03	0.82 - 1.30	no
Transverse myelitis	3	1.88	0.17 - 55.81	no
Thrombotic thrombocytopenic purpura	5	1.39	0.27 - 8.02	no
Thrombosis with thrombocytopenia syndrome (TTS)	66	0.79	0.52 - 1.20	no
Venous thromboembolism	579	1.07	0.92 - 1.25	no
Pulmonary embolism	484	0.99	0.84 - 1.18	no

* Adjusted for VSD site, 5-year age group, sex, race/ethnicity, and calendar date. ne=not estimable

VSD age-stratified analysis: Chart confirmed myocarditis/pericarditis events in 12–39-year-olds in the 21-day risk interval compared with events in vaccinated comparators on the same calendar days

(thru Jun 5, 2021)

Vaccine (dose #)	Events in risk interval	Adj Rate ratio*	95% CI
Any mRNA (both doses)	26	3.5	1.1–15.0
Any mRNA (dose 1)	8	3.7	0.8–23.4
Any mRNA (dose 2)	18	3.6	1.1–15.7
Pfizer-BioNTech (both doses)	10	1.2	0.3–6.2
Pfizer-BioNTech (dose 1)	3	1.6	0.2–12.6
Pfizer-BioNTech (dose 2)	7	1.5	0.3–7.7
Moderna (both doses)†	16	.	2.4–ne‡
Moderna (dose 1)	5	.	0.8–ne‡
Moderna (dose 2)	11	.	2.4–ne‡

* Adjusted for VSD site, 5-year age group and then the single year of age for 12-19 year olds, sex, race/ethnicity, and calendar date

† Moderna COVID-19 Vaccine is not authorized in persons aged <18 years

‡ ne=not estimable, no events in comparison interval (22–42 days after final dose)

VSD age-stratified analysis: Chart confirmed myocarditis/pericarditis events in 12–39-year-olds in the 7-day risk interval compared with events in vaccinated comparators on the same calendar days

(thru Jun 5, 2021)

Vaccine (dose #)	Events in risk interval	Adj Rate ratio*	95% CI
Any mRNA (both doses)	22	10.0	2.9–46.5
Any mRNA (dose 1)	4	6.2	0.9–69.8
Any mRNA (dose 2)	18	10.8	3.2–49.0
Pfizer-BioNTech (both doses)	7	2.4	0.4–24.9
Pfizer-BioNTech (dose 1)	0	0	0–20.4
Pfizer-BioNTech (dose 2)	7	6.0	1.1–53.6
Moderna (both doses)†	15	.	6.9–ne
Moderna (dose 1)	4	.	2.1–ne
Moderna (dose 2)	11	.	6.6–ne

* Adjusted for VSD site, 5-year age group, sex, race/ethnicity, and calendar date

