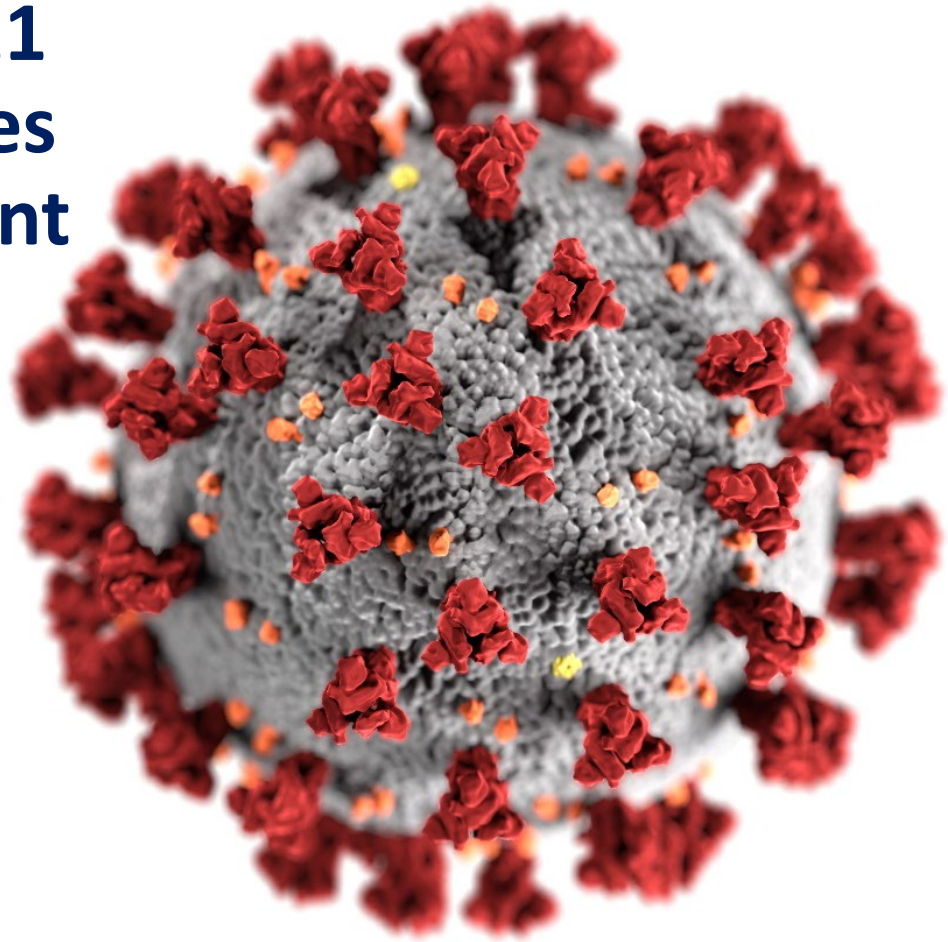
Adverse events among children ages 5–11 years after COVID-19 vaccination: updates from v-safe and the Vaccine Adverse Event Reporting System (VAERS)



Dec 13, 2021

John R. Su, MD, PhD, MPH
Vaccine Safety Team
CDC COVID-19 Vaccine Task Force

cdc.gov/coronavirus

Data from v-safe

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 U.S.

- Uses text messaging and web surveys to check in with vaccine recipients after vaccination
- Can register at any time: after first or subsequent doses
- Solicits participants' reports on how they feel after COVID-19 vaccination
  - Local injection site reactions (i.e., pain, redness, swelling)
  - Systemic reactions (i.e., 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

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

This Photo by Unknown Author is licensed under CC BY-SA

Vaccine recipient

v-safe after vaccination health checker

2. Clinically important event(s) reported

✓ Received medical care

Call center

This Photo by Unknown Author is licensed under CC BY-SA

3. A VAERS customer service representative conducts active telephone follow-up on a medically attended health impact event and takes a report if appropriate

Demographic summary of 41,232 v-safe participants ages 5–11 years (as of Dec 12, 2021)*

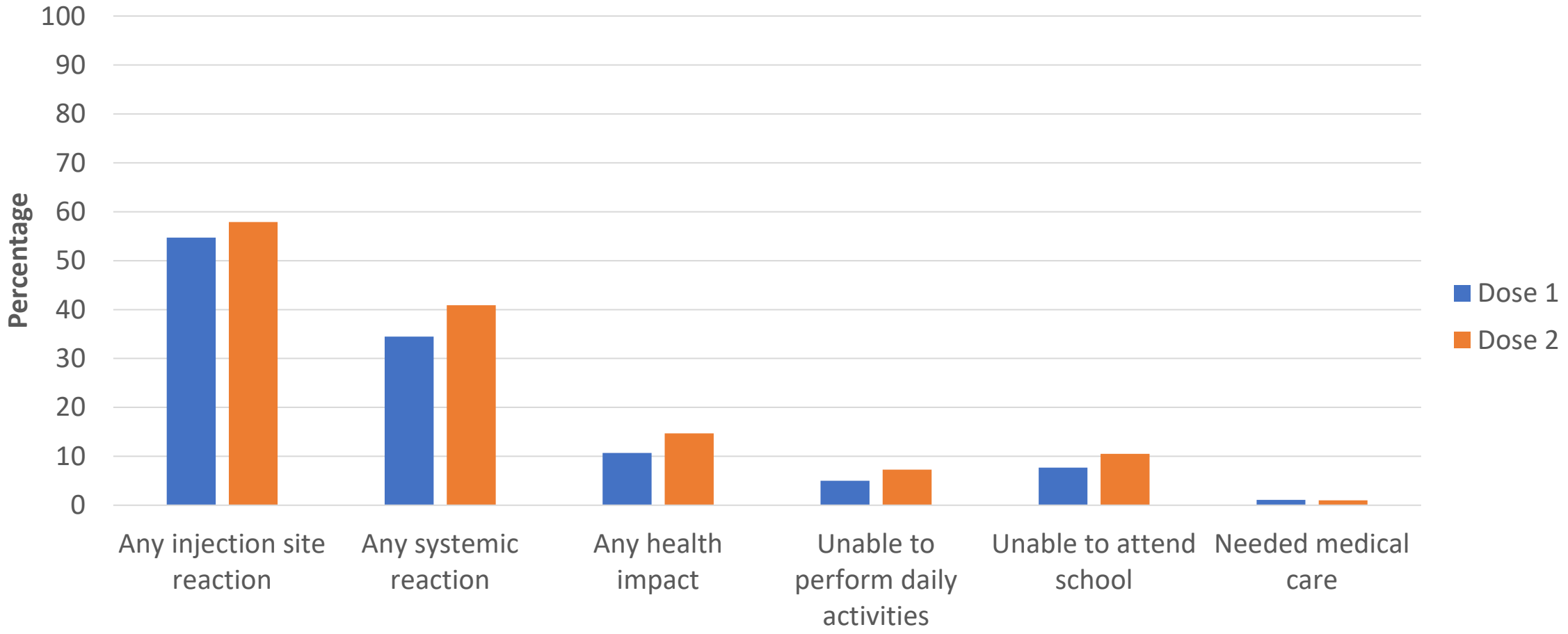
Characteristic	% of participants
Sex	
Female	49.7
Male	50.0
Unknown	0.4

