COVID-19 vaccine safety updates: Primary series in children ages 5–11 years

Advisory Committee on Immunization Practices (ACIP)

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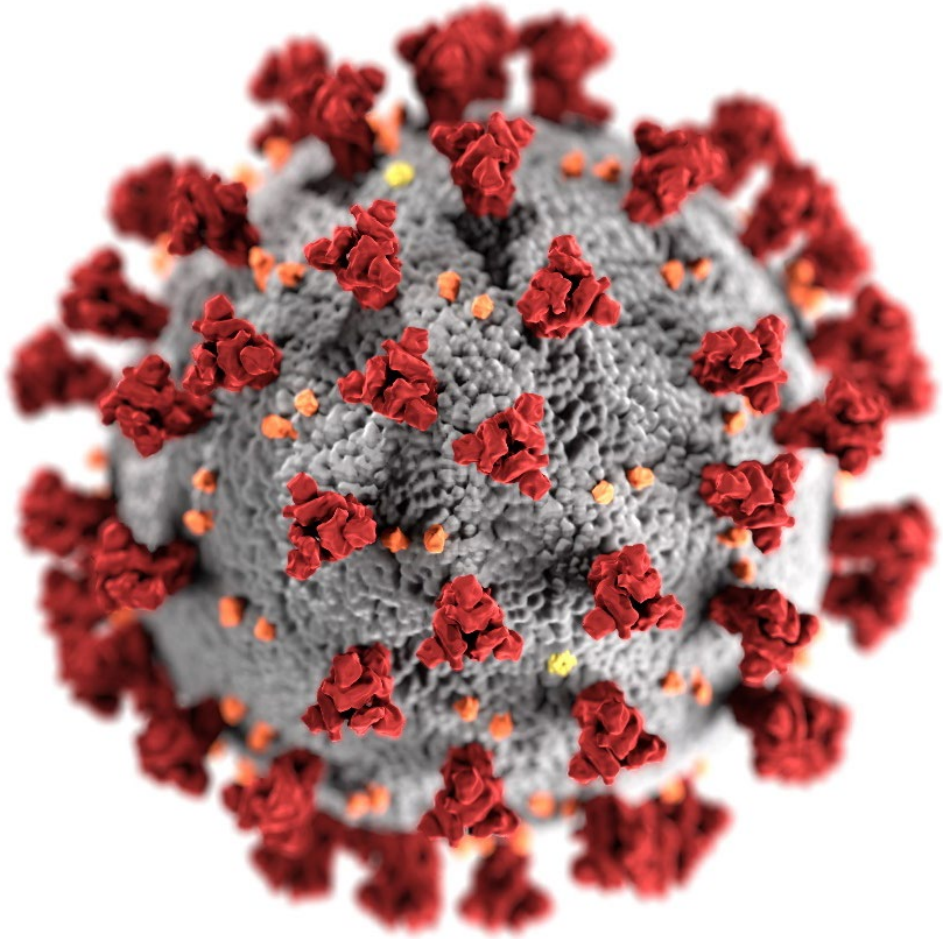


cdc.gov/coronavirus

Topics

- Post-authorization safety monitoring for primary series Pfizer-BioNTech (COMIRNATY) COVID-19 vaccination* in children ages 5–11 years†
  - Vaccine Adverse Event Reporting System (VAERS)
  - V-safe
  - Vaccine Safety Datalink (VSD)

* 2-dose (10 µg) series separated by at least 3 weeks

† Published analysis (Hause et al. Pediatrics, 2022) available at: https://publications.aap.org/pediatrics/article/doi/10.1542/peds.2022-057313/188023/Safety-of-COVID-19-Vaccination-in-US-Children-Ages

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 reports from everyone (healthcare professionals, patients, parents, caregivers, manufacturers, etc.) 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

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

Reports to VAERS after primary series Pfizer-BioNTech vaccination among children ages 5–11 years

Summary of U.S. reports to VAERS among children ages 5–11 years after Pfizer-BioNTech vaccination* (as of April 24, 2022)

Age group	Doses admin†	Total reports	Median age	Male‡ n (%)	Female‡ n (%)	Non-serious n (%)	Serious§,¶ n (%)
5–11 years	18,182,496	9001	8 years	4258 (47)	4261 (47)	8750 (97)	251 (3)

* Among children ages 5–11 years vaccinated during Nov 3, 2021–Apr 24, 2022; reports received and processed as of Apr 25, 2022

† Dose 1 and dose 2 administered among children ages 5–11 years during Nov 4, 2021–Apr 28, 2022

‡ Sex not reported for 482 (5%) reports

§ 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 7 deaths: 3 with complex health issues, 2 with final autopsy reports pending, 1 with unexplained cardiorespiratory arrest; 1 with influenza (+) on autopsy

U.S. reports to VAERS among children ages 5–11 years after Pfizer-BioNTech vaccination, by race and ethnicity*

(as of April 24, 2022)

Race and ethnicity	Ages 5–11 years n (%)
Unknown or not reported	3331 (37)
Non-Hispanic White	2725 (30)
Hispanic†	1260 (14)
Non-Hispanic other	588 (7)
Non-Hispanic Black	483 (5)
Non-Hispanic Asian	363 (4)
Non-Hispanic multiracial	159 (2)
Non-Hispanic American Indian/Alaskan Native	76 (<1)
Non-Hispanic Native Hawaiian or Other Pacific Islander	16 (<1)
Total	**9001**

* Among children ages 5–11 years vaccinated during Nov 3, 2021–Apr 24, 2022; reports during this period that were received and processed as of April 25, 2022

† Includes persons reported as of Hispanic ethnicity, but of unreported or unknown race

Most frequent MedDRA Preferred Terms* in non-serious reports to VAERS following Pfizer-BioNTech vaccination in children ages 5–11 years† (as of April 24, 2022)

N=8750, all reports

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	No Adverse Event	1891 (22)
2	Product Preparation Issue	1595 (18)
3	Incorrect Dose Administered	1569 (18)
4	Product Storage Error	940 (11)
5	Pyrexia	624 (7)
6	Vomiting	608 (7)
7	Headache	527 (6)
8	Dizziness	413 (5)
9	Underdose	398 (5)
10	Fatigue	381 (4)

N=8750, clinical outcomes only‡

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	Pyrexia	624 (7)
2	Vomiting	608 (7)
3	Headache	527 (6)
4	Dizziness	413 (5)
5	Fatigue	381 (4)
6	Syncope	379 (4)
7	Nausea	366 (4)
8	Rash	348 (4)
9	Urticaria	336 (4)
10	Pain In Extremity	300 (3)

* Medical Dictionary for Regulatory Activities Preferred Terms (https://www.meddra.org/how-to-use/basics/hierarchy)

† Among children ages 5–11 years vaccinated during Nov 3, 2021 – Apr 24, 2022; reports received and processed as of Apr 25, 2022

‡ Determined by subject matter expert consensus

Most frequent MedDRA Preferred Terms* in serious reports to VAERS following Pfizer-BioNTech vaccination in children ages 5–11 years† (as of April 24, 2022)

N=251, all reports

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	Fever	84 (33)
2	Vomiting	54 (22)
3	Multisystem Inflammatory Syndrome In Children	45 (18)
4	C-Reactive Protein Increased	38 (15)
5	**SARS-CoV-2 Test Negative**	**35 (14)**
6	Rash	34 (14)
7	COVID-19	33 (13)
8	Abdominal Pain	29 (12)
9	Immunoglobulin Therapy	29 (12)
10	**Echocardiogram Normal**	**28 (11)**

N=251, clinical outcomes only‡

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	Fever	84 (33)
2	Vomiting	54 (22)
3	Multisystem Inflammatory Syndrome In Children	45 (18)
4	C-Reactive Protein Increased	38 (15)
5	Rash	34 (14)
6	COVID-19	33 (13)
7	Abdominal Pain	29 (12)
8	Immunoglobulin Therapy	29 (12)
9	Headache	27 (11)
10	Troponin Increased	27 (11)

* Medical Dictionary for Regulatory Activities Preferred Terms (https://www.meddra.org/how-to-use/basics/hierarchy)

† Among children ages 5–11 years vaccinated during Nov 3, 2021 – Apr 24, 2022; reports received and processed as of Apr 25, 2022

