COVID-19 vaccine safety update: Primary series in young children and booster doses in older children and adults

Advisory Committee on Immunization Practices (ACIP)

September 1, 2022

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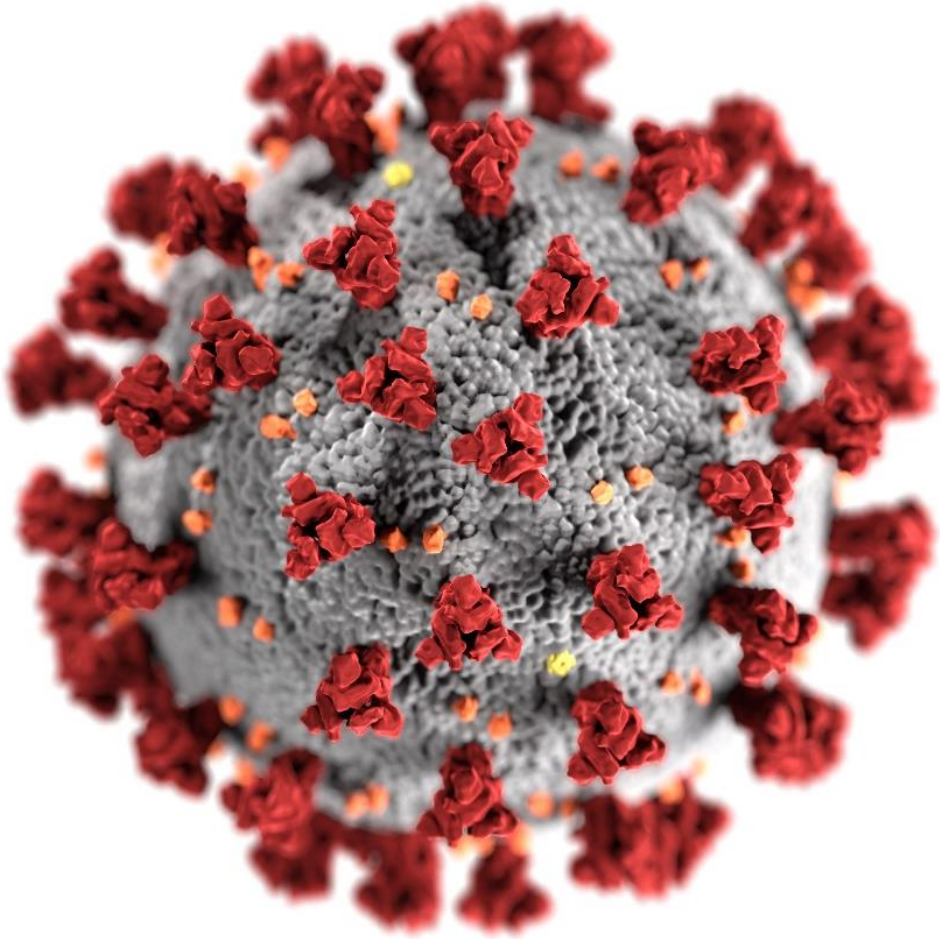


cdc.gov/coronavirus

Topics

- Background on CDC vaccine safety monitoring systems
- Safety of primary series mRNA COVID-19 vaccination in children ages 6 months–5 years
- Safety of mRNA COVID-19 booster vaccinations in people ages 5 years and older
- Summary

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

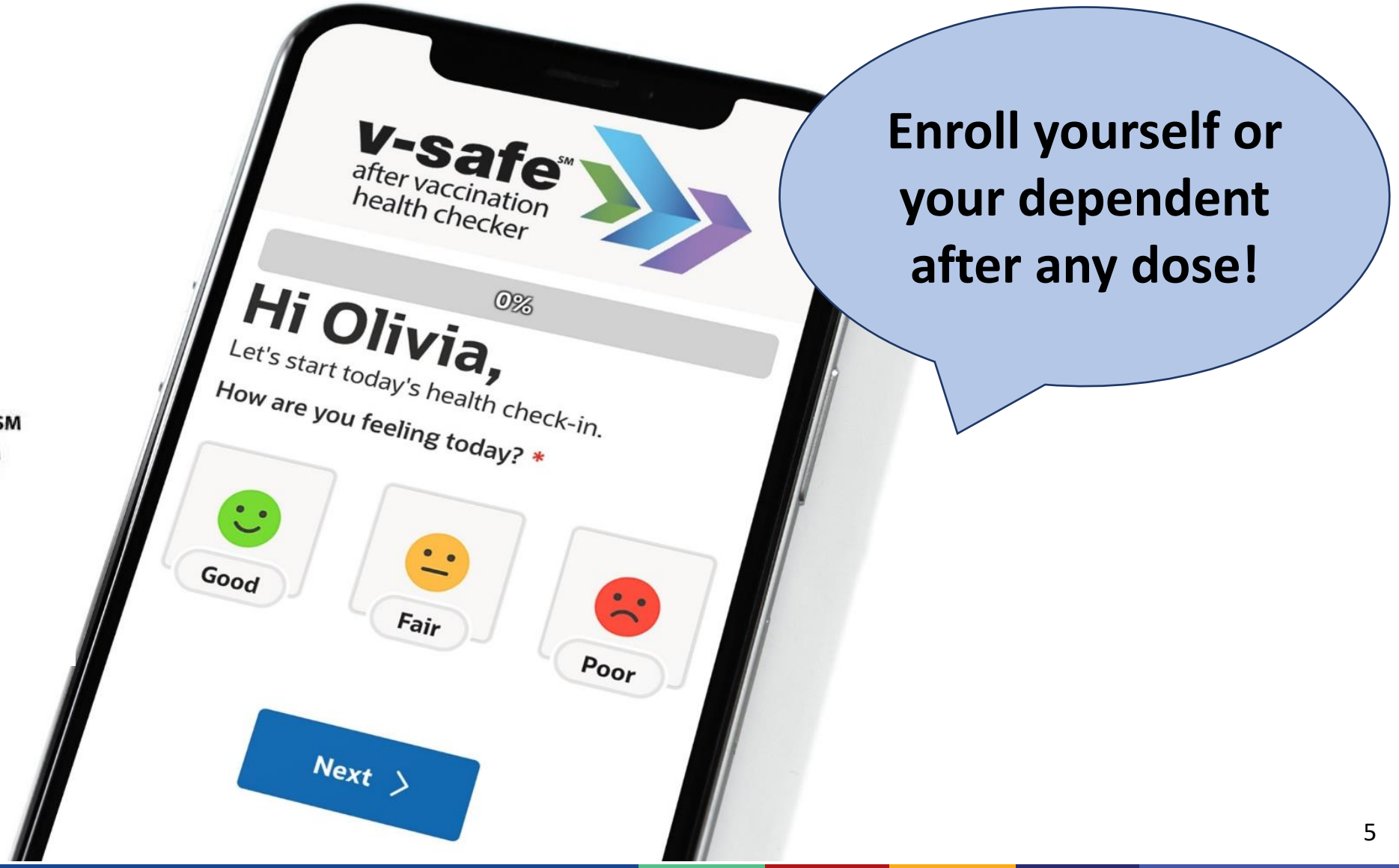
- Passive surveillance system
- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect

CDC + FDA

VAERS

Smartphone-based active safety monitoring

v-safe[SM]
after vaccination
health checker



Enroll yourself or your dependent after any dose!