- Doses of Pfizer-BioNTech vaccine administered = **7,141,428** (as of Dec 9, 2021)
  - Dose 1 in v-safe: 41,232
  - Dose 2 in v-safe: 23,583

Characteristic	% of participants
Ethnicity	
Hispanic or Latino	12.8
Not Hispanic/ Latino	84.1
Unknown	3.1
Race	
AI/AN	0.5
Asian	6.9
Black or AA	4.5
NHPI	0.3
White	74.6
Multiracial	8.1
Other	2.7
Unknown	2.4

* Includes participants who completed at least one survey in the first week after dose 1, data collected during November 3-December 12, 2021
Abbreviations: AI/AN = American Indian/Alaska Native; NHPI = Native Hawaiian or other Pacific Islander; AA=African American.

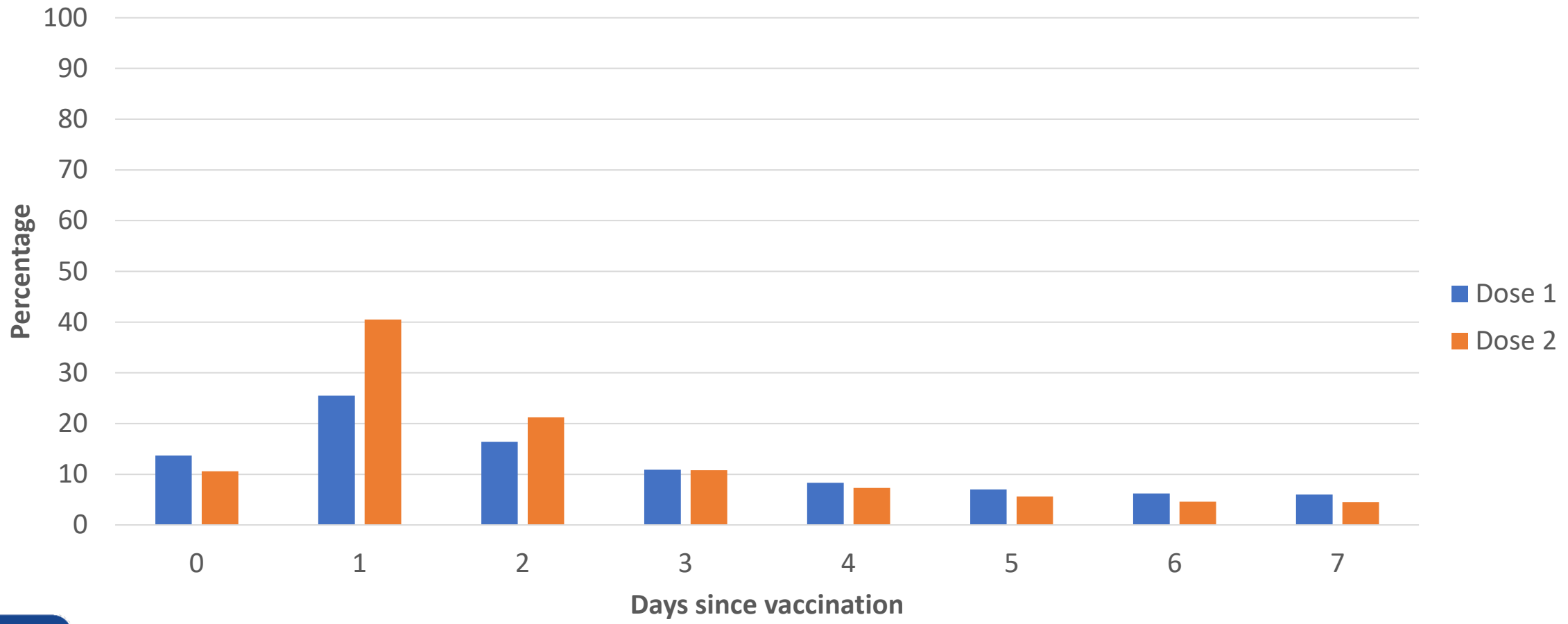
Reactions and health impact events reported by children ages 5–11 years at least once 0–7 days after Pfizer-BioNTech vaccine, by dose (as of Dec 12, 2021)



* Questions asked separately on questionnaire, specifying “select all that apply”
Includes 41,232 participants who completed at least one survey in the first week after dose 1, data collected during November 3-December 12, 2021