‡ Determined by subject matter expert consensus

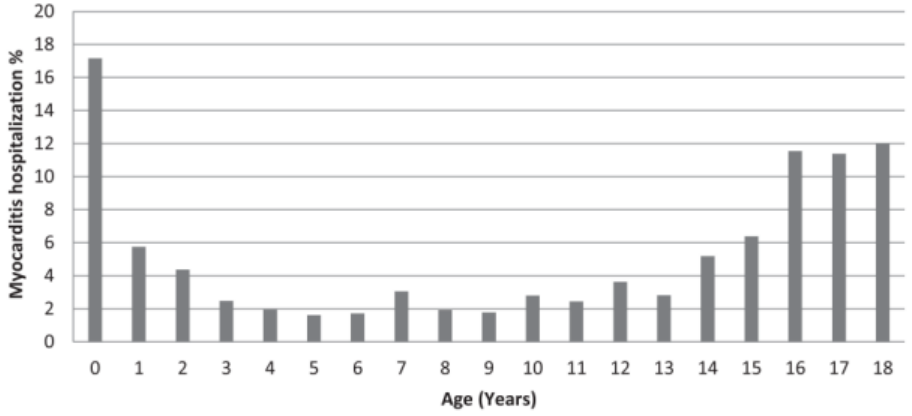
Epidemiology of classic myocarditis in children (excluding infants)

- Usually an infectious cause, typically viral or presumed to be viral, although infection with a pathogen is frequently not identified (only ~40% of time a pathogen is identified)[1,2,3]
- Can be due to direct microbial infection of myocardial cells and/or ongoing inflammatory response, with or without clearance of pathogen[4,5,6]
  - Can also be toxin-mediated or in setting of systemic infection or infection of non-cardiac tissue
- Rarer causes include autoimmune, hypersensitivity, giant cell
- Incidence males > females starting after age 5 years[7]
- Previously unrecognized myocarditis was identified as cause of death in 8% of cases of sudden, unexplained death in 1–17- year-olds[8] and 9% of sudden death in athletes[9]
- It is common to not identify a pathogen or possible infectious etiology for myocarditis
  - Based on case series, where autopsy tissues were examined and tissue-based infectious disease testing was performed, a specific infectious cause was only identified in 13%–36% of cases across age groups[6,10,11]
  - For a case series where endomyocardial biopsy tissues were tested, viral nucleic acids were detected in heart tissues in ~38% (adults and children combined)[1]

[1]Bowles et al. J Am Coll Cardiol. 2003;42:466-72. [2]Simpson et al. J Am Coll Cardiol. 2013;61:(10_Supplement) E1264. [3]Park et al. J Korean Med Sci. 2021;36:e232. [4]Caforio et al. Eur Heart J. 2013;34:2636-48, 2648a-2648d. [5]Feldman et al. N Engl J Med. 2000;343:1388-98. [6]Guarner et al. Hum Pathol. 2007;38:1412-9. [7]Arola et al. J Am Heart Assoc. 2017;6:e005306. [8]Burns et al. J Pediatr X. 2020;2:100023. [9]Maron et al. Circulation. 2009;119:1085-92. [10]Weber et al. Arch Dis Child. 2008;93:594-8. [11]Ilina et al. Pediatrics. 2011;128:e513-20.

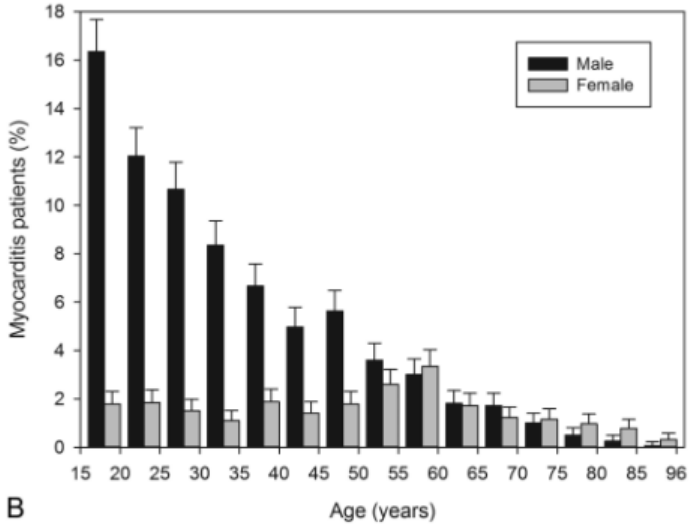
Epidemiology of myocarditis

- Children
  - Annual incidence 0.8 per 100,000
    - In 15-18yo, 1.8 per 100,000 in 2015-2016
  - 66% male
  - Median LOS 6.1 days



Vasudeva et al. *American J Cardiology.* 2021.

- Adults
  - Gradual decrease in incidence with age
  - 76% male



Kyto et al. *Heart*. 2013.

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/02-COVID-Oster-508.pdf

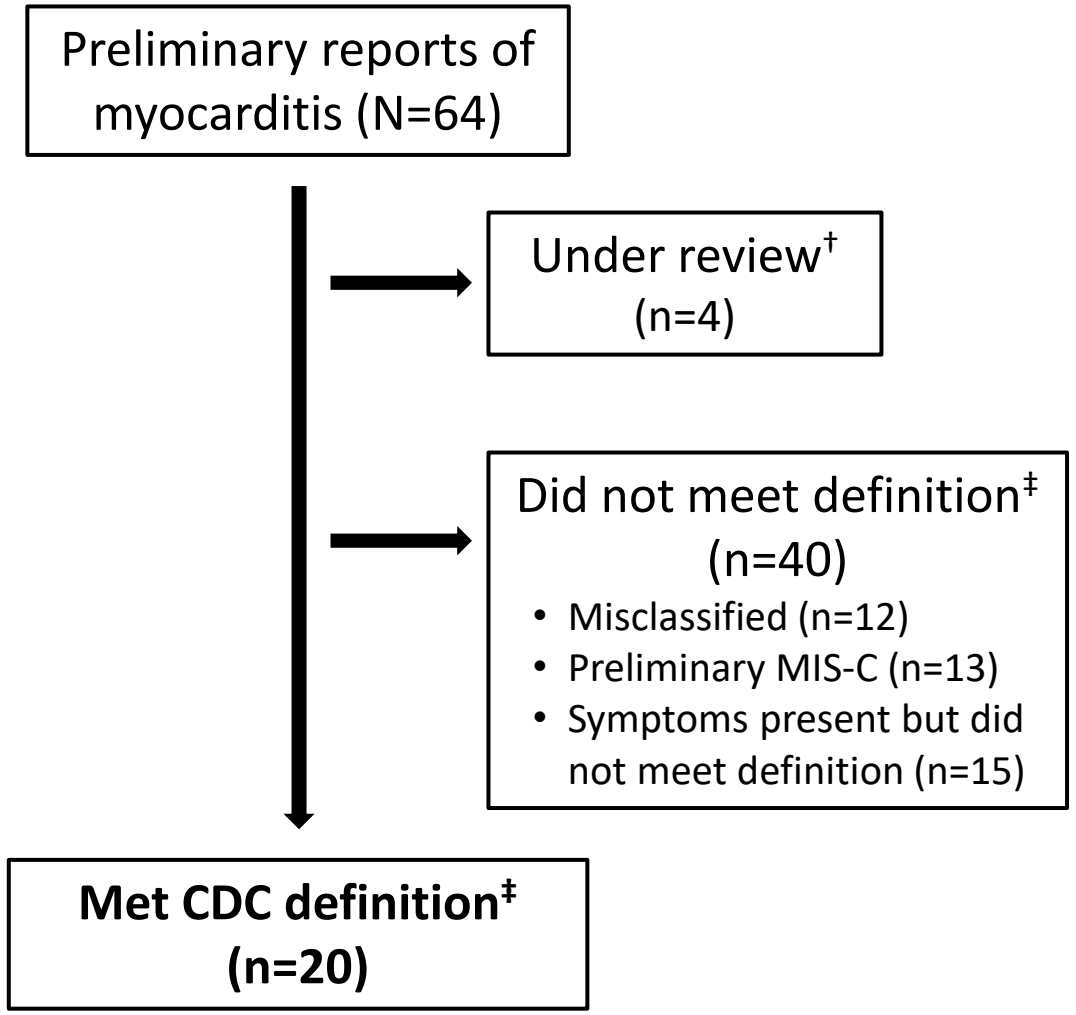
Characteristic	Myocarditis associated with COVID-19 mRNA vaccination*	Viral myocarditis†
Inciting exposure	mRNA COVID-19 vaccination • Dose 2 > Dose 1	Viral illness • 30–60% with asymptomatic viral course
Demographics	Most cases in adolescents and young adults, males > females	Males > females, male incidence peaks in adolescence and gradually declines
Symptom onset	A few days after vaccination, most within a week	1–4 weeks after viral illness
Fulminant course	Rare‡	23%
ICU level support	2%	~50%
Mortality/transplant	Rare‡	11–22%
Cardiac dysfunction	12%	60%
Recovery of cardiac function	Nearly all	~75%
Time to recovery of cardiac function (ejection fraction on cardiac echo), if initially poor	Hours to days	Days to weeks to months