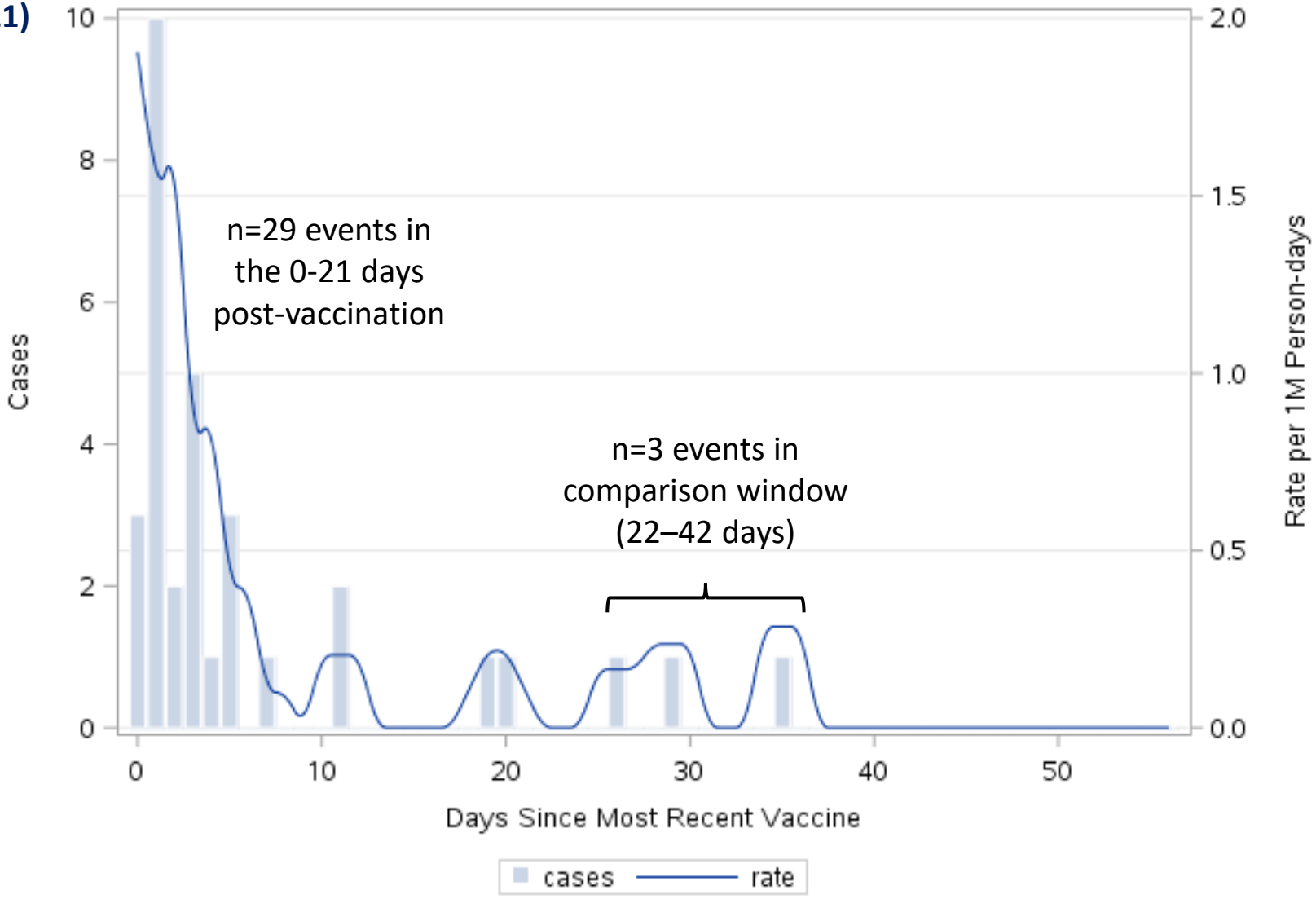
† Moderna COVID-19 Vaccine is not authorized in persons aged <18 years

‡ ne=not estimable, no events in comparison interval (22–42 days after final dose)

Chart confirmed myocarditis/pericarditis cases in VSD by day of symptom onset since most recent mRNA COVID-19 vaccination, 12–39-year-olds

(thru Jun 5, 2021)

- Most likely clusters
  - Days 0–5
  - Days 0–3
  - Days 0–6
- All have a p-value <0.000001
- Parameters for the scan
  - Includes days 0–56
  - Scans all possible windows of length 1–28 days



Myocarditis/pericarditis chart confirmed rates in VSD in 21-day risk interval, 12–39-year-olds

(thru Jun 5, 2021)

Vaccine(s) (dose #)	Cases	Doses admin	Rate per million doses (95% CI)
mRNA (both doses)	26	3,418,443	8 (5.3–11.8)
mRNA (dose 1)	8	1,879,585	4.4 (1.9–8.8)
mRNA (dose 2)	18	1,538,858	12.6 (7.5–19.9)
Pfizer-BioNTech (dose 1)	3	1,211,080	2.6 (0.5–7.7)
Pfizer-BioNTech (dose 2)	7	958,721	8.0 (3.2–16.5)
Moderna (dose 1)	5	668,505	7.5 (2.4–17.6)
Moderna (dose 2)	11	580,137	19.8 (9.9–35.5)

Care and status of chart confirmed myocarditis/pericarditis cases in VSD within 0–21 days following mRNA COVID-19 vaccination (N=29)*

Care and status	n (%)
Highest level of care received	
Outpatient	1 (3.4)
Emergency department	4 (13.8)
Inpatient hospitalization	22 (75.9)
Intensive care unit (ICU)	2 (5.7)
Median length of hospital stay (days, range)	1 (0–13)
Discharged to home at time of chart review	29 (100)
Follow-up visit noted at time of chart review	27 (93.1)

* 3 of the 29 cases (10.3%) had a history of COVID-19 infection

Follow-up qualitative summary

Current symptoms

- Nearly all follow-up visit notes indicated resolution of symptoms at the time of follow-up
- Of those that had follow-up ECG/echo, lab testing, most had returned to normal or baseline

Ongoing treatment/plan

- Most follow-up visit notes indicate tapering of some medications (NSAIDS, prednisone, etc.)
- Notes indicated maintenance of colchicine and activity limitations for 3–6 months

Myocarditis/pericarditis rates based on ICD-10 coded cases in VSD in 21-day risk interval, ages 12–39 years old

(thru Jun 5, 2021)