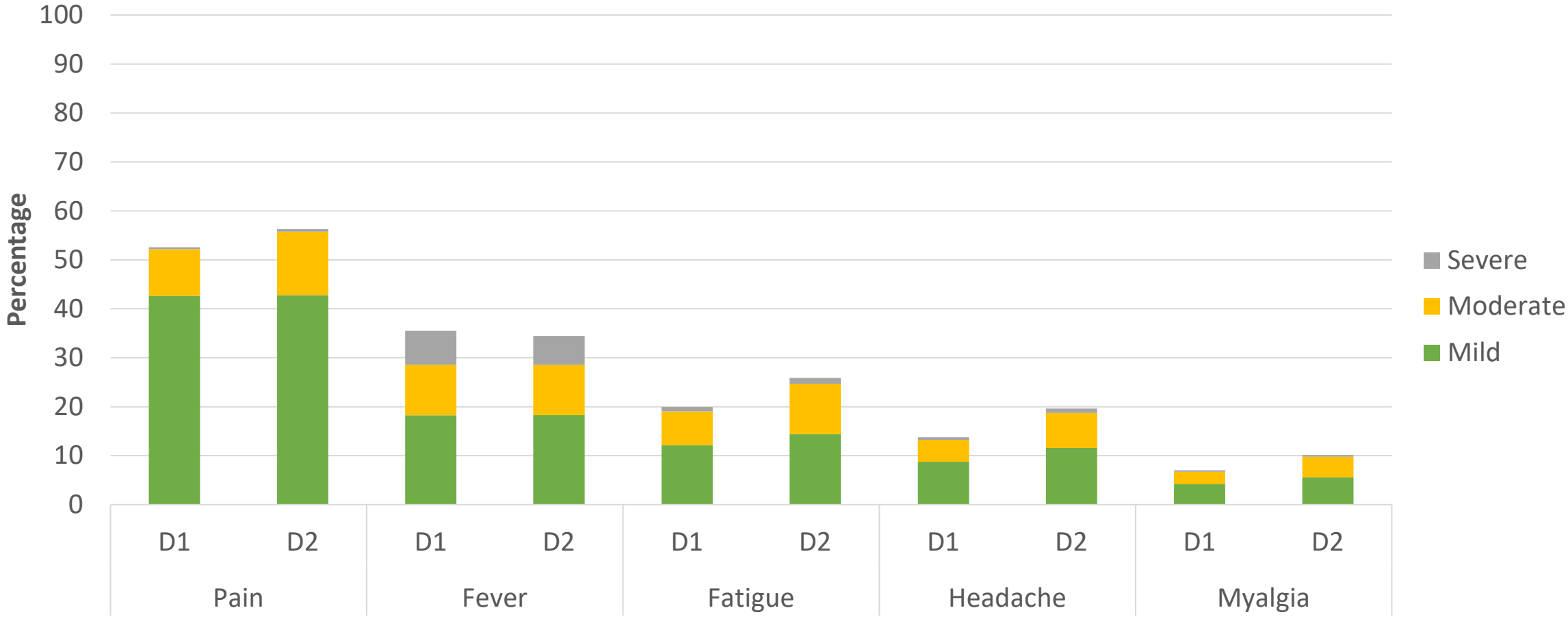
Any systemic reaction reported by children ages 5–11 years at least once 0–7 days after Pfizer-BioNTech vaccine, by dose and days since vaccination

(as of Dec 12, 2021)



Includes 41,232 participants who completed at least one survey in the first week after dose 1, data collected during November 3-December 12, 2021

Top 5 solicited reactions reported by children ages 5–11 years at least once 0–7 days Pfizer-BioNTech vaccine, by dose and severity* (as of Dec 12, 2021)



Includes 41,232 participants who completed at least one survey in the first week after dose 1, data collected during November 3-December 12, 2021
* Mild = noticeable, not problematic; moderate = limits normal daily activity; severe = daily activities difficult or impossible. Severity of fever was determined by temperature: mild = 38.0–38.4 C; moderate = 38.5–38.9 C; severe = 40.0+ C.

Limitations of early safety monitoring in v-safe for children 5–11 years of age

- v-safe population likely not representative of the vaccinated U.S. population (e.g., selected population, reporting bias)
- At this time, data are limited to describe reactions following the second dose of Pfizer-BioNTech vaccine

Summary

- Most reported reactions were
  - Mild to moderate in severity
  - Most frequently reported the day after vaccination
  - Slightly more frequently reported after dose 2
  - Transient in nature
- For both dose 1 and dose 2:
  - Missing school was infrequently reported
  - Few (approximately 1%) reported seeking medical care
- Local and systemic reactions were reported with similar frequency as during clinical trials