* https://www.cdc.gov/vaccines/acip/meetings/index.html, https://www.cdc.gov/vaccinesafety/research/publications/index.html

† Law et al. Circulation. 2021;144:e123-e135. Ghelani et al. Circ Cardiovasc Qual Outcomes. 2012;5:622-7. Kim et al. Korean Circ J. 2020;50:1013-1022. Messroghli et al. Am Heart J. 2017;187:133-144. Oster et al. JAMA. 2022;327:331-340. Patel et al. J Am Heart Assoc. 2022;11:e024393.

‡ There are rare reports in the literature, especially from other countries, but it is unclear to what extent such cases were investigated

Reports to VAERS of myocarditis after Pfizer-BioNTech vaccination among children ages 5–11 years* (as of April 24, 2022; ~18.1 million doses administered)

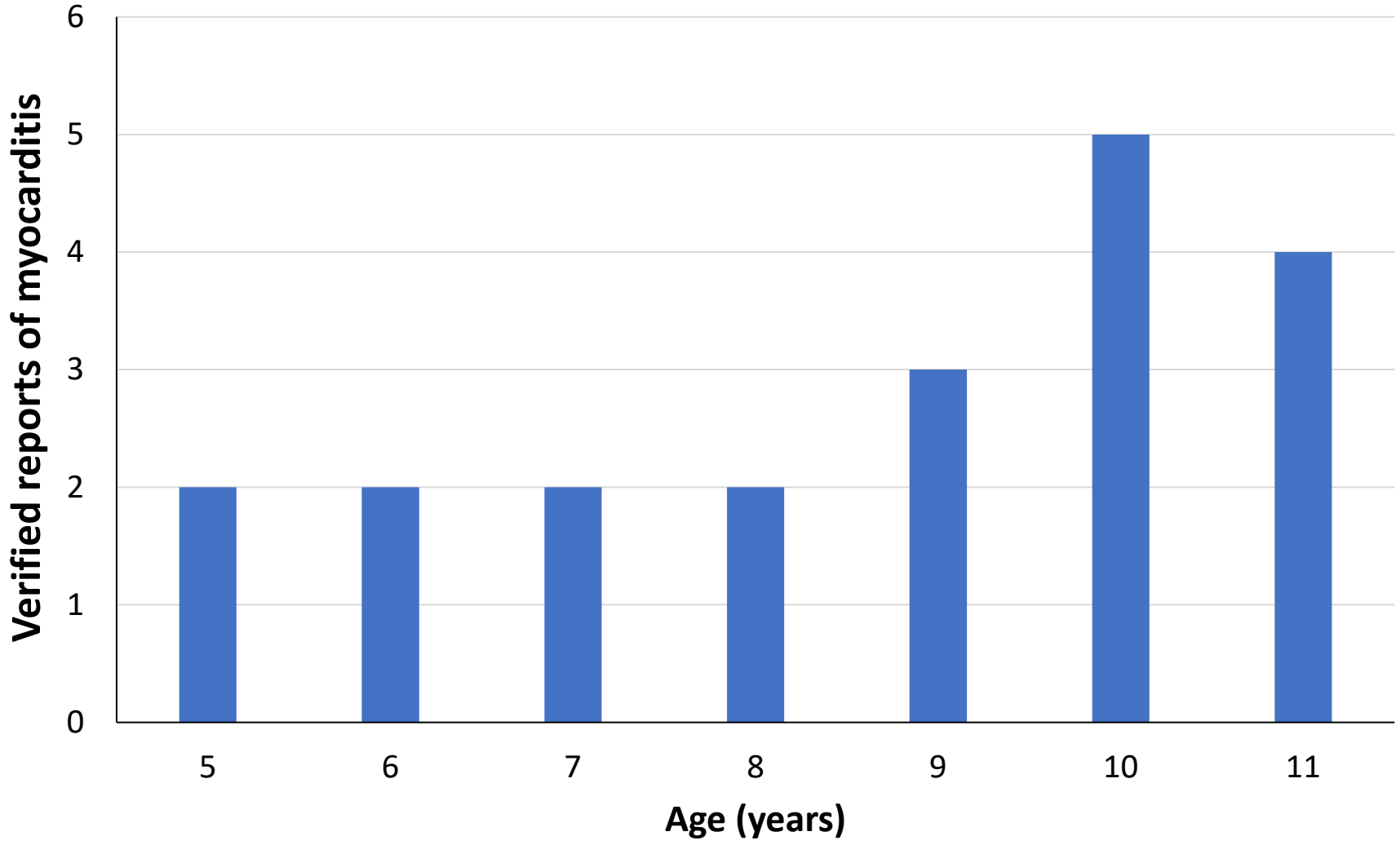


* Among children ages 5–11 years vaccinated during Nov 3, 2021–Apr 24, 2022; † Awaiting medical records and/or healthcare provider interview; some still processing; ‡ Adjudicated after healthcare provider interview and/or medical record review

Reports to VAERS of myocarditis after Pfizer-BioNTech vaccination among children ages 5–11 years* (as of April 24, 2022; ~18.1 million doses administered)

- 20 reports verified using CDC case definition
  - Median age: 9 years (IQR: ages 7–10 years)
  - Median time to symptom onset after vaccination: 3 days (IQR: 2–3 d)
    - 4 reports with symptom onset >7 days after vaccination (8, 11, 12, and 12 days)
  - After dose 2 (n=14), after dose 1 (n=6)
  - Male cases (n=15), female cases (n=5)
  - 17/20 hospitalized; 3 treated only as outpatients
    - 14/17 recovered from symptoms at time of VAERS report
  - None reported a vaccination error involving receipt of an adult dose
  - 1 report with history of viral prodrome 3–4 days prior to symptom onset, 3 with current COVID-19 disease at time of symptom onset, no reports with a documented history of COVID-19 disease prior to symptom onset
  - 1 death in a male child with onset of fever 12 days after dose 1 and abdominal pain, vomiting, and death the following day (day 13 after dose 1); rapid clinical course, histopathologic evidence of myocarditis on autopsy, testing did not find evidence of viral infection at time of death, CDC continues to assist with case review

Verified reports to VAERS of myocarditis after Pfizer-BioNTech vaccination among children ages 5–11 years* (as of April 24, 2022)



* Among children ages 5–11 years vaccinated during Nov 3, 2021–Apr 24, 2022

VAERS reporting rates of myocarditis (per 1 million doses administered) after Pfizer-BioNTech vaccine, days 0–7 after vaccination*,†

	0–7 days				0–7 days			
	Males				Females			
Ages (yrs)	Dose 1	Dose 2			Dose 1	Dose 2		
5–11	**0.2**	**2.7**			**0.2**	**0.8**		
12–15	5.1	48.1			0.9	4.3		
16–17	6.9	74.2			0.0	7.2		
18–24	2.6	35.3			0.7	3.1		
25–29	1.3	12.8			0.2	2.0		
30–39	0.8	6.0			0.6	1.0		
40–49	0.3	3.0			0.2	1.6		
50–64	0.3	0.5			0.4	0.6		
65+	0.2	0.1			0.1	0.5		

For reference

* As of April 24, 2022; reports verified to meet case definition by provider interview or medical record review. Doses administered as of April 21, 2022

† An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for days 0–7 risk interval, this estimated background is **0.2 to 2.2 per 1 million person-day 0–7 risk interval**

VAERS reporting rates of myocarditis (per 1 million doses administered) after Pfizer-BioNTech vaccine, days 0–7 and 8–21 after vaccination*,†