https://vsafe.cdc.gov

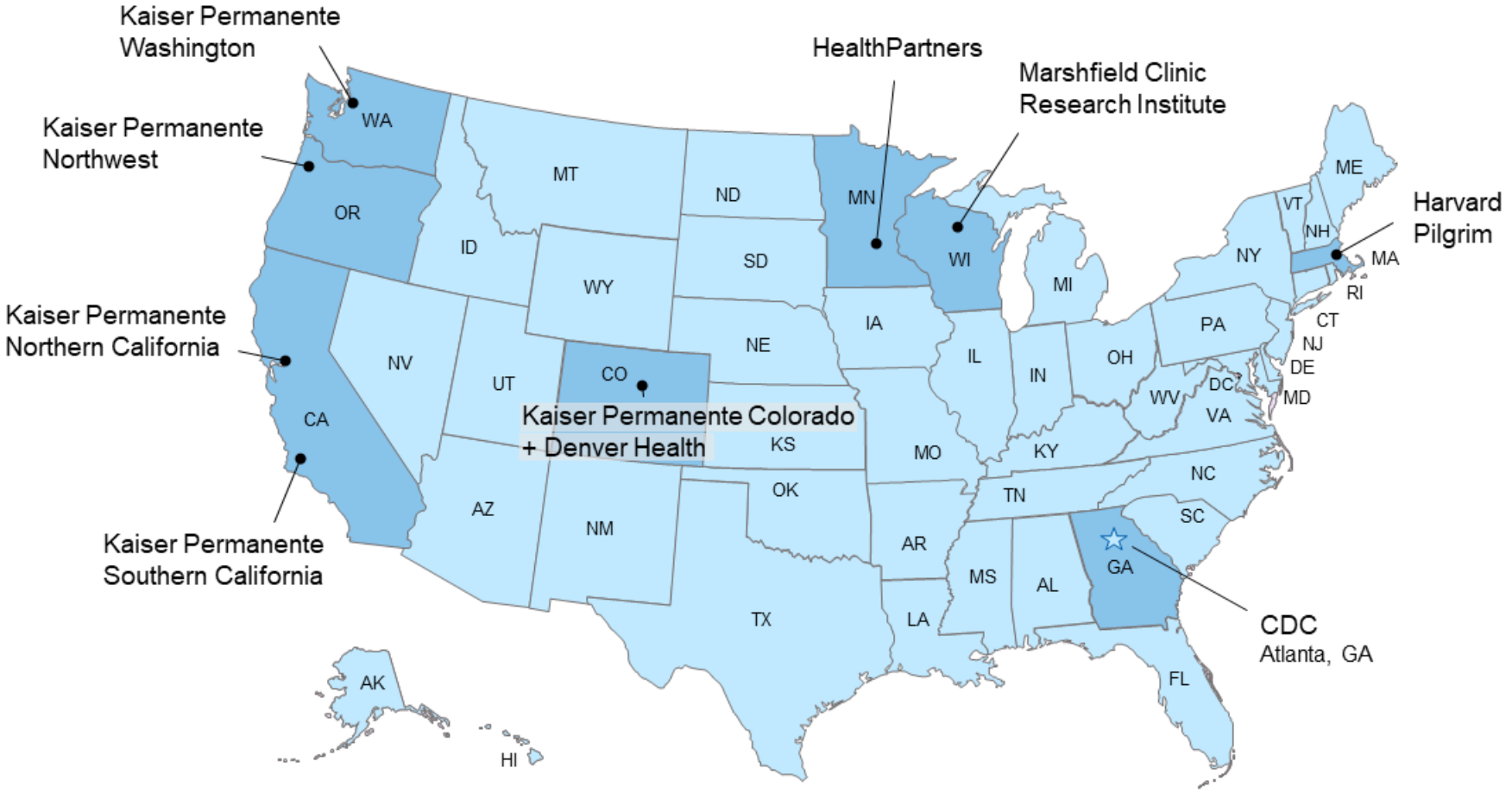
Active safety monitoring for COVID-19 vaccines

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)
- Parents can register and complete surveys on behalf of their child

v-safe
after vaccination
health checker

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

mRNA COVID-19 vaccine safety of primary series vaccination in children ages 6 months–5 years

U.S. reports to VAERS among children after primary series Pfizer-BioNTech (ages 6 months–4 years) or Moderna (ages 6 months–5 years) vaccination* (as of August 21, 2022)

Manufacturer	Doses admin†	Total reports	Median age	Male‡ n (%)	Female‡ n (%)	Non-serious n (%)	Serious§ n (%)	Myocarditis reports (n)
Pfizer-BioNTech	890,378	496	3 years	249 (50)	245 (49)	486 (98)	10 (2)	0
Moderna	664,484	521	2 years	272 (52)	240 (46)	512 (98)	9 (2)	0
Total	**1,554,862**	**1,017**	**3 years**	**521 (51)**	**485 (48)**	**998 (98)**	**19 (2)**	**0**

* Among children ages 6 months–4 years after Pfizer-BioNTech, and among children ages 6 months–5 years after Moderna, vaccinated during June 18–August 21, 2022; reports received and processed as of August 23, 2022

† Dose 1 and dose 2 administered among children described in previous footnote during June 16–August 18, 2022.

‡ 2 reports after Pfizer-BioNTech and 9 reports after Moderna did not have sex reported

§ 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

CDC + FDA VAERS

Most frequent MedDRA Preferred Terms* in reports to VAERS following primary series Pfizer-BioNTech vaccination in children ages 6 months–4 years† (as of August 21, 2022)

N=496, all reports

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	Incorrect Dose Administered	87 (18)
2	Pyrexia/fever	84 (17)
3	Product Administered to Patient of Inappropriate Age	55 (11)
4	No Adverse Event	54 (11)
5	Rash	52 (11)
6	Product Preparation Issue	50 (10)
7	Vomiting	39 (8)
8	Wrong Product Administered	34 (7)
9	Fatigue	30 (6)
10	SARS-CoV-2 Test Negative	24 (5)

N=496, clinical outcomes only shown‡

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	Pyrexia/fever	84 (17)
2	Rash	52 (11)
3	Vomiting	39 (8)
4	Fatigue	30 (6)
5	Urticaria	23 (5)
6	COVID-19	19 (4)
7	Diarrhoea	19 (4)
8	SARS-CoV-2 Test Positive	18 (4)
9	Cough	17 (3)
10	Decreased Appetite	17 (3)

CDC + FDA

VAERS

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

† Among children ages 6 months–4 years vaccinated during June 18–August 21, 2022; reports received and processed as of August 23, 2022

‡ Determined by subject matter expert review

Most frequent MedDRA Preferred Terms* in reports to VAERS following primary series Moderna vaccination in children ages 6 months–5 years† (as of August 21, 2022)

N=521, all reports

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	Pyrexia/Fever	115 (22)
2	Rash	45 (9)
3	Vomiting	45 (9)
4	Urticaria	43 (8)
5	No Adverse Event	42 (8)
6	Expired Product Administered	36 (7)
7	Cough	35 (7)
8	Incorrect Dose Administered	35 (7)
9	SARS-CoV-2 Test Negative	35 (7)
10	Irritability	33 (6)

N=521, clinical outcomes only shown‡

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	Pyrexia/Fever	115 (22)
2	Rash	45 (9)
3	Vomiting	45 (9)
4	Urticaria	43 (8)
5	Cough	35 (7)
6	Irritability	33 (6)
7	Fatigue	31 (6)
8	Decreased Appetite	30 (6)
9	Rash Erythematous	28 (5)
10	Diarrhoea	27 (5)

CDC + FDA

VAERS

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

† Among children ages 6 months–5 years vaccinated during June 18–August 21, 2022; reports received and processed as of August 23, 2022