Product (dose)	Female cases	Female rates per million doses (95% CI)	Male cases	Male rates per million doses (95% CI)
Any mRNA (both doses)	6	3.2 (1.2–6.9)	26	16.9 (11.0–24.8)
Any mRNA (dose 1)	2	1.9 (0.2–7.0)	4	4.7 (1.3–12.0)
Any mRNA (dose 2)	4	4.7 (1.3–12.0)	22	32.0 (20.1–48.5)
Pfizer-BioNTech (both doses)	1	0.8 (0.0–4.7)	11	11.1 (5.5–19.8)
Pfizer-BioNTech (dose 1)	1	1.5 (0.0–8.5)	1	1.8 (0.0–10.0)
Pfizer-BioNTech (dose 2)	0	. (. – .)	10	23.0 (11.0–42.3)
Moderna (both doses)	5	7.1 (2.3–16.6)	15	27.5 (15.4–45.4)
Moderna (dose 1)	1	2.7 (0.1–14.9)	3	10.2 (2.1–29.9)
Moderna (dose 2)	4	12.2 (3.3–31.2)	12	47.7 (24.6–83.3)

Preliminary myocarditis/pericarditis crude reporting rates to VAERS following mRNA COVID-19 vaccination (data thru Jun 11, 2021)

	Overall reporting rate per million doses			Reporting rate in females per million doses			Reporting rate in males per million doses		
Age groups	**All doses**	**Dose 1**	**Dose 2**	**All doses**	**Dose 1**	**Dose 2**	**All doses**	**Dose 1**	**Dose 2**
12-17 yrs	18.1	5.3	37.0	4.2	1.1	9.1	32.4	9.8	66.7
18-24 yrs	15.9	4.8	28.4	3.6	1.5	5.5	30.7	8.7	56.3
25-29 yrs	6.7	2.5	10.8	2.0	0.8	2.6	12.2	4.5	20.4
30-39 yrs	4.2	1.7	5.6	1.8	1.4	1.8	6.9	2.0	10.0
40-49 yrs	2.7	0.9	3.8	2.0	0.9	2.8	3.5	1.0	5.1
50-64 yrs	1.7	1.0	2.0	1.6	1.0	1.8	1.9	1.0	2.3
65+ yrs	1.1	0.7	1.3	1.1	0.6	1.2	1.2	0.7	1.4

- Myocarditis/pericarditis reports per million mRNA vaccine doses administered by sex and dose number with no restrictions on post-vaccination observation time

Summary

Summary

- Initial safety findings from Pfizer-BioNTech COVID-19 vaccination of 12–15-year-olds from v-safe and VAERS surveillance are consistent with results from pre-authorization clinical trials
- Analysis of VAERS preliminary reports of myocarditis/pericarditis is in progress, including follow-up to obtain medical records, complete reviews, apply CDC working case definition, and adjudicate cases
- Preliminary VAERS findings suggest:
  - Median age of reported patients is younger for reports after dose 2 vs. dose 1
  - Symptom onset clusters within the week following vaccination (mostly within 4 days)
  - Predominance of male patients in younger age groups, especially after dose 2
  - Observed reports > expected cases, especially after dose 2 in younger age groups
- Early VSD data for myocarditis/pericarditis in 12–39-year-olds also suggest:
  - More cases after mRNA COVID-19 vaccination with dose 2 vs. dose 1
  - Rate of 12.6 cases per million 2nd doses of any mRNA vaccine in the 21 days following vaccination
    - Rates appear higher in males vs. females
  - Clustering of myocarditis/pericarditis within the week following vaccination (most likely 0–5 days)
- Available outcome data indicate that patients generally recover from symptoms and do well

Next steps for assessing myocarditis/pericarditis following mRNA COVID-19 vaccination

- Continue monitoring in VAERS
  - Follow-up to obtain medical records, conduct case reviews, apply CDC working case definition, and adjudicate case reports
  - Surveillance review focusing on myocarditis and myopericarditis to describe epidemiology and characterize clinical features of cases is in progress
- Continue monitoring and assessment in VSD
  - Quantify risk and characterize clinical features of cases
- Conduct follow-up on vaccine-associated cases to assess longer-term outcomes (i.e., at 3–6 months)

CDC educational materials*

Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination

Updated May 27, 2021 Languages Print

What You Need to Know

- More than 165 million people have received at least one dose of COVID-19 vaccine in the United States, and CDC continues to monitor the safety of COVID-19 vaccines for any health problems that happen after vaccination.
- Since April 2021, there have been increased reports to the Vaccine Adverse Event Reporting System (VAERS) of cases of inflammation of the heart—called myocarditis and pericarditis—happening after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna) in the United States.
- These reports are rare, given the number of vaccine doses administered, and have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults.
- CDC and its partners are actively monitoring these reports, by reviewing data and medical records, to learn more about what happened and to see if there is any relationship to COVID-19 vaccination.
- Most patients who received care responded well to medicine and rest and quickly felt better.

Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults

Summary

Since April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults. There has not been a similar reporting pattern observed after receipt of the Janssen COVID-19 Vaccine (Johnson & Johnson).

In most cases, patients who presented for medical care have responded well to medications and rest and had prompt improvement of symptoms. Reported cases have occurred predominantly in male adolescents and young adults 16 years of age and older. Onset was typically within several days after mRNA COVID-19 vaccination, and cases have occurred more often after the second dose than the first dose. CDC and its partners are investigating these reports of myocarditis and pericarditis following mRNA COVID-19 vaccination.

CDC continues to recommend COVID-19 vaccination for everyone 12 years of age and older given the risk of COVID-19 illness and related, possibly severe complications, such as long-term health problems, hospitalization, and even death.

* CDC: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html and https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html

How to report an adverse event to VAERS

- Go to vaers.hhs.gov
- Submit a report online
- For help:

  Call 1-800-822-7967

  Email info@VAERS.org

  video instructions https://youtu.be/sbCWhcQADFE

- Please send records to VAERS ASAP if contacted and asked
  - HIPAA permits reporting of protected health information to public health authorities including CDC and FDA

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COVID-19 Vaccine Task Force
Vaccine Safety Team
Immunization Safety Office
Division of Healthcare Quality Promotion
Clinical Immunization Safety Assessment Project
Vaccine Safety Datalink

Food and Drug Administration

Center for Biologics Evaluation and Research

CDC vaccine safety monitoring

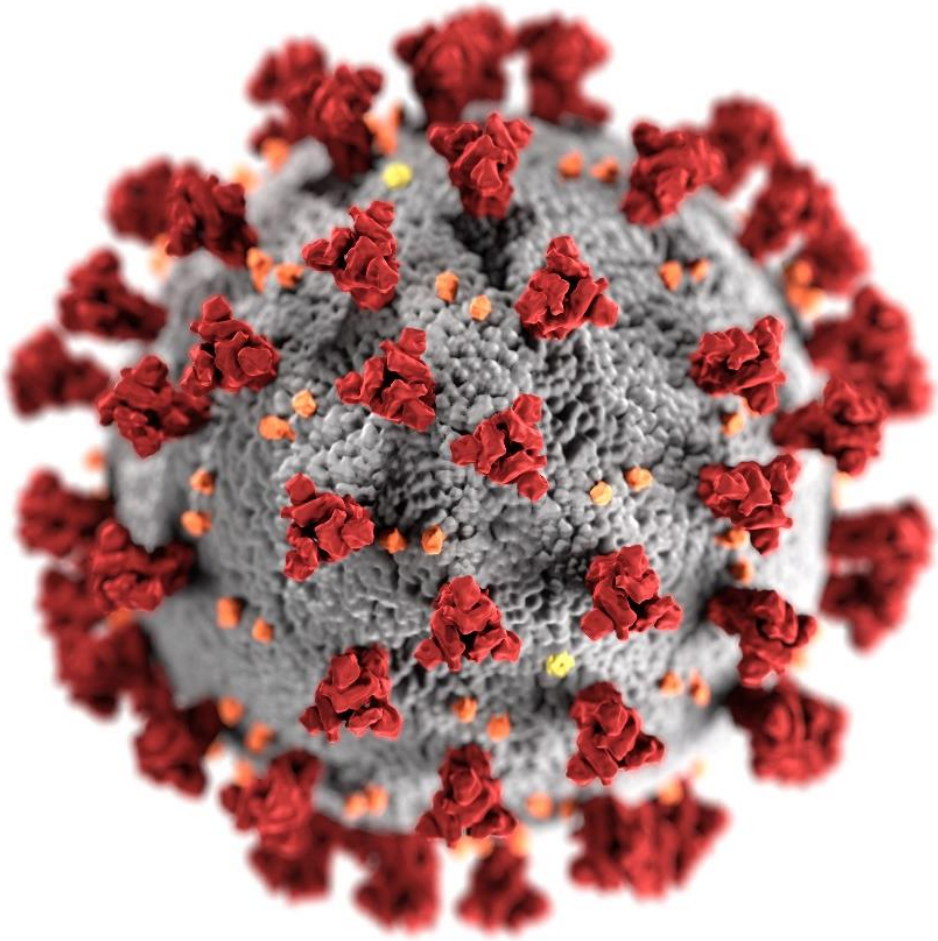
- Authorized COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**
- Strong, complementary systems are in place—both new and established

v-safe	VAERS	VSD	CISA Project

Full list of U.S. COVID-19 vaccine safety monitoring systems

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

Thank you!



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.