	0–7 days		8–21 days		0–7 days		8–21 days	
	Males		Males		Females		Females	
Ages (yrs)	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
5–11	**0.2**	**2.7**	**0.6**	**0.0**	**0.2**	**0.8**	**0.2**	**0.0**
12–15	5.1	48.1	1.6	1.3	0.9	4.3	0.5	0.2
16–17	6.9	74.2	1.7	2.8	0.0	7.2	0.7	0.4
18–24	2.6	35.3	1.2	2.2	0.7	3.1	0.1	0.7
25–29	1.3	12.8	0.4	0.8	0.2	2.0	0.4	0.0
30–39	0.8	6.0	0.0	0.7	0.6	1.0	0.1	0.1
40–49	0.3	3.0	0.1	0.3	0.2	1.6	0.2	0.1
50–64	0.3	0.5	0.0	0.2	0.4	0.6	0.2	0.6
65+	0.2	0.1	0.1	0.3	0.1	0.5	0.3	0.4

For reference

* As of April 24, 2022; reports verified to meet case definition by provider interview or medical record review. Doses administered as of April 21, 2022

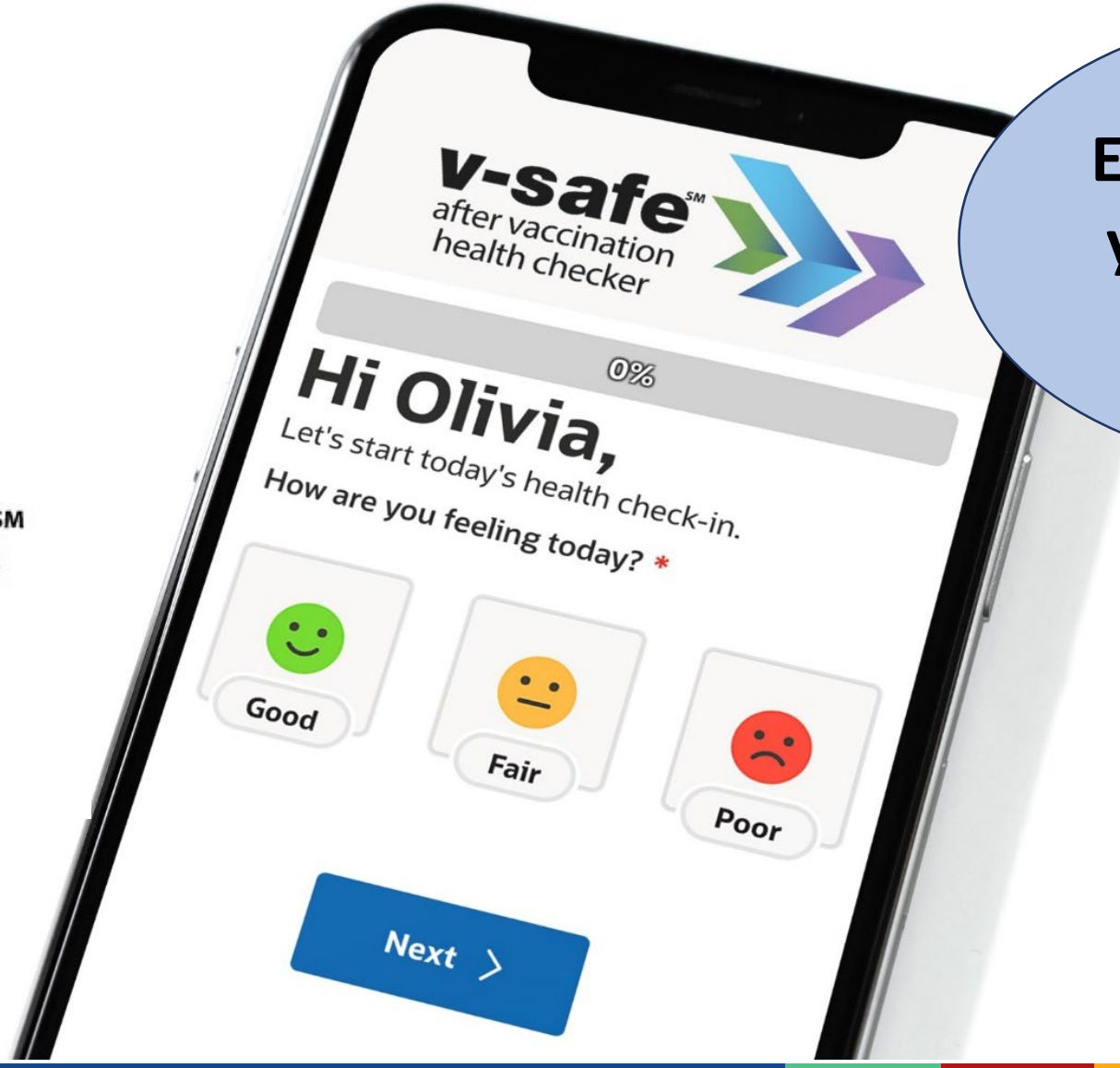
† An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for days 0–7 and 8–21 risk intervals, this estimated background is **0.2 to 2.2 per 1 million person-day 0–7 risk interval and 0.4 to 3.8 per 1 million person-day 8–21 risk interval**

Summary of VAERS findings — Reports after Pfizer-BioNTech vaccination among children ages 5–11 years

- Since authorization, 18.1 million doses of Pfizer-BioNTech vaccine have been administered to children ages 5–11 years in the United States
- Most VAERS reports (8750/9001, 97%) were non-serious
  - Most frequently reported adverse events for non-serious reports were known and well-characterized AEs associated with Pfizer-BioNTech vaccination, including potential allergic reactions
  - Most frequently reported adverse events for serious reports were consistent with MIS-C
  - 20 reports of myocarditis verified to meet CDC case definition among children ages 5–11 years
    - Male predominance of myocarditis reports and mostly after dose 2, similar to older age groups
    - One death in a male with symptom onset 12 days after dose 1; rapid clinical course, histopathologic evidence of myocarditis on autopsy
    - Reporting rates for males ages 5–11 years are lower than for males ages 12–15 and 16–17 years, especially after dose 2; reporting rates for males after dose 1 and for females after either dose 1 or dose 2 are within background rates (using 0–7-day risk interval)
- CDC will continue monitoring COVID-19 vaccine safety among this age group and is following up on VAERS case reports of myocarditis to assess functional status and clinical outcomes at least 90 days after the onset of myocarditis symptoms

Smartphone-based active safety monitoring

v-safe[SM]
after vaccination
health checker



Enroll yourself or your dependent after any dose!

http://cdc.gov/vsafe

Active safety monitoring for COVID-19 vaccines

V-safe is a voluntary CDC smart phone-based monitoring program for COVID-19 vaccine safety in the United States

- Uses text messaging and web surveys to check in with vaccine recipients after vaccination
- Solicits participants' reports on how they feel after COVID-19 vaccination
  - Local injection site reactions (e.g., pain, redness, swelling)
  - Systemic reactions (e.g., fatigue, headache, joint pain)
  - Health impacts (unable to perform normal daily activities, missed school or work, or received care)

v-safe after vaccination health checker

Demographic summary of 49,396 v-safe participants ages 5–11 years who reported a Pfizer-BioNTech vaccination