‡ Determined by subject matter expert review

V-safe enrollment among children ages 6 months–≤4 years (Pfizer-BioNTech) and 6 months–≤5 years (Moderna)

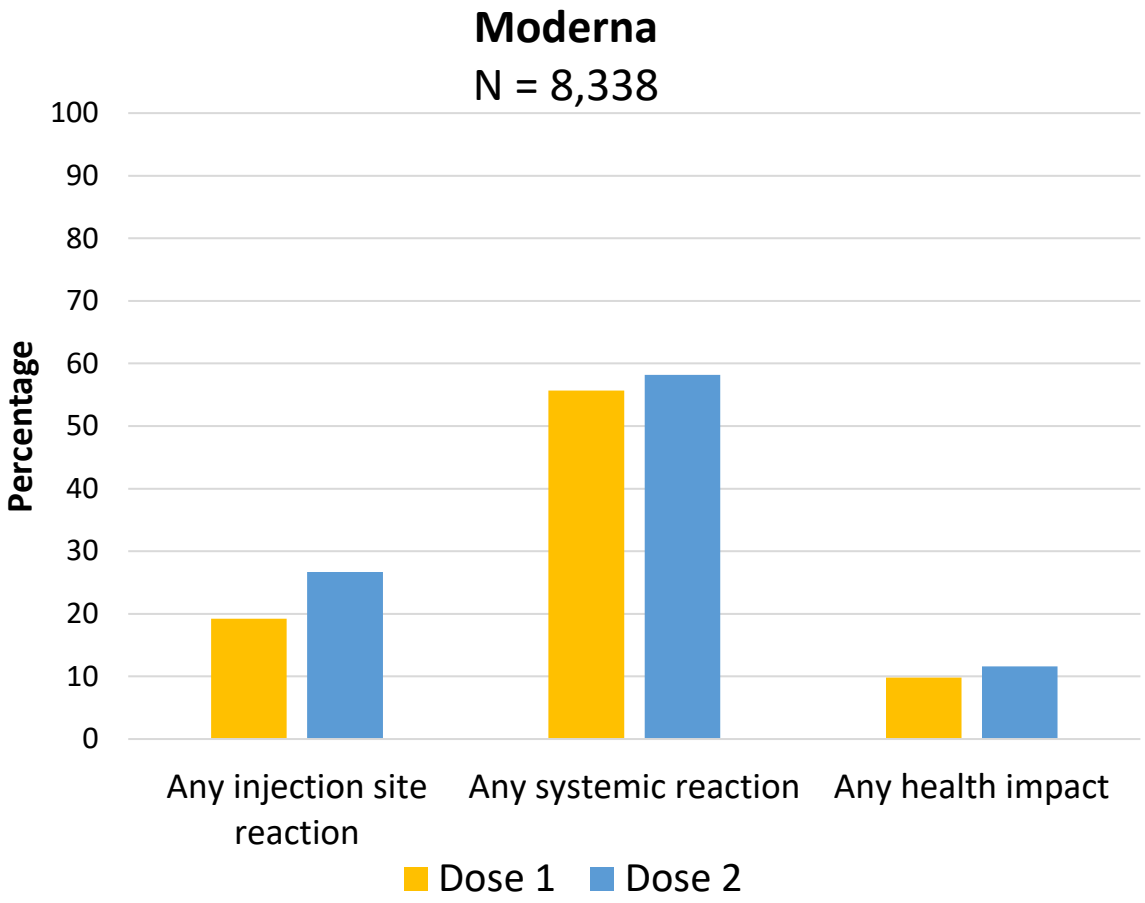
Vaccine and age group	Primary series doses administered nationally*	V-safe enrollment
Moderna in children ≤5 years	664,484	14,725 children
Pfizer-BioNTech in children ≤4 years	890,378	8,541 children

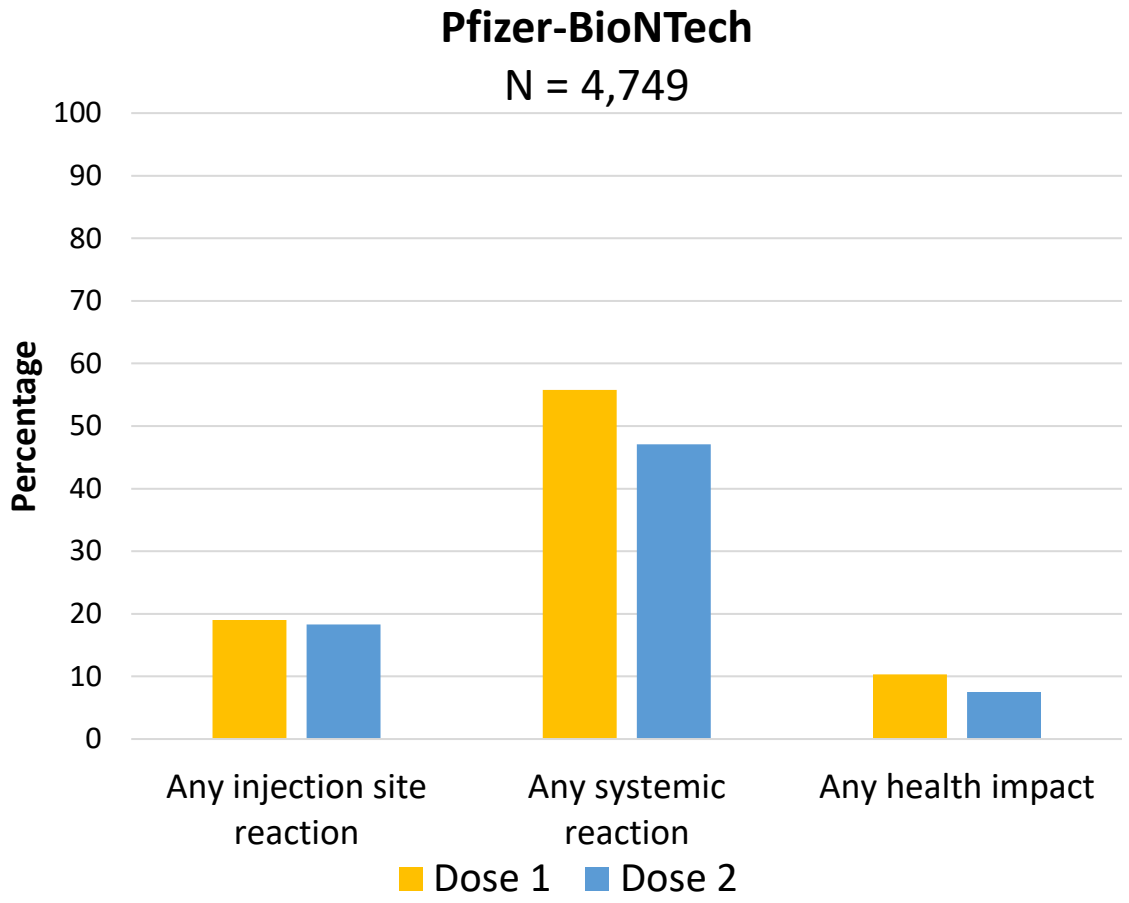
v-safe after vaccination health checker

Data as of August 21, 2022

* Dose 1 and dose 2 administered among children described in previous footnote during June 16–August 18, 2022.