Data from VAERS

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

CDC + FDA

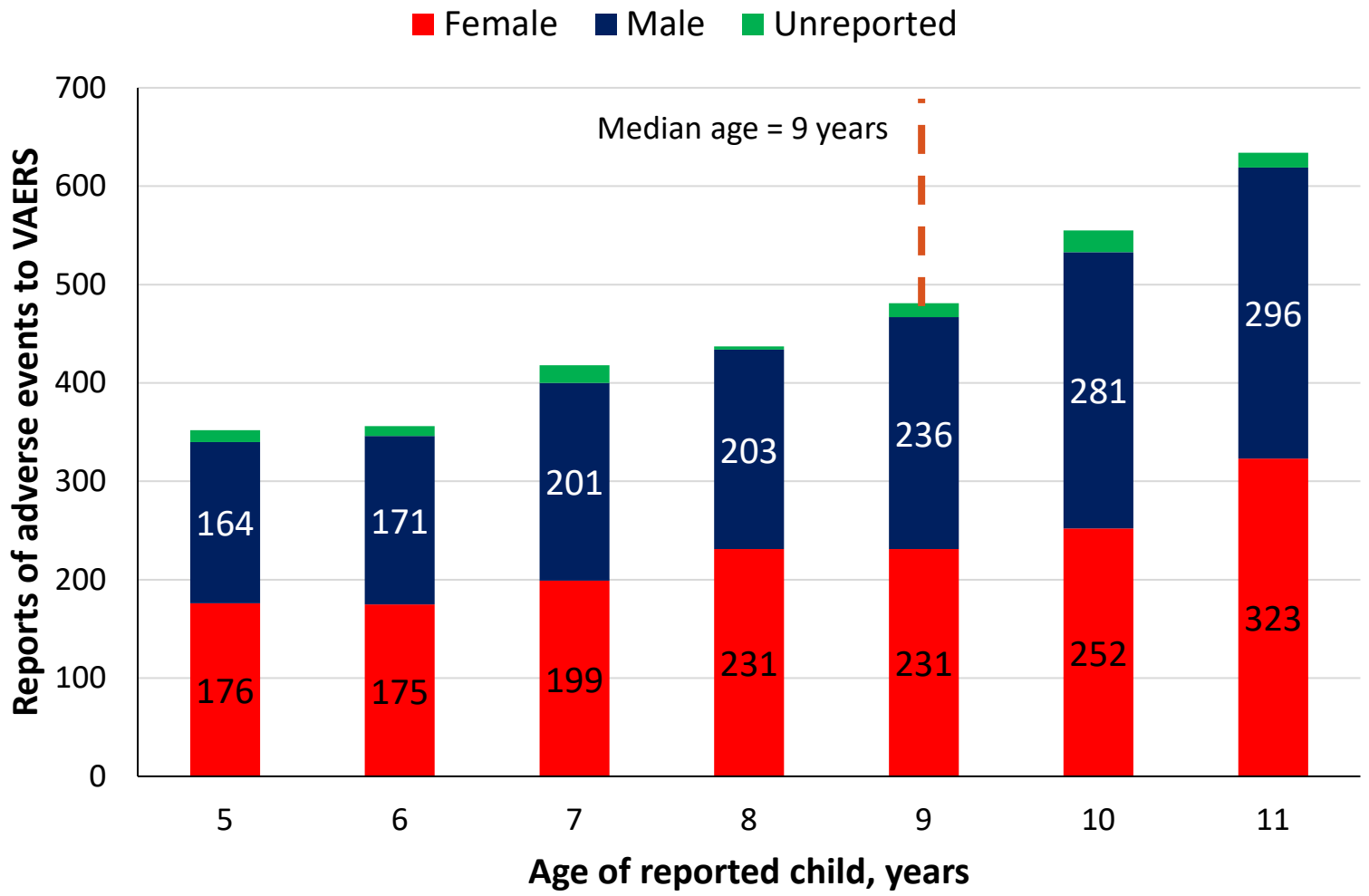
VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

U.S. reports to VAERS among children ages 5–11 years after COVID-19 vaccination (N=3,233 reports) (as of Dec 10, 2021)

- Doses administered = **7,141,428** (as of Dec 9, 2021)
  - Dose 1 = 5,126,642 doses
  - Dose 2 = 2,014,786 doses
- Median age = 9 years
- Sex:
  - Male = 1,552 (48%)
  - Female = 1,587 (49%)
  - Unreported = 94 (3%)



Reports among children ages 5–11 years after COVID-19 vaccination, by race and ethnicity*
(as of Dec 10, 2021)

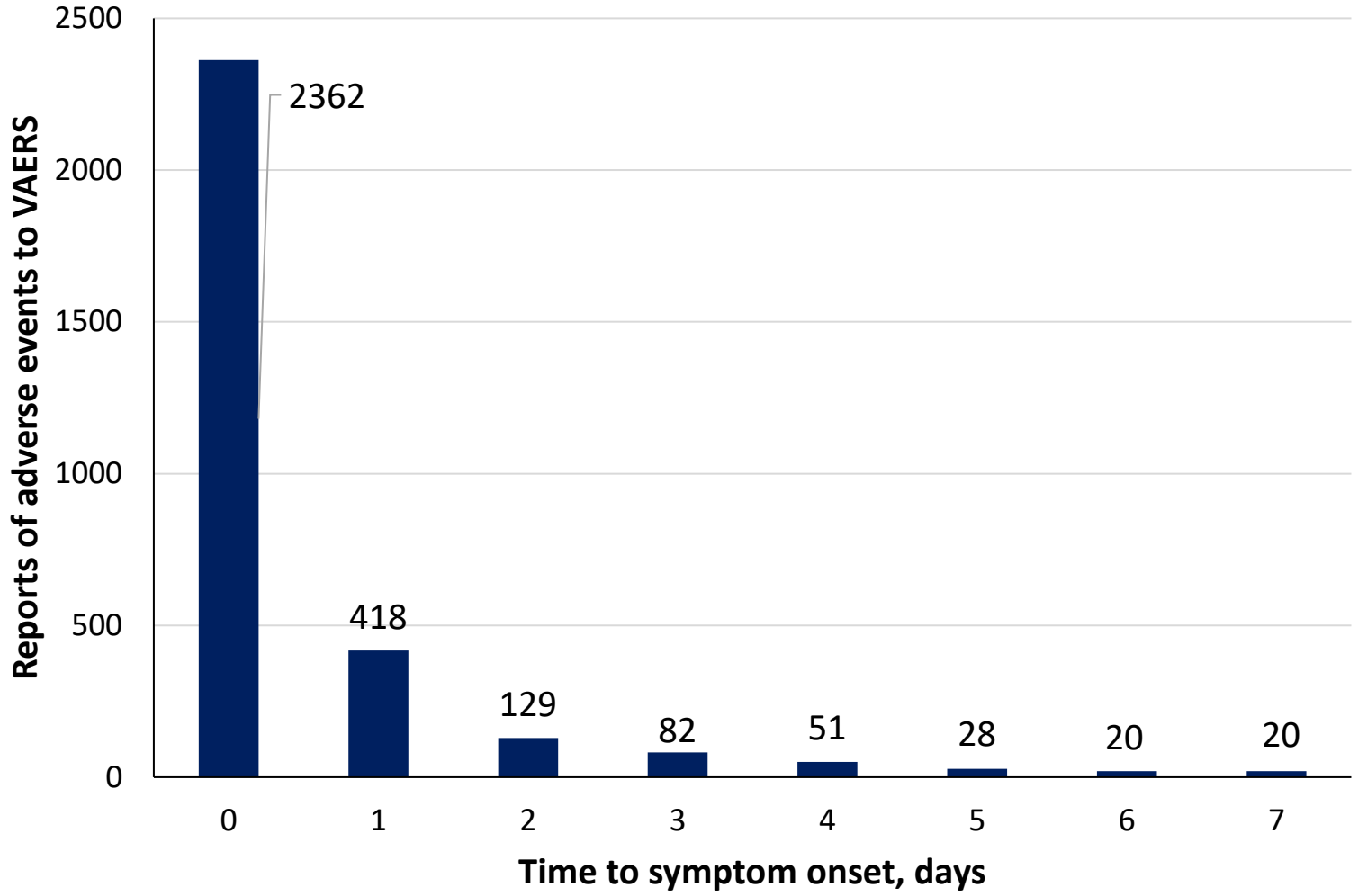
- Most children were of White, non-Hispanic race and ethnicity, or unknown race or ethnicity