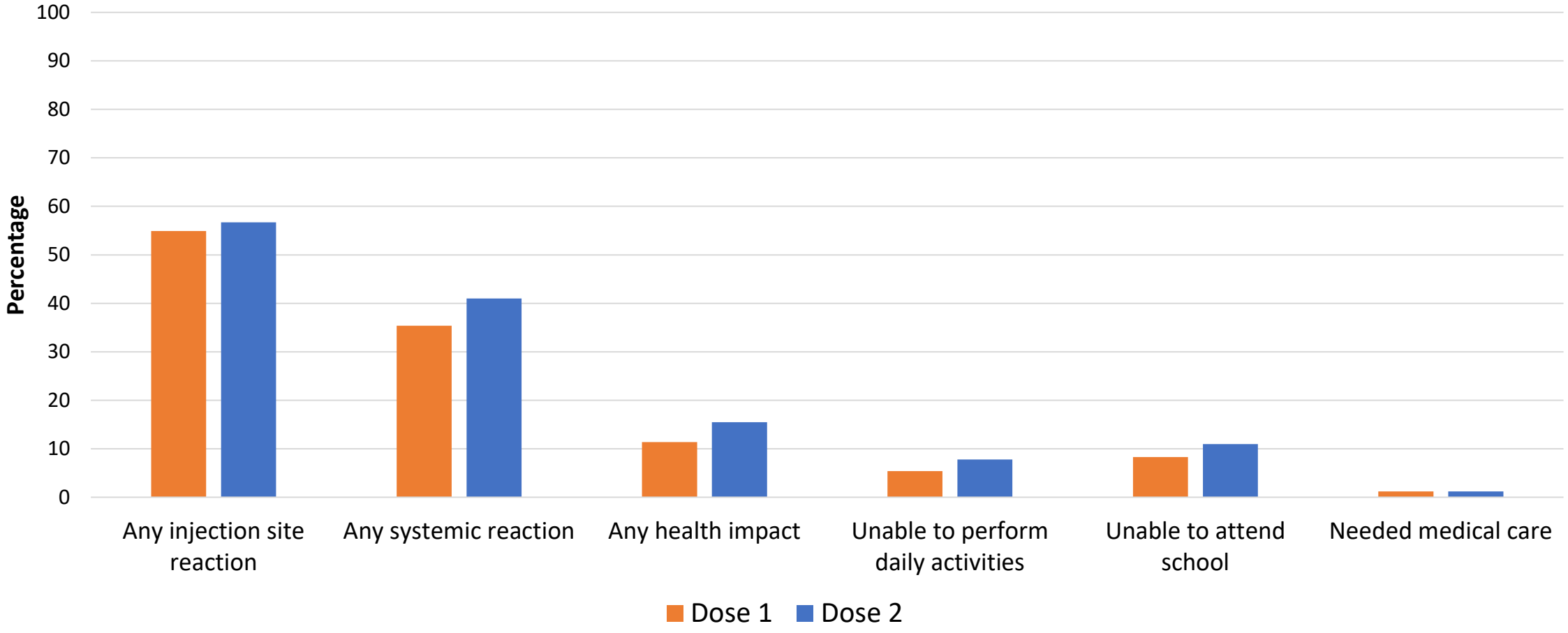
Characteristic	% of participants
Sex	
Female	49.6
Male	50.0
Unknown	0.3

Characteristic	% of participants
Ethnicity	
Hispanic or Latino	14.6
Not Hispanic/ Latino	82.1
Unknown	3.3
Race	
AI/AN	0.6
Asian	7.3
Black or AA	5.8
NHPI	0.3
White	71.9
Multiracial	8.1
Other	3.3
Unknown	2.7

Data as of Apr 24, 2022; includes participants who completed at least one survey in the first week after dose 1

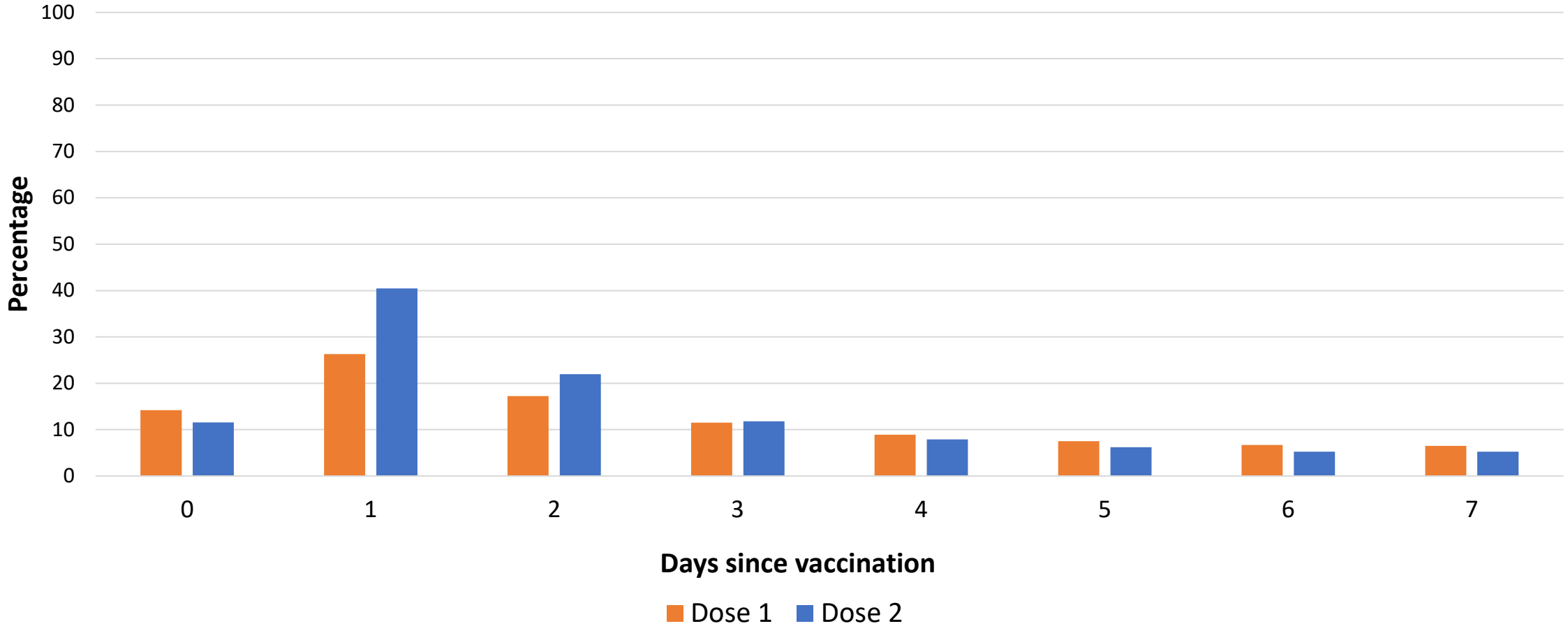
Abbreviations: AI/AN = American Indian/Alaska Native; NHPI = Native Hawaiian or other Pacific Islander; AA=African American.

Reactions and health impact events reported at least once in days 0–7 after Pfizer-BioNTech vaccination for children ages 5–11 years, by dose



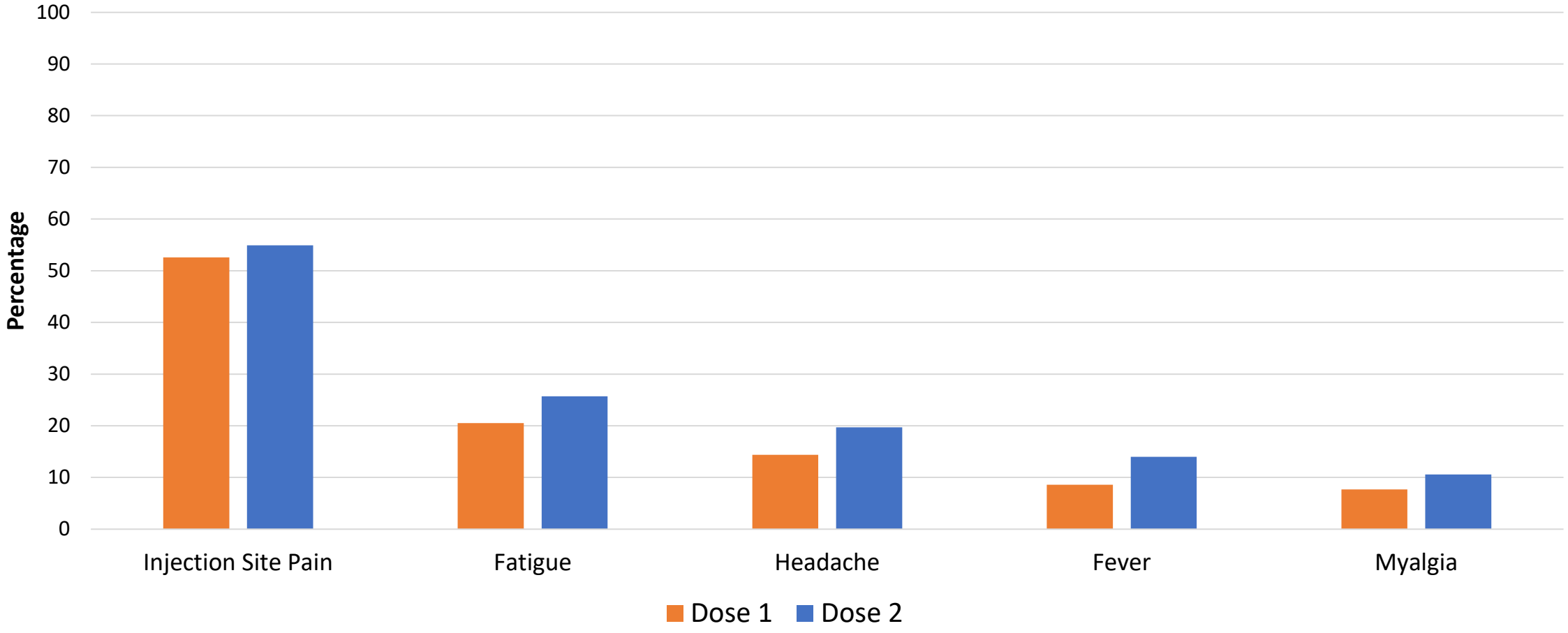
Includes 40,224 participants who completed at least one survey in the first week after dose 2, data as of Apr 24, 2022