Reactions and health impacts reported for children aged 6 months–≤2 years at least once in days 0–7 following COVID-19 vaccination, by dose

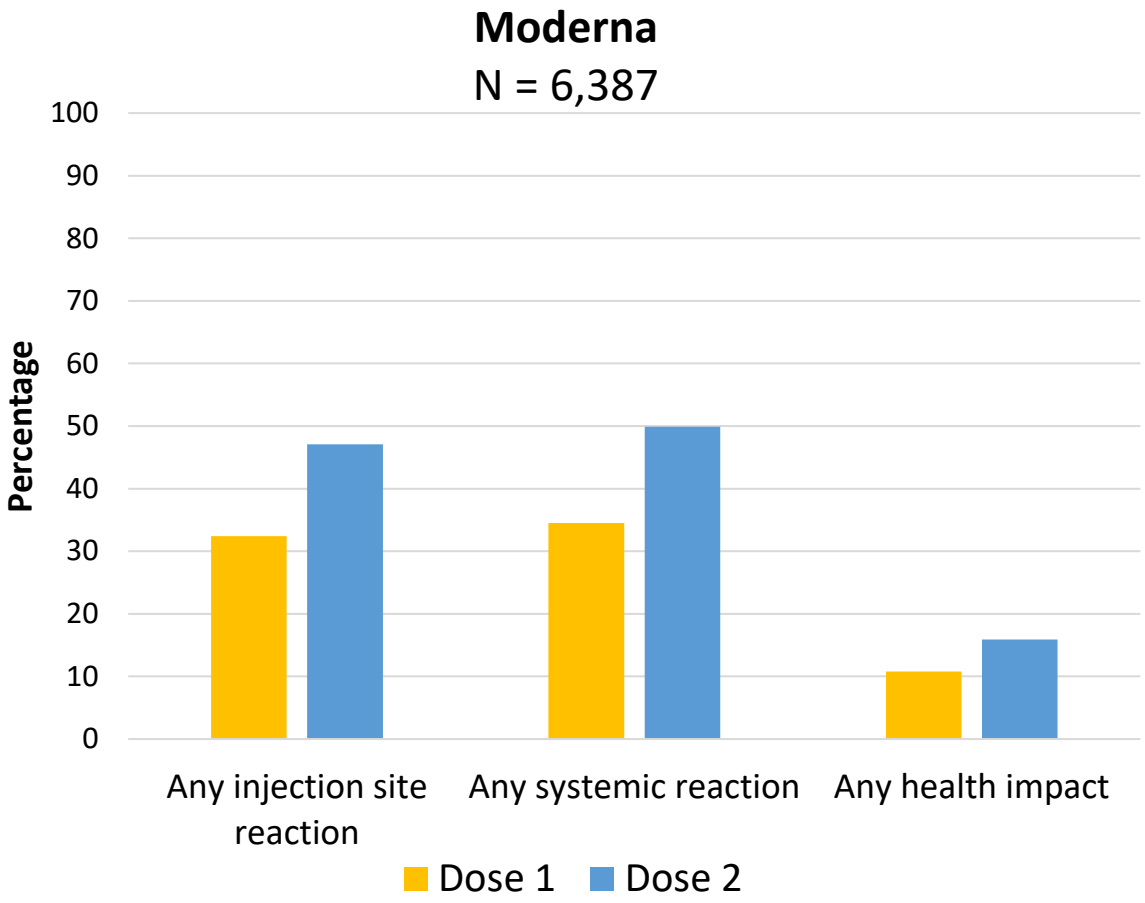


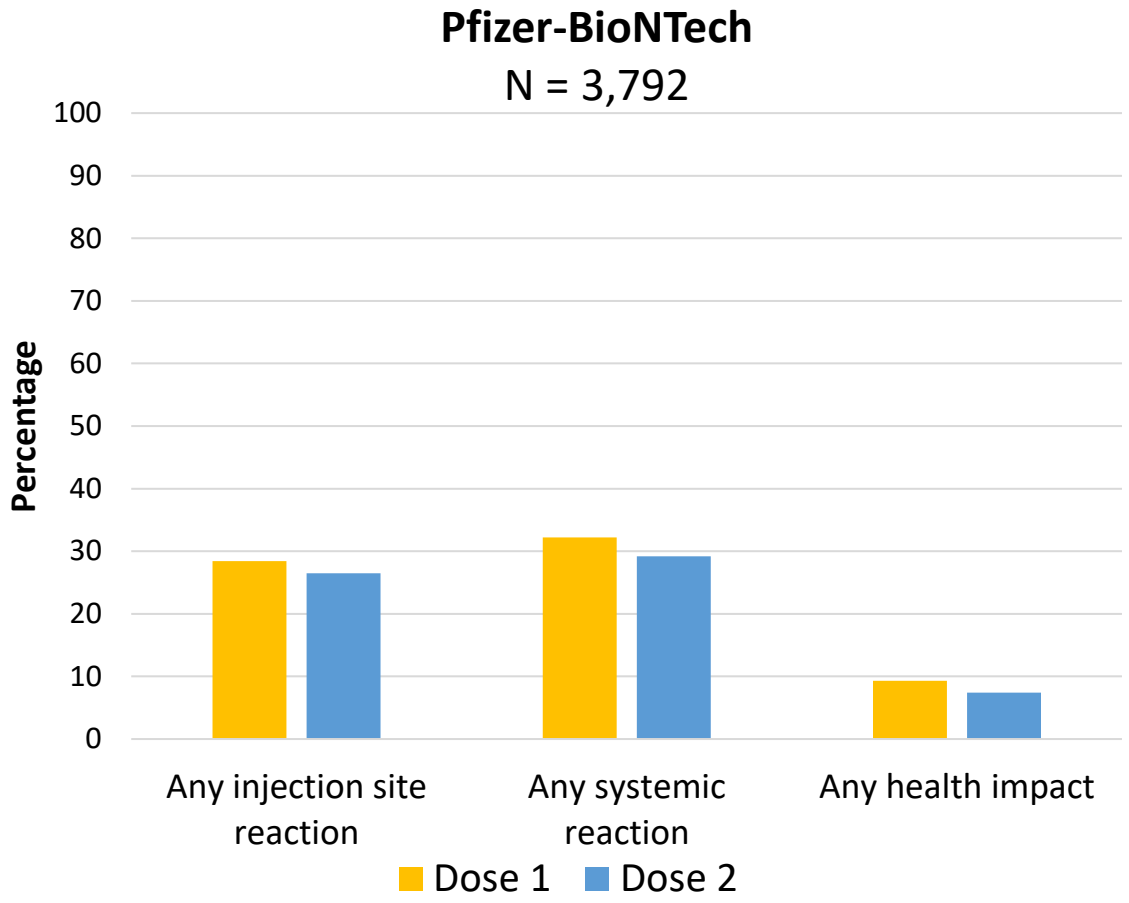


v-safe after vaccination health checker

Data as of August 21, 2022. Includes 4,749 children (aged 6 months–2 years) who received Pfizer-BioNTech and 8,338 who received Moderna.

Reactions and health impacts reported for children aged 3–5 years at least once in days 0–7 following COVID-19 vaccination, by dose





v-safe after vaccination health checker

Data as of August 21, 2022. Includes 3,792 children (aged 3–4 years) who received Pfizer-BioNTech and 6,387 who received Moderna (aged 3–5 years) .