Race and ethnicity	Reports (%)
Non-Hispanic White	**1,204 (37)**
Unknown or not reported	**1,060 (33)**
Hispanic*	399 (12)
Non-Hispanic other	187 (6)
Non-Hispanic Black	151 (5)
Non-Hispanic Asian	138 (4)
Non-Hispanic multiracial	71 (2)
Non-Hispanic American Indian/Alaskan Native	17 (1)
Non-Hispanic Native Hawaiian or Other Pacific Islander	Not reported**
Total	**3,233**

* Includes persons reported as of Hispanic ethnicity, but of unreported or unknown race
** < 10 reports

Time from COVID-19 vaccination to symptom onset in children ages 5–11 years (N=3,233 reports) (as of Dec 10, 2021)

- Median time to symptom onset = 0 days (i.e., day of vaccination) (interquartile range = 0–1 days)



Most frequent adverse events among non-serious reports to VAERS following COVID-19 vaccination, children ages 5–11 years (n=3,152) (as of Dec 10, 2021)

Rank	Adverse event (not mutually exclusive)*	n (%)
1	Incorrect dose administered	581 (18)
2	No adverse event	573 (18)
3	Product preparation issue	386 (12)
4	Vomiting	269 (9)
5	Fever	235 (7)
6	Syncope	219 (7)
7	Dizziness	205 (6)
8	Headache	204 (6)
9	Fatigue	175 (6)
10	Product administered to patient of inappropriate age	165 (5)

* Reported adverse events reflect vaccination errors and symptoms observed during preauthorization clinical trials

Most frequent adverse events among serious reports to VAERS following COVID-19 vaccination, children ages 5–11 years (n=81) (as of Dec 10, 2021)

Rank	Adverse event (not mutually exclusive)	n (%)
1	Fever	21 (26)
2	Vomiting	17 (21)
3	Chest pain	11 (14)
4	C-reactive protein increased	10 (12)
5	Echocardiogram normal	10 (12)
6	Troponin increased	10 (12)
7	Intensive care	8 (10)
8	Respiratory viral panel	8 (10)
9	Seizure*	8 (10)
10	Blood test	7 (9)

* Upon review, seizure reports include: assessed as syncope (1), febrile seizure (1), history of seizures (2), potential seizure disorder (1); new onset seizure (3)

Two reported deaths (both still under review)

- Female, age 5 years with complicated medical history:
  - Twin-to-twin transfusion, spastic cerebral palsy, seizure disorder; continuous positive air pressure (CPAP) at night
  - Admitted to PICU for respiratory failure from rhinovirus and *Mycoplasma* infection; stabilized. Observed overnight day of vaccination, discharged home. At baseline when put to bed two nights later. In the morning, found pulseless and not breathing. Unable to resuscitate.
- Female, age 6 years with complicated medical history:
  - Hypoxic encephalopathy, spastic cerebral palsy, dysautonomia, neurogenic bladder, frequent urinary tract infections
  - Ten days after vaccination, developed fever and lactic acidosis; progressive weakness, flaccid paralysis and loss of gag reflex; ultimately, experienced respiratory failure and hypotension; subsequently died; autopsy unrevealing

Reports of myocarditis to VAERS among children ages 5–11 years (n=10) (as of Dec 10, 2021)

- Doses administered = 7,141,428 (as of Dec 9, 2021)
- 3,233 reports to VAERS among children ages 5–11 years
  - 14 reports of myocarditis
    - 5 reports; follow up in progress
    - 9 reports with follow up information obtained
      - **8 reports met CDC working case definition for myocarditis**
        - 4 male, 4 female
        - After dose 1 = 2 cases; after dose 2 = 6 cases
      - 1 report under review

Verified reports of myocarditis among children ages 5–11 years (n=8), continued (as of Dec 10, 2021)

Patient	Age*	Sex	Onset*	Dose	Clinical course
1	6	Male	3	2	Chest pain; elevated troponins (277 ng/L)
2	7	Female	2	2	Chest pain, elevated troponins (5.11 ng/mL); normal EKG and echo; still recovering at time of report
3	8	Female	2	2	Chest pain; elevated troponins (15.0 ng/mL); EKG with ST elevations, echo with mitral regurgitation; improved with treatment (steroids, IVIG); **symptoms resolved**; discharged home
4	9	Male	3	2	Chest pain; elevated troponins (280 ng/L); normal echo and EKG. **Symptoms resolved;** discharged home.
5	10	Female	4	1	Chest pain, shortness of breath; elevated troponins (2.6 ng/mL), normal echo and EKG. **Symptoms resolved**; discharged.
6	10	Male	0	2	Chest pain, vomiting; elevated troponins (12.9 ng/mL); **symptoms resolved** at time of report
7	10	Male	3	2	Diffuse ST elevation on EKG; elevated troponin (value not provided); additional information pending.
8	11	Female	12**	1	Pleuritic chest pain and difficulty breathing; elevated troponins (5.3 ng/mL), EKG with nonspecific ST and T wave changes, normal echo. **Symptoms resolved**; discharged home.