Any systemic reaction reported for children ages 5–11 years at least once in 0–7 days after Pfizer-BioNTech vaccine, by dose and days since vaccination



Includes 40,224 participants who completed at least one survey in the first week after dose 2, data as of Apr 24, 2022

Top 5 reactions reported at least once in 0–7 days after Pfizer-BioNTech vaccine for children ages 5–11 years, by dose

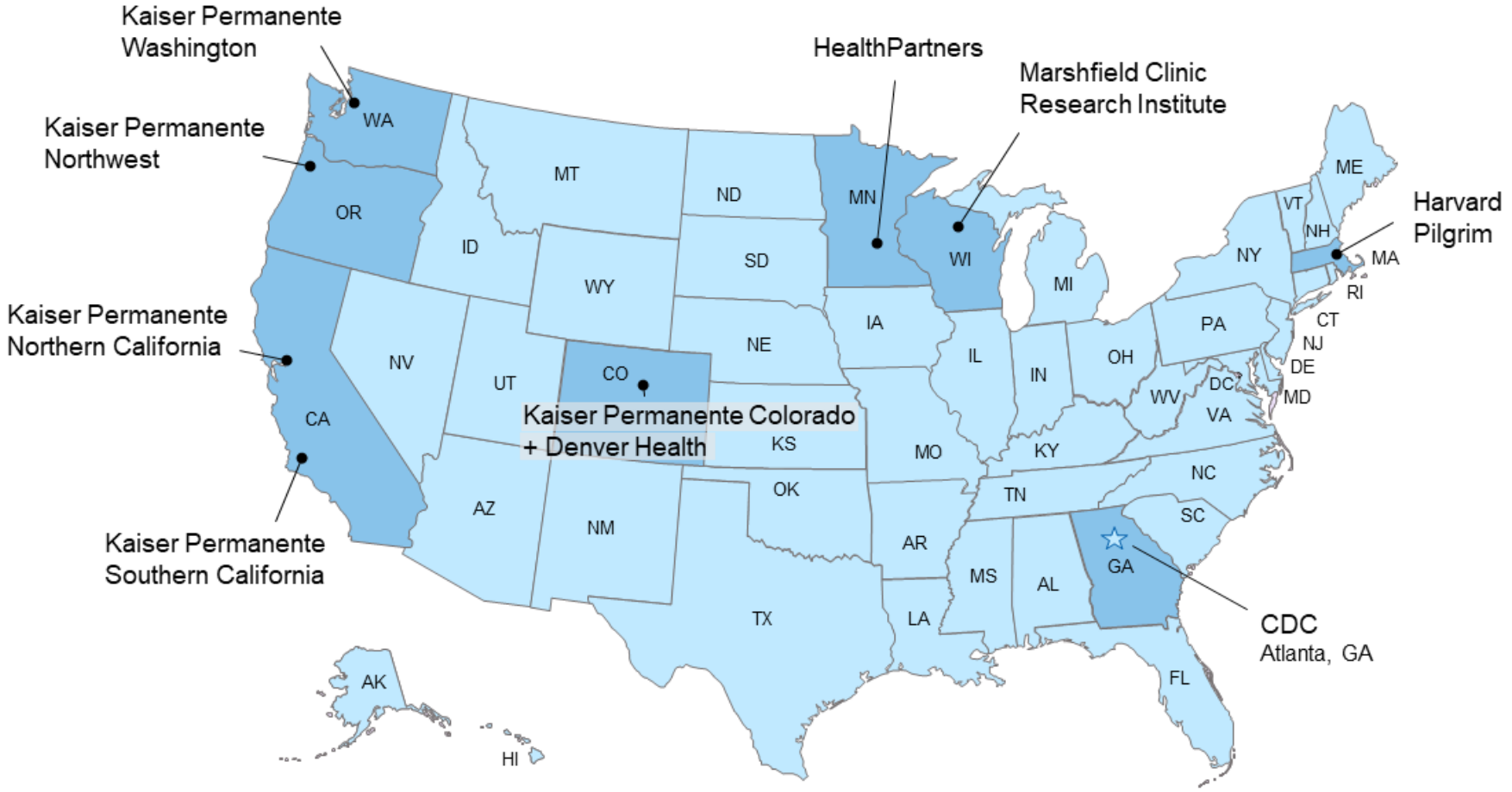


Includes 40,224 participants who completed at least one survey in the first week after dose 2, data as of Apr 24, 2022

Summary of v-safe findings — Reports after Pfizer-BioNTech vaccination for children ages 5–11 years

- 49,396 v-safe participants ages 5–11 years have reported Pfizer-BioNTech vaccination
  - Reactions were generally mild to moderate and most frequently reported the day after vaccination
  - Generally, reactions were more frequently reported after dose 2 than dose 1
  - Patterns are generally similar to those observed in people ≥12 years

Vaccine Safety Datalink (VSD)



- Established in 1990
- Collaborative project between CDC and 9 integrated healthcare organizations

VSD Rapid Cycle Analysis (RCA)

Aims:

- To monitor the safety of COVID-19 vaccines weekly using pre-specified outcomes of interest among VSD members
- To describe the uptake of COVID-19 vaccines over time among eligible VSD members overall and in strata by age, site, and race/ethnicity

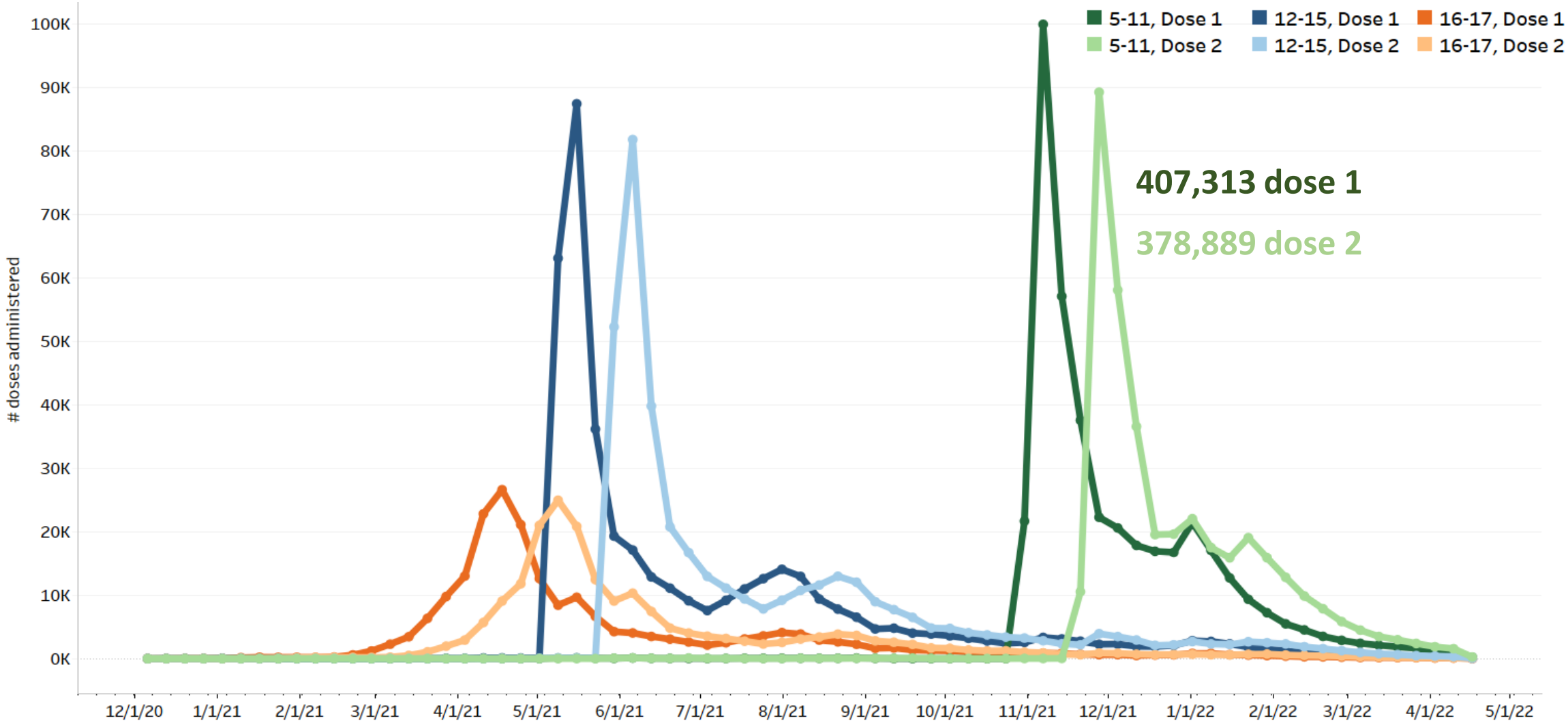
VSD COVID-19 vaccine RCA prespecified surveillance outcomes