VSD COVID-19 vaccine RCA prespecified surveillance outcomes

EHR = Electronic health record

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 (including 0-7 days for youngest ages)	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 vaccine safety datalink

VSD RCA results in children ages 6 months–4 years (Pfizer-BioNTech) and 6 months–5 years (Moderna) for primary series mRNA COVID-19 vaccination

- Doses administered:

Doses	Pfizer-BioNTech	Moderna	Total
Dose 1	31,784	34,466	66,250
Dose 2	18,729	17,940	36,669
Total	**50,513**	**52,406**	**102,919**

- No statistical signals to date* for any pre-specified surveillance outcomes for either mRNA COVID-19 vaccine

VSD
vaccine safety datalink

* Data through Aug 13, 2022

Summary: mRNA COVID-19 vaccine safety of primary series vaccination in children ages 6 months–5 years

- Initial safety findings of both mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna) are consistent with those observed in the clinical trials
- Systemic and local reactions are commonly reported adverse events
- Vaccination errors are also being reported to VAERS
- No unexpected safety findings to date
- No evidence of an increased risk for myocarditis following mRNA COVID-19 vaccination in children ages 6 months–5 years

COVID-19 vaccine safety of booster doses in people ages 5 years and older

U.S. reports to VAERS following 1st and 2nd mRNA COVID-19 booster vaccinations* (as of August 21, 2022)

Booster dose	Doses admin†	Total reports	Median age	Male‡ n (%)	Female‡ n (%)	Non-serious n (%)	Serious n (%)
1st booster (5–11 years)	1,153,611	727	9 years	369 (51)	348 (48)	723 (99)	4 (1)
1st booster (≥12 years)	102,063,616	64,265	53 years	21,841 (34)	41,234 (64)	57,048 (89)	7,217 (11)
2nd booster (≥50 years)	20,145,400	12,619	68 years	4,556 (36)	7,973 (63)	11,895 (94)	724 (6)

* Among persons receiving Pfizer-BioNTech dose 3: children ages 5–11 years vaccinated during May 17–August 21, 2022; children and adolescents ages 12–15 years vaccinated during January 3–August 21, 2022, and ages 16–17 years vaccinated during December 9, 2021–August 21, 2022; adults ages ≥18 years vaccinated during September 22, 2021–August 21, 2022. Among persons receiving Moderna dose 3: adults ages ≥18 years vaccinated during October 20, 2021–August 21, 2022. Among persons ages ≥50 years: dose 4 Pfizer-BioNTech or Moderna vaccine received during March 29–August 21, 2022.

† Doses of Pfizer-BioNTech dose 3 administered among children ages 5–11 years during June 16–August 18, 2022; children and adolescents ages 12–15 years during January 6–August 18, 2022; adolescents ages 16–17 years during December 9, 2021–August 18, 2022; adults ages ≥18 years during September 22, 2021–August 18, 2022. Doses of Moderna dose 3 administered among adults ages ≥18 years during October 28, 2021–August 18, 2022. Among adults ages ≥50 years, 2nd booster dose of Pfizer-BioNTech or Moderna vaccine administered during March 28–August 18, 2022.

‡ Sex was not reported in approximately 2% of reports.

CDC + FDA

VAERS

Most frequent MedDRA Preferred Terms* in reports to VAERS following 1st booster dose mRNA COVID-19 vaccinations, ages 5–11 years† (as of August 21, 2022)

N=727, all reports

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	Product Preparation Issue	197 (27)
2	Incorrect Dose Administered	164 (23)
3	No Adverse Event	139 (19)
4	Product Preparation Error	69 (9)
5	Product Administered To Patient Of Inappropriate Age	67 (9)
6	Expired Product Administered	53 (7)
7	Pyrexia/Fever	51 (7)
8	Pain In Extremity	40 (6)
9	Fatigue	37 (5)
10	Vomiting	27 (4)

N=727, clinical outcomes only shown‡

Rank	MedDRA PT (not mutually exclusive)	n (%)
1	Pyrexia/Fever	51 (7)
2	Pain In Extremity	40 (6)
3	Fatigue	37 (5)
4	Vomiting	27 (4)
5	Dizziness	24 (3)
6	Headache	23 (3)
7	Injection Site Pain	23 (3)
8	Pain	21 (3)
9	Chills	18 (2)
10	Lymphadenopathy	18 (2)

CDC + FDA

VAERS

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

† Among children ages 5–11 years receiving Pfizer-BioNTech dose 3 during May 17–August 21, 2022; reports received and processed as of August 23, 2022

‡ Determined by subject matter expert review

Most frequent MedDRA Preferred Terms* in reports to VAERS following 1st booster dose mRNA COVID-19 vaccinations, ages ≥12 years† (as of August 21, 2022)

N=57,048, non-serious reports (clinical outcomes)

Rank	Adverse event (not mutually exclusive)	n (%)
1	Headache	7,006 (12)
2	Pyrexia/Fever	6,804 (12)
3	Pain	6,702 (12)
4	Fatigue	6,542 (11)
5	Chills	5,310 (9)
6	COVID-19	4,957 (9)
7	Pain In Extremity	4,272 (7)
8	Nausea	3,548 (6)
9	Dizziness	3,353 (6)
10	Urticaria	3,240 (6)

N=7,217, serious reports (clinical outcomes)

Rank	Adverse event (not mutually exclusive)	n (%)
1	COVID-19	2,479 (34)
2	SARS-CoV-2 Test Positive	2,017 (28)
3	Dyspnoea	1,223 (17)
4	Death	794 (11)
5	Asthenia	730 (10)
6	Pyrexia/Fever	651 (9)
7	Fatigue	646 (9)
8	Vaccine Breakthrough Infection	618 (9)
9	Condition Aggravated	615 (9)
10	Chest Pain	578 (8)

CDC + FDA

VAERS

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

† Among persons receiving Pfizer-BioNTech dose 3: children and adolescents ages 12–15 years vaccinated during January 3–August 21, 2022, and ages 16–17 years vaccinated during December 9, 2021–August 21, 2022; adults ages ≥18 years vaccinated during September 22, 2021–August 21, 2022. Among persons receiving Moderna dose 3: adults ages ≥18 years vaccinated during October 20, 2021–August 21, 2022.

Most frequent MedDRA Preferred Terms* in reports to VAERS following 2nd booster dose mRNA COVID-19 vaccinations, ages ≥50 years† (as of August 21, 2022)

N=11,895, non-serious reports (clinical outcomes)

Rank	Adverse event (not mutually exclusive)	n (%)
1	COVID-19	3,951 (33)
2	SARS-CoV-2 Test Positive	2,757 (23)
3	Fatigue	2,057 (17)
4	Cough	1,724 (14)
5	Headache	1,645 (14)
6	Pyrexia/Fever	1,622 (14)
7	Pain	1,247 (10)
8	Oropharyngeal Pain	1,235 (10)
9	Rhinorrhoea	838 (7)
10	Malaise	811 (7)

N=724, serious reports (clinical outcomes)

Rank	Adverse event (not mutually exclusive)	n (%)
1	COVID-19	218 (30)
2	SARS-CoV-2 Test Positive	165 (23)
3	Dyspnoea	91 (13)
4	Asthenia	76 (11)
5	Fatigue	76 (11)
6	Death	66 (9)
7	Vaccine Breakthrough Infection	65 (9)
8	Headache	64 (9)
9	Cough	60 (8)
10	Pyrexia/Fever	60 (8)

CDC + FDA

VAERS

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

† Among persons receiving Pfizer-BioNTech or Moderna dose 4 during March 29–August 21, 2022

VAERS reporting rates of verified myocarditis per 1 million mRNA COVID-19 1st and 2nd booster vaccinations (Pfizer-BioNTech or Moderna), days 0–7 post-vaccination*,†

	1st booster (≥5 years)		2nd booster (≥50 years)	
Age group	Male	Female	Male	Female
5–11 years	0.0	0.0	-	-
12–15 years	12.9	0.7	-	-
16–17 years	21.6	0.0	-	-
18–24 years	13.1	0.6	-	-
25–29 years	4.4	2.2	-	-
30–39 years	1.9	0.9	-	-
40–49 years	0.2	0.6	-	-
50–64 years	0.4	0.1	0.0	0.3
65+ years	0.7	0.2	0.0	0.0

CDC + FDA

VAERS

* As of August 18, 2022. Reports verified to meet case definition by provider interview or medical record review.