- In 6 reports with known outcomes, 5 children recovered from symptoms

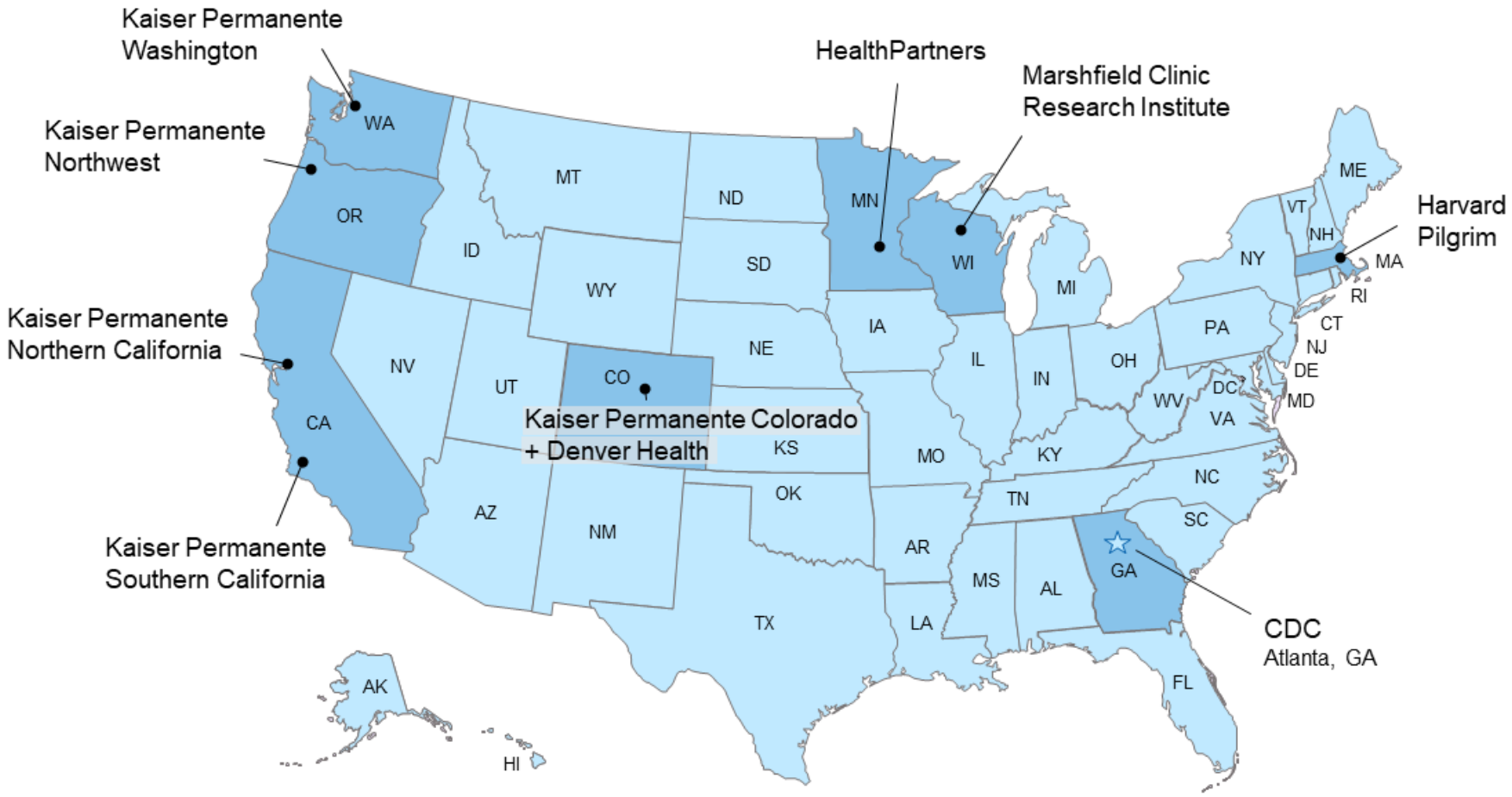
* Age listed in years, time to symptom onset listed in days

** History of headache and gastrointestinal symptoms (vomiting, diarrhea) 3 or 4 days before chest pain began; potential viral syndrome.