Prespecified outcomes	Settings
Acute disseminated encephalomyelitis	Emergency dept, Inpatient
Acute myocardial infarction – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient
Acute respiratory distress syndrome	Emergency dept, Inpatient
Anaphylaxis – **First in 7 days in EHR in ICD-10 era**	Emergency dept, Inpatient
Appendicitis	Emergency dept, Inpatient
Bell's palsy – **First ever in EHR in ICD-10 era**	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 – **First in 60 days in EHR in ICD-10 era**	Emergency dept, Inpatient
Narcolepsy / cataplexy	Emergency dept, Inpatient, Outpatient
Pulmonary embolism – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient
Seizures	Emergency dept, Inpatient
Stroke, hemorrhagic	Emergency dept, Inpatient
Stroke, ischemic	Emergency dept, Inpatient
Thrombosis with thrombocytopenia syndrome – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient
Thrombotic thrombocytopenic purpura	Emergency dept, Inpatient
Transverse myelitis	Emergency dept, Inpatient
Venous thromboembolism – **First ever in EHR in ICD-10 era**	Emergency dept, Inpatient, Outpatient

VSD RCA analytic strategy

- For the primary analysis, the number of outcomes observed in the risk interval after COVID-19 vaccination were compared to the number expected
- The expected was derived from “vaccinated concurrent comparators” who were in a comparison interval after COVID-19 vaccination
- On each day that an outcome occurred, vaccinees who were in their risk interval were compared with similar vaccinees who were concurrently in their comparison interval
  - Comparisons were adjusted for age group, sex, race/ethnicity, VSD site, as well as calendar date

Vaccination totals by week for Pfizer-BioNTech in pediatric age groups



Summary of VSD RCA analyses for children ages 5–11 years (April 23, 2022)

- There are ~877,855 children ages 5–11 years in the VSD
  - 786,202 total doses of Pfizer-BioNTech vaccine have been administered in this age group
  - 41% of children ages 5–11 years have completed the primary series
- **No statistical signals for any outcomes identified to date**

Myocarditis and Pericarditis

- 10 potential cases of myocarditis or pericarditis were identified in the 98 days post-vaccination, 6 (60%) of which were verified through chart review:
  - Male age 7 years with acute myocarditis 16 days after dose 1
  - Male age 11 years with acute pericarditis 19 days after dose 1
  - Female age 9 years with acute pericarditis 14 days after dose 1

Within 0–7-day risk interval

  - **Male age 8 years with acute myocarditis 3 days after dose 2**
  - **Male age 9 years with acute myocarditis the day of vaccination after dose 2**
  - **Male age 10 years with acute myocarditis 2 days after dose 2**

And

- 4 were determined not to be cases (history of myocarditis (x2), congenital heart defect, chest pain but normal troponin and ECG)

Summary of VSD RCA analyses for children ages 5–11 years (April 23, 2022)

Anaphylaxis

- 3 verified anaphylaxis cases identified on days 0–1 after vaccination
  - 3.8 (95% CI: 0.8–11.2) cases per 1 million doses administered (any dose)
  - 4.9 (95% CI: 0.6–17.7) cases per 1 million first doses administered
  - 2.6 (95% CI: 0.1–14.7) cases per 1 million second doses administered
- Anaphylaxis rates in children ages 5–11 years are consistent with rates observed in people ages ≥12 years

*CDC MIS-C case definition available at Information for Healthcare Providers about Multisystem Inflammatory Syndrome in Children (MIS-C) | CDC

Summary of VSD RCA analyses for children ages 5–11 years (April 23, 2022)

MIS-C*

- 12 potential cases of MIS-C identified after vaccination
- 8 were verified as meeting the CDC case definition (7 Brighton Collaboration level 1, 1 Brighton Collaboration level 4); 4 ruled out
  - 5 (63%) were male, 6 (75%) were following dose 1
  - All 8 admitted to the hospital, 5 (63%) were admitted to the ICU, median length of stay was 3 days (range 1-7 days)
  - Median time from vaccination to symptom onset was 19.5 days
  - 6 had both documented COVID-19 infection and COVID-19 vaccination before diagnosis
    - 3 with infection (<12 weeks prior to vaccination) -> vaccination-> MIS-C
    - 1 with vaccination-> infection-> MIS-C
    - 2 with unclear timing but with infection and vaccination prior to MIS-C diagnosis
  - 2 with vaccination -> known exposure to COVID-19 -> MIS-C

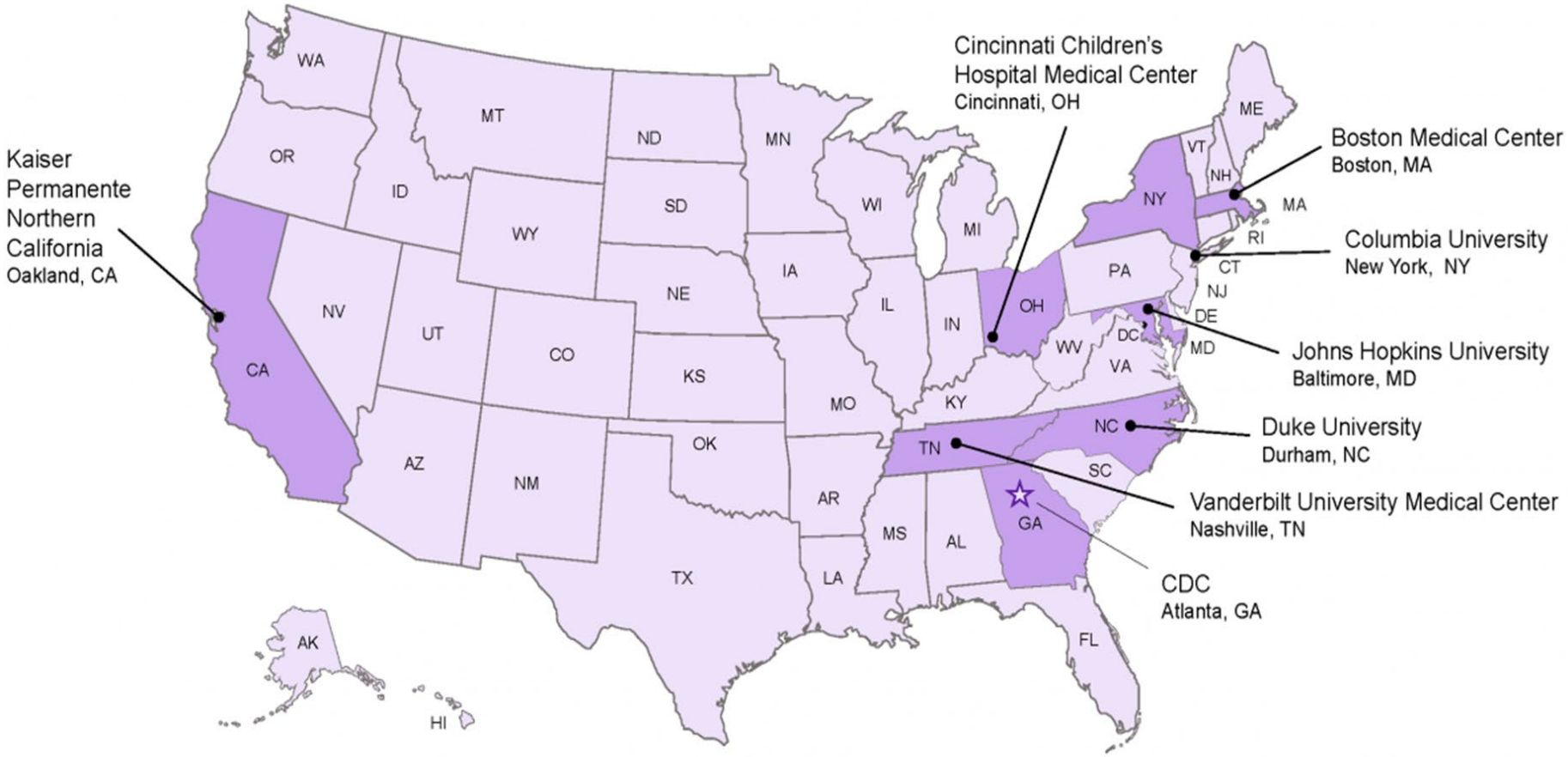
*CDC MIS-C case definition available at Information for Healthcare Providers about Multisystem Inflammatory Syndrome in Children (MIS-C) | CDC