† 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** (peach shaded cells indicate that reporting rate exceeded estimated background incidence for the period)

VAERS reporting rates of verified myocarditis per 1 million mRNA COVID-19 vaccinations (Pfizer-BioNTech and Moderna combined), days 0–7 post-vaccination*,†

	Dose 2 (primary series)		1st booster dose	
Age group	**Male**	**Female**	**Male**	**Female**
5–11 years	2.5	0.7	0.0	0.0
12–15 years	47.1	4.2	12.9	0.7
16–17 years	78.7	7.4	21.6	0.0
18–24 years	39.3	3.9	13.1	0.6
25–29 years	15.3	3.5	4.4	2.2
30–39 years	7.8	1.0	1.9	0.9
40–49 years	3.3	1.6	0.2	0.6
50–64 years	0.7	0.5	0.4	0.1
65+ years	0.3	0.5	0.7	0.2

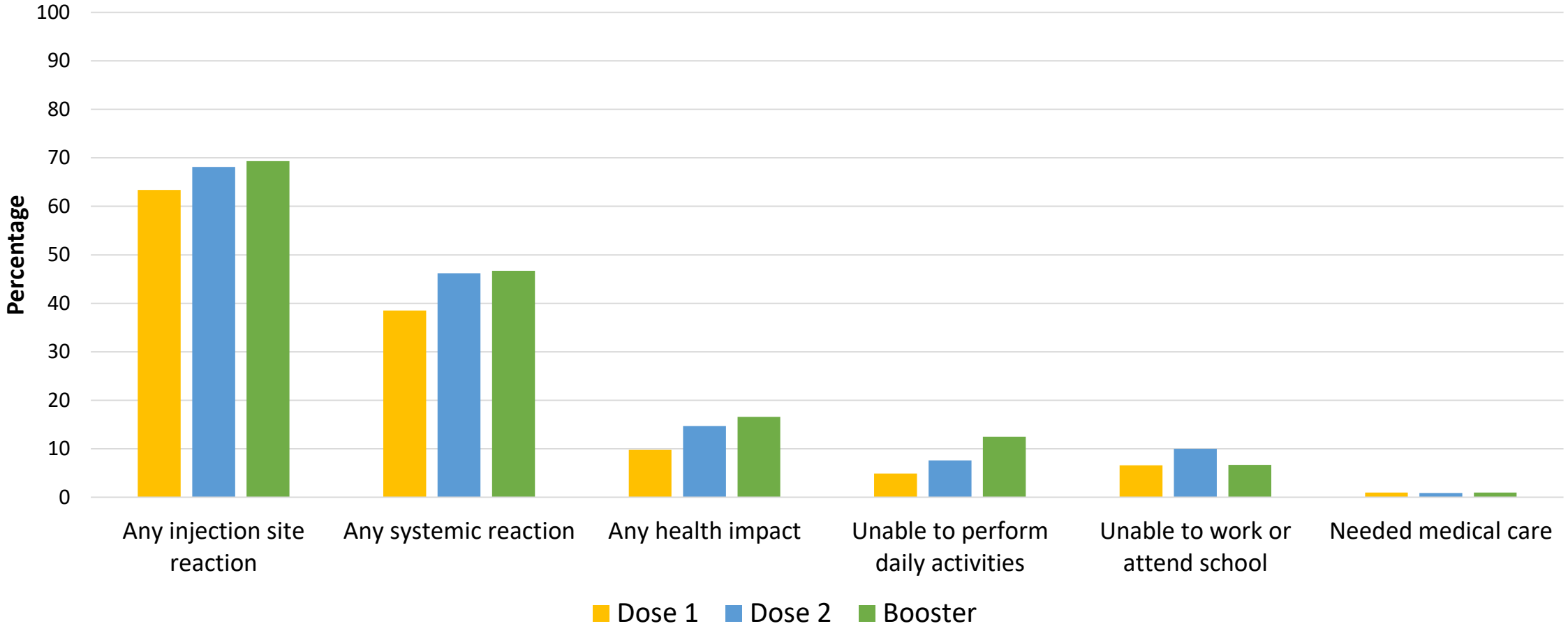
From previous slide

* As of August 18, 2022. Reports verified to meet case definition by provider interview or medical record review.

† 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** (peach shaded cells indicate that reporting rate exceeded estimated background incidence for the period)

CDC + FDA VAERS

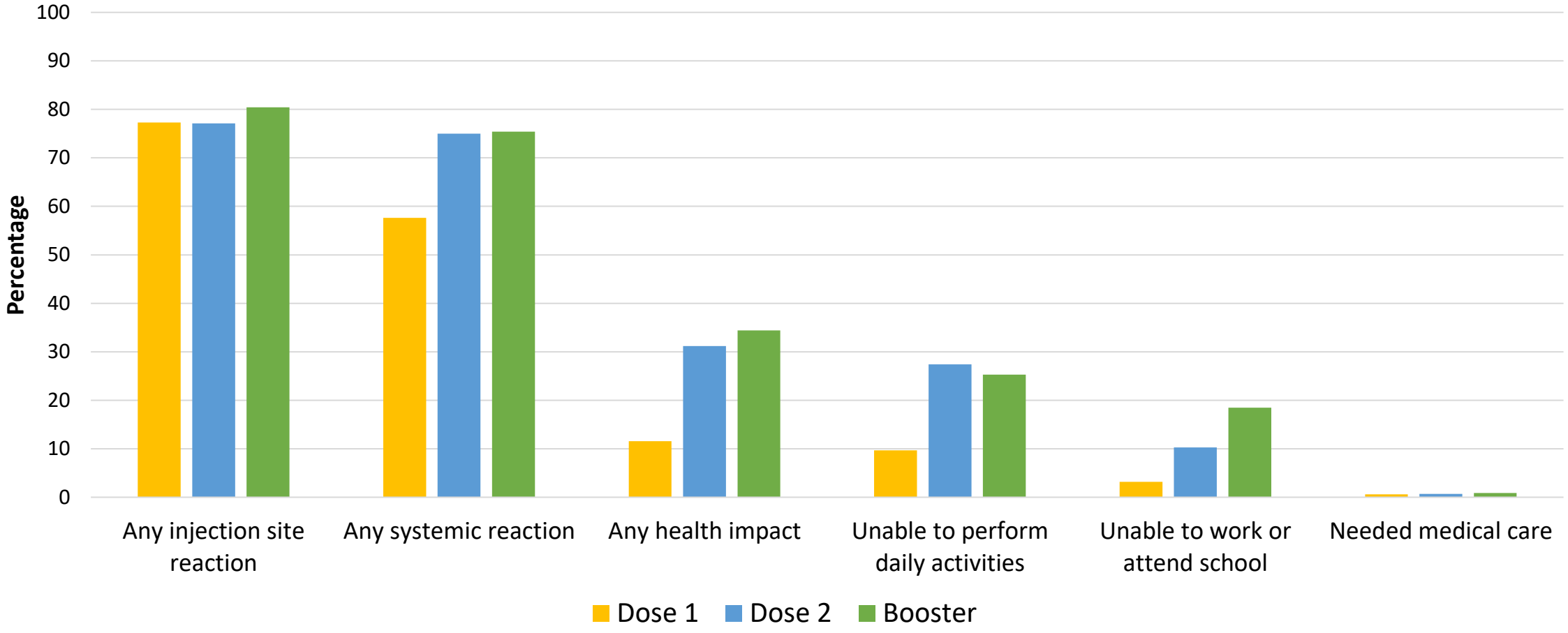
Reactions and health impact events reported by v-safe participants aged 5-11 years at least once in days 0-7 after homologous Pfizer-BioNTech vaccination, by dose



v-safe after vaccination health checker

Includes 3,622 participants who completed at least one survey in the first week after each dose, data collected during May 17–Aug 21, 2022