Data from VSD

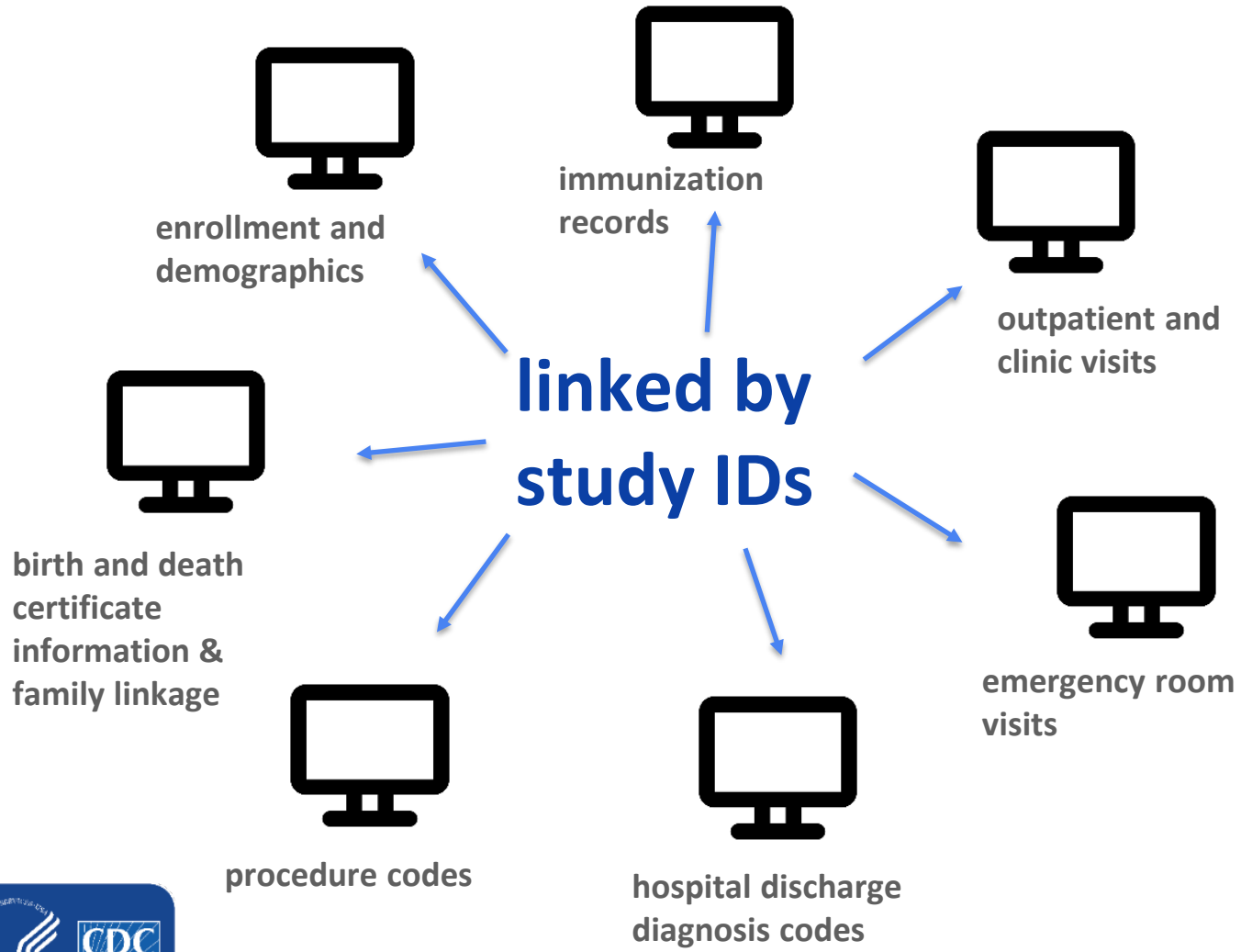
VSD

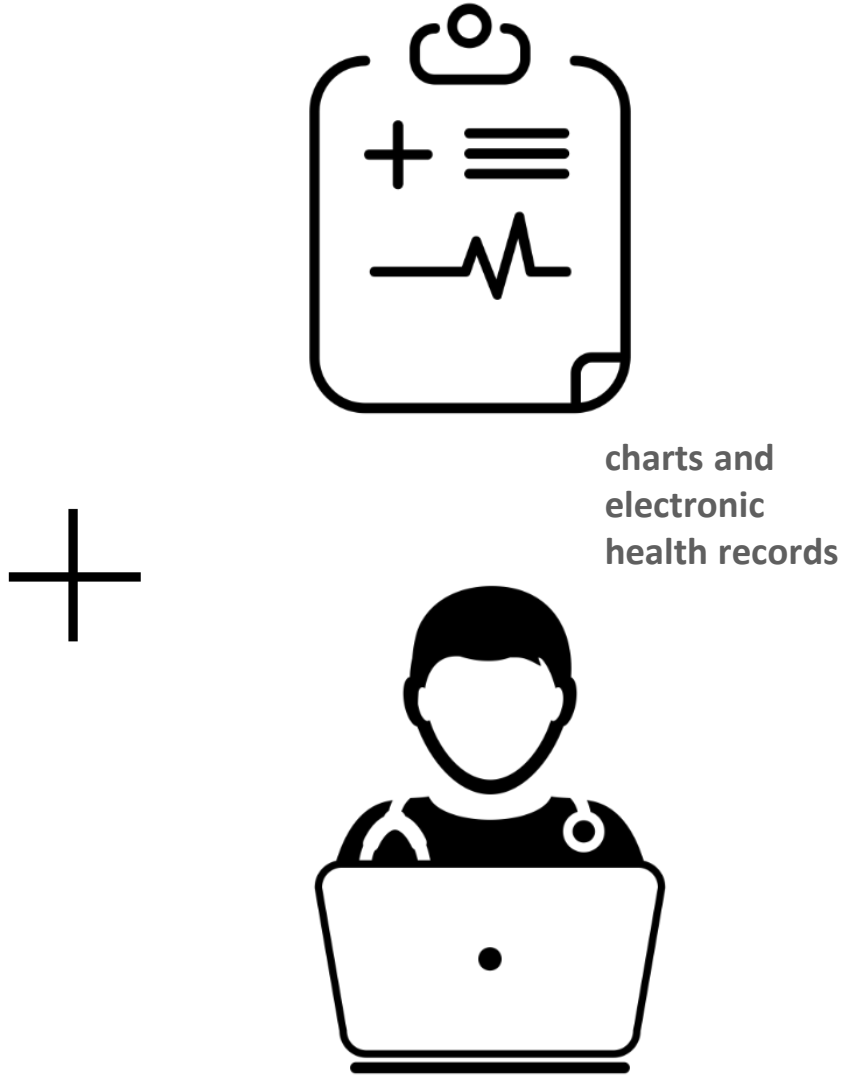
Vaccine Safety Datalink



- **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

- Near real-time sequential (i.e., weekly) monitoring (rapid cycle analysis) as data become available
- As of Dec 14, 2021
  - 333,000 doses administered (226,000 dose 1, 107,000 dose 2)
  - No confirmed reports of myocarditis in 0–7; 0–21-day risk windows)