Overall summary: Safety of primary series Pfizer-BioNTech COVID-19 vaccination in children ages 5–11 years

- Findings from post-authorization safety monitoring of Pfizer-BioNTech primary series vaccination are generally consistent with those from the clinical trials
  - Systemic and local reactions are relatively common with more systemic reactions after dose 2
- The reporting rate for myocarditis in VAERS in males after dose 2 is slightly elevated when compared to background incidence; otherwise, reporting rates are below background incidence
- No statistical signal for myocarditis has been observed in VSD Rapid Cycle Analysis
- Anaphylaxis rates in children ages 5–11 years following Pfizer-BioNTech COVID-19 vaccination are comparable to rates in people ages ≥12 years
- MIS-C cases detected in VSD following vaccination had a history of COVID-19 infection or a know exposure to COVID-19 prior to MIS-C diagnosis
- Enhanced safety monitoring continues, including following up on recovery status and longer-term outcomes in myocarditis case reports

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

Promoting v-safe in practice – Vaccinators, we need your help!

How:

- Provide the **v-safe** information sheet to patients
  - Ideally this should occur prior to vaccination for young children
- Display posters of **v-safe**
- Direct patients to vsafe.cdc.gov to enroll

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

Get vaccinated.
Get your smartphone.
Get started with v-safe.

What is v-safe?

V-safe provides personalized and confidential health check-ins via text messages and web surveys so you can quickly and easily share with CDC how you or your dependent feel after getting a COVID-19 vaccine. It takes just a few minutes to enroll and your participation in **v-safe** helps us monitor the safety of COVID-19 vaccines for everyone.

V-safe features:

- **Enroll your dependents** and complete check-ins on their behalf
- **Enter** and report how you feel after **first, second, additional, and booster doses**

How can I enroll and how does it work?

You can enroll in **v-safe** after any dose of COVID-19 vaccine by using your smartphone and going to vsafe.cdc.gov.

During the first week after each vaccination, **v-safe** will send you a text message each day to ask how you are feeling. After that, you will receive occasional check-ins, which you can opt out of at any time. Depending on your answers, someone from CDC may call to get more information. Your personal information in **v-safe** is protected so it's safe and private*.

How can I enroll my dependent?

You can enroll any family member (or friend) who is eligible to be vaccinated in **v-safe.** Children under 16 years old must be enrolled using a parent or guardian's **v-safe** account. You can add a dependent to your existing account or create a new account if you don't have one yet. Creating an account to enroll a dependent does not require that you enter your own vaccination information or complete health check-ins for yourself.

Need step-by-step instructions? Go to: www.cdc.gov/vsafe

*v-safe uses existing information systems managed by CDC, FDA, and other federal agencies. These systems use strict security measures to keep information confidential. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

v-safe
after vaccination health checker

Sign up with your smartphone's browser at vsafe.cdc.gov

Share with your friends and CDC that you are using v-safe! Post a selfie and use the hashtag #BeSafeVSafe

Need help with *v-safe*?
Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
Visit www.cdc.gov/vsafe

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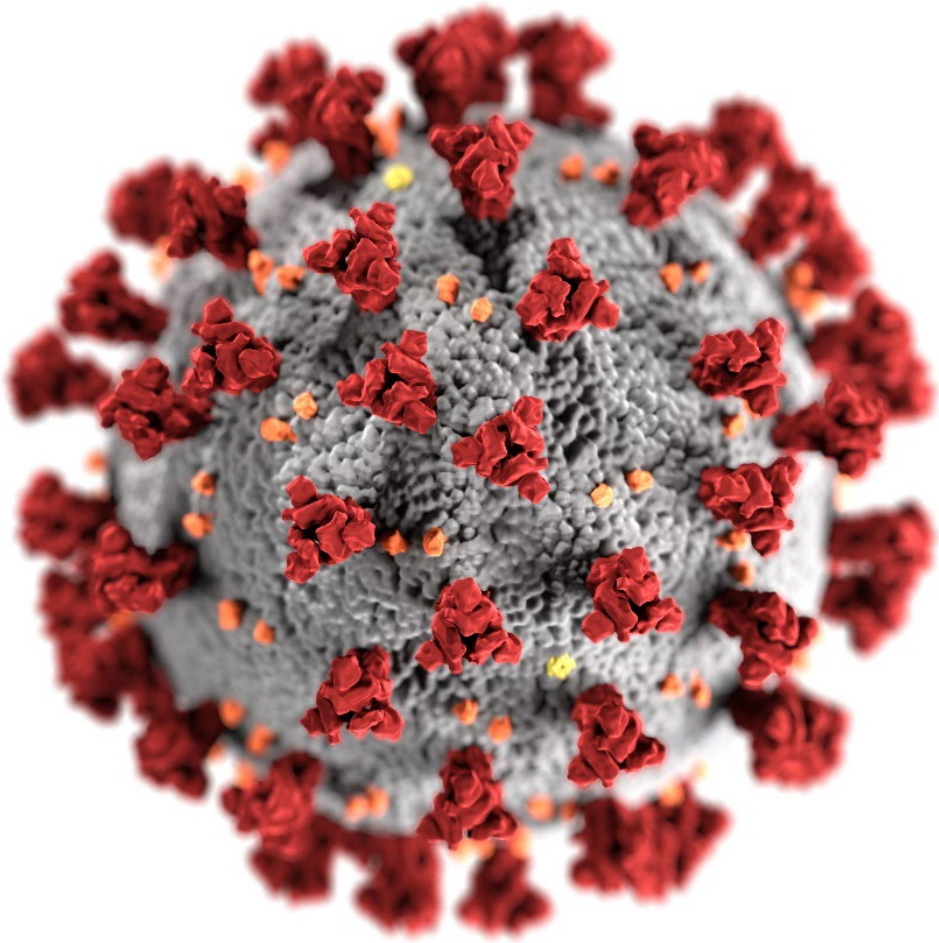
- Kaiser Permanente Northern California (VSD)
- Marshfield Clinic Research Institute (VSD)
- VSD sites
  - HealthPartners Institute, Minneapolis, MN
  - Kaiser Permanente Colorado, Denver, CO
  - Kaiser Permanente Northwest, Portland, OR
  - Kaiser Permanente Southern California, Los Angeles, CA
  - Kaiser Permanente Washington, Seattle, WA
  - Denver Health, Denver, CO

Disclaimer

- 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

Thank you!



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

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