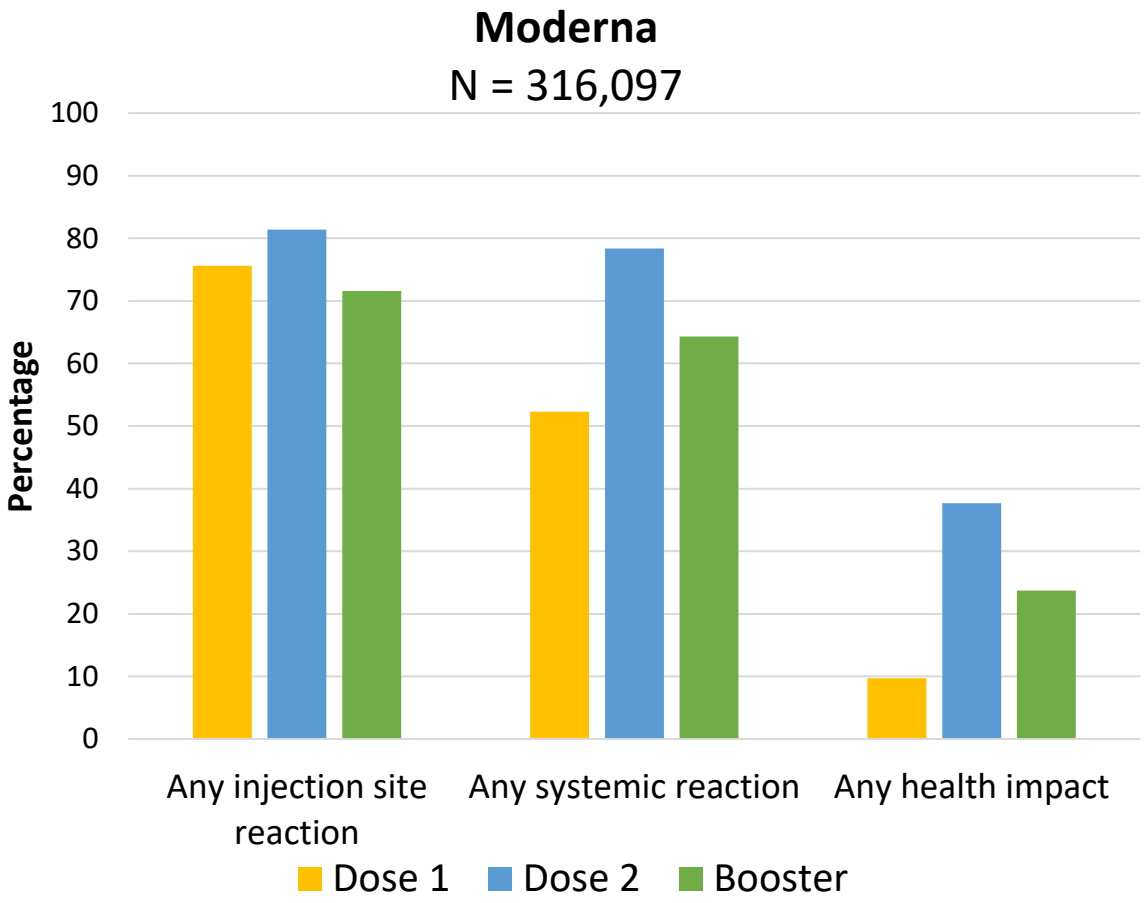
Reactions and health impact events reported by v-safe participants aged 12-17 years at least once in days 0-7 after homologous Pfizer-BioNTech vaccination, by dose

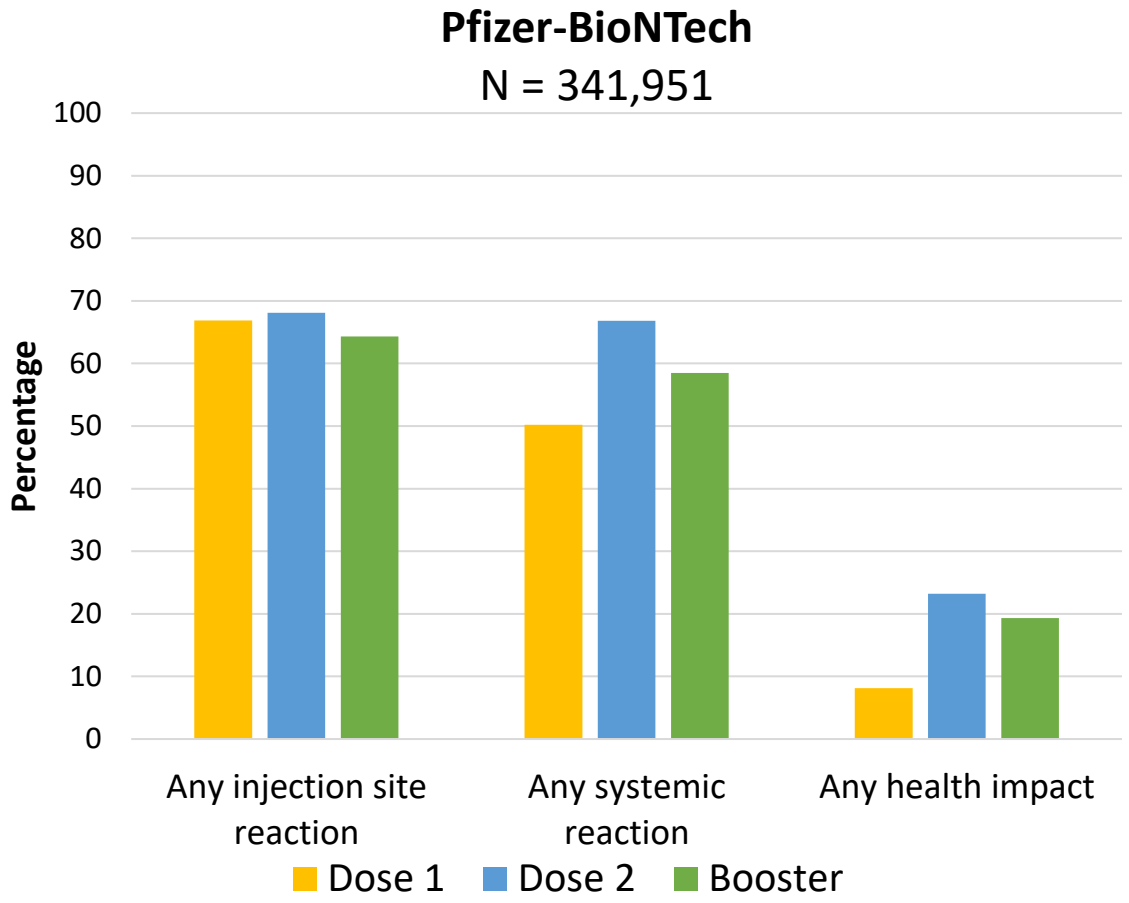


v-safe after vaccination health checker

Includes 4,369 participants who completed at least one survey in the first week after each dose, data collected during Dec 9, 2021–Aug 21, 2022