VSD COVID-19 vaccine prespecified surveillance outcomes	Settings	Risk window (days)
Acute disseminated encephalomyelitis	E, I	1-21, 1-42
Acute myocardial infarction – **First Ever**	E, I	1-21, 1-42
Acute respiratory distress syndrome*	E, I	0-84
Anaphylaxis – **First in 7 days***	E, I	0-1
Appendicitis	E, I	1-21, 1-42
Bell's palsy – **First Ever**	E, I, O	1-21, 1-42
Cerebral venous sinus thrombosis	E, I	1-21, 1-42
Disseminated intravascular coagulation	E, I	1-21, 1-42
Encephalitis / myelitis / encephalomyelitis	E, I	1-21, 1-42
Guillain-Barré syndrome	E, I	1-21, 1-42
Immune thrombocytopenia	E, I, O	1-21, 1-42
Kawasaki disease	E, I	1-21, 1-42
Multisystem inflammatory syndrome in children/adults*	E, I	0-84
Myocarditis / pericarditis – **First in 60 Days**	E, I	1-21, 1-42
Narcolepsy / cataplexy*	E, I, O	0-84
Pulmonary embolism – **First Ever**	E, I	1-21, 1-42
Seizures	E, I	1-21, 1-42
Stroke, hemorrhagic	E, I	1-21, 1-42
Stroke, ischemic	E, I	1-21, 1-42
Thrombosis with thrombocytopenia syndrome – **First Ever**	E, I	1-21, 1-42
Thrombotic thrombocytopenic purpura	E, I	1-21, 1-42
Transverse myelitis	E, I	1-21, 1-42
Venous thromboembolism – **First Ever**	E, I, O	1-21, 1-42

Abbreviations: E=ED, I=Inpatient, O=Outpatient; *Descriptive monitoring

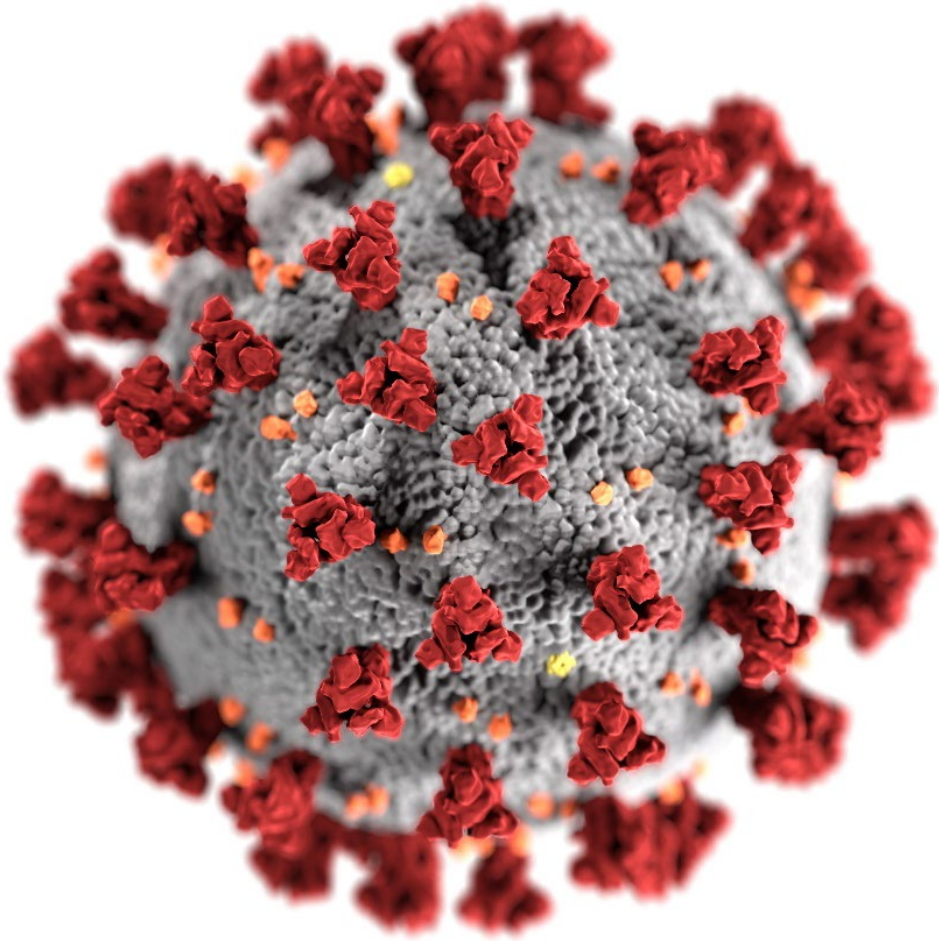
Summary

- During November 2 – December 10, 2021, VAERS received 3,233 reports among children ages 5–11 years
  - As of December 9, **7,141,428** doses of pediatric Pfizer-BioNTech vaccine administered
  - Median age = 9 years; sex distribution by age comparable
  - Most reports among non-Hispanic White children, or children without race or ethnicity reported
  - Median time to symptom onset = 0 days (day of vaccination)
  - Majority of reports (97%) non-serious
    - **Two reported deaths in children with complicated medical histories**
    - **8 reports meeting myocarditis case definition; clinical course mild**

Summary (continued)

- Most common adverse events = vaccination errors and symptoms observed in preauthorization clinical trials
- Reported race and ethnicity in v-safe and VAERS comparable
- In v-safe,
  - Reactions following dose 2 were slightly more frequent
  - Most reactions were mild to moderate and transient
  - Regardless of dose, ≤10% reported missing school
  - Few (approximately 1%) reported seeking medical care
- No reports of myocarditis in 0–7, 0–21-day risk windows in VSD

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.