Reactions and health impact events reported by v-safe participants aged ≥18 years at least once in days 0-7 after homologous vaccination, by dose

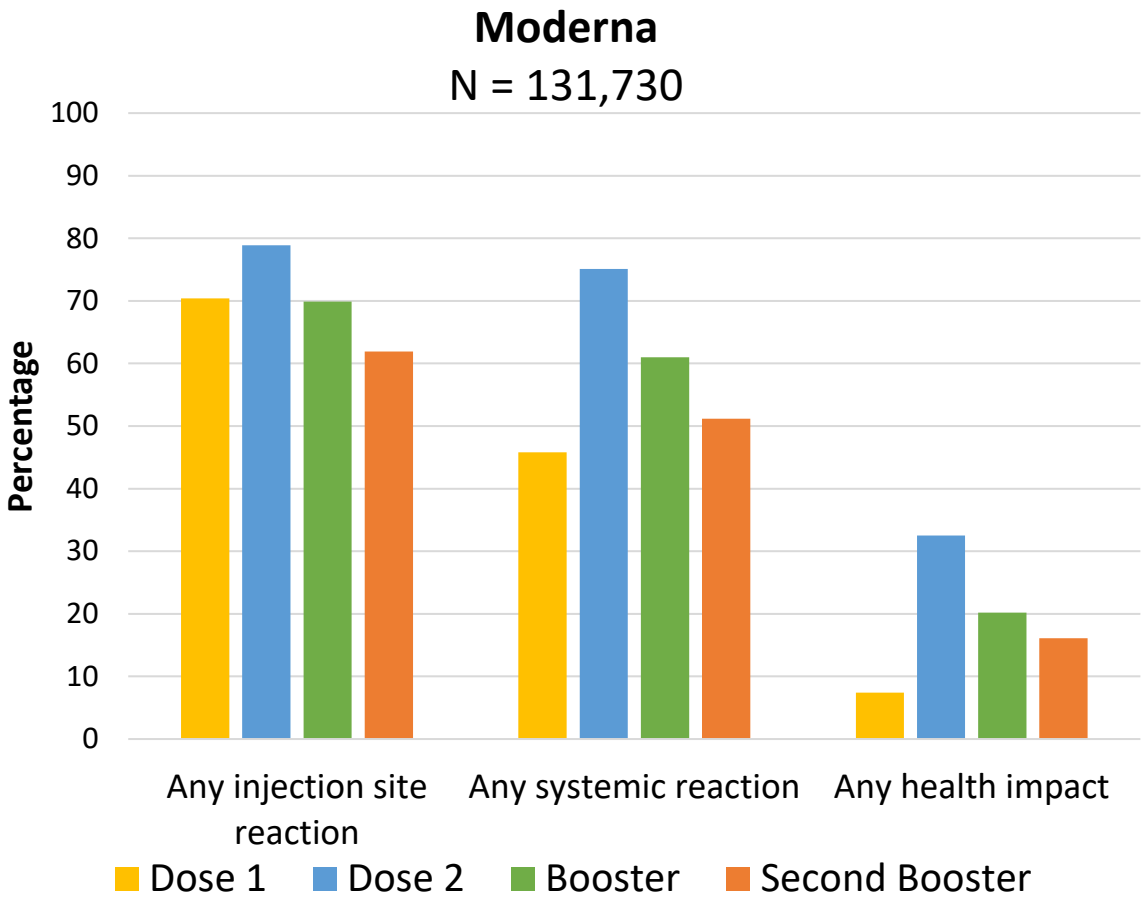


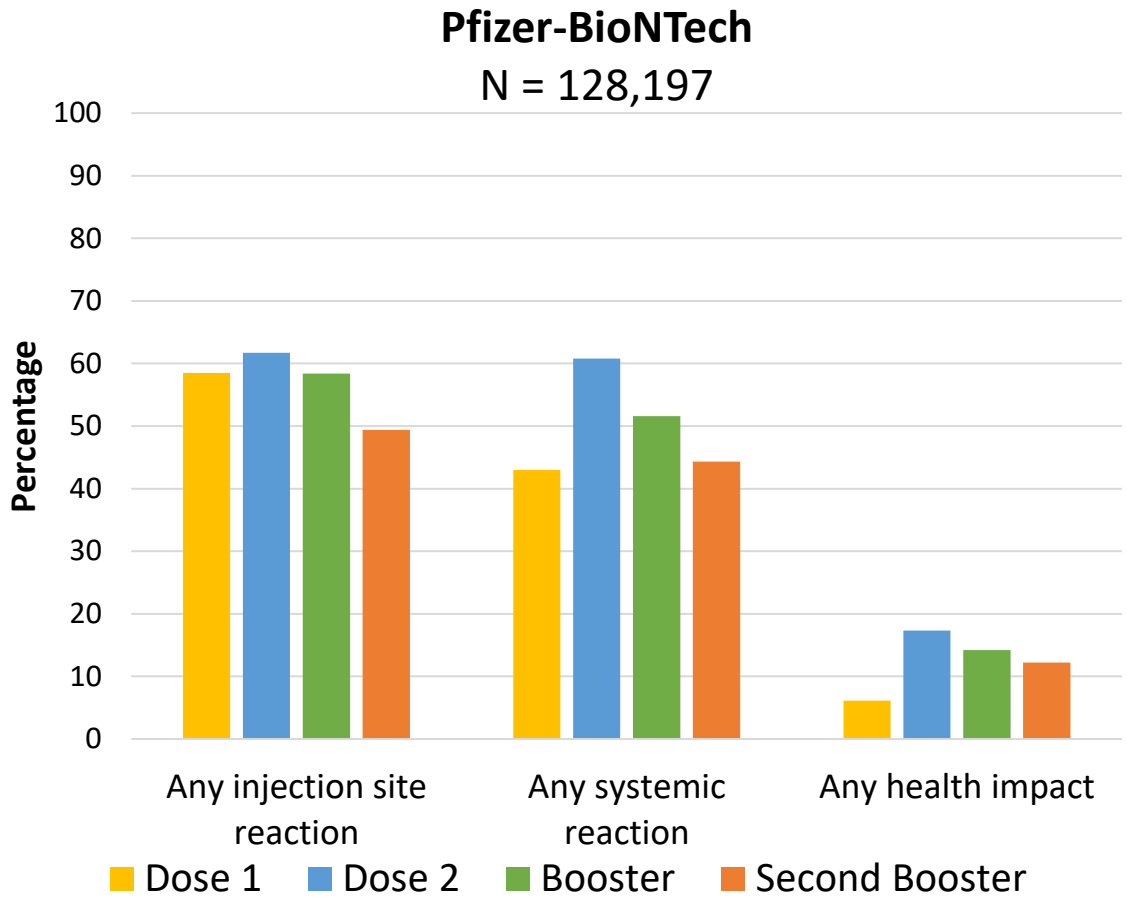


v-safe after vaccination health checker

Includes participants who completed at least one survey in the first week after each dose, data collected during Sept 22, 2021–Aug 21, 2022

Reactions and health impact events reported by v-safe participants aged ≥50 years at least once in days 0-7 after homologous vaccination, by dose





v-safe after vaccination health checker

Includes participants who completed at least one survey in the first week after each dose, data collected during Mar 29–Aug 21, 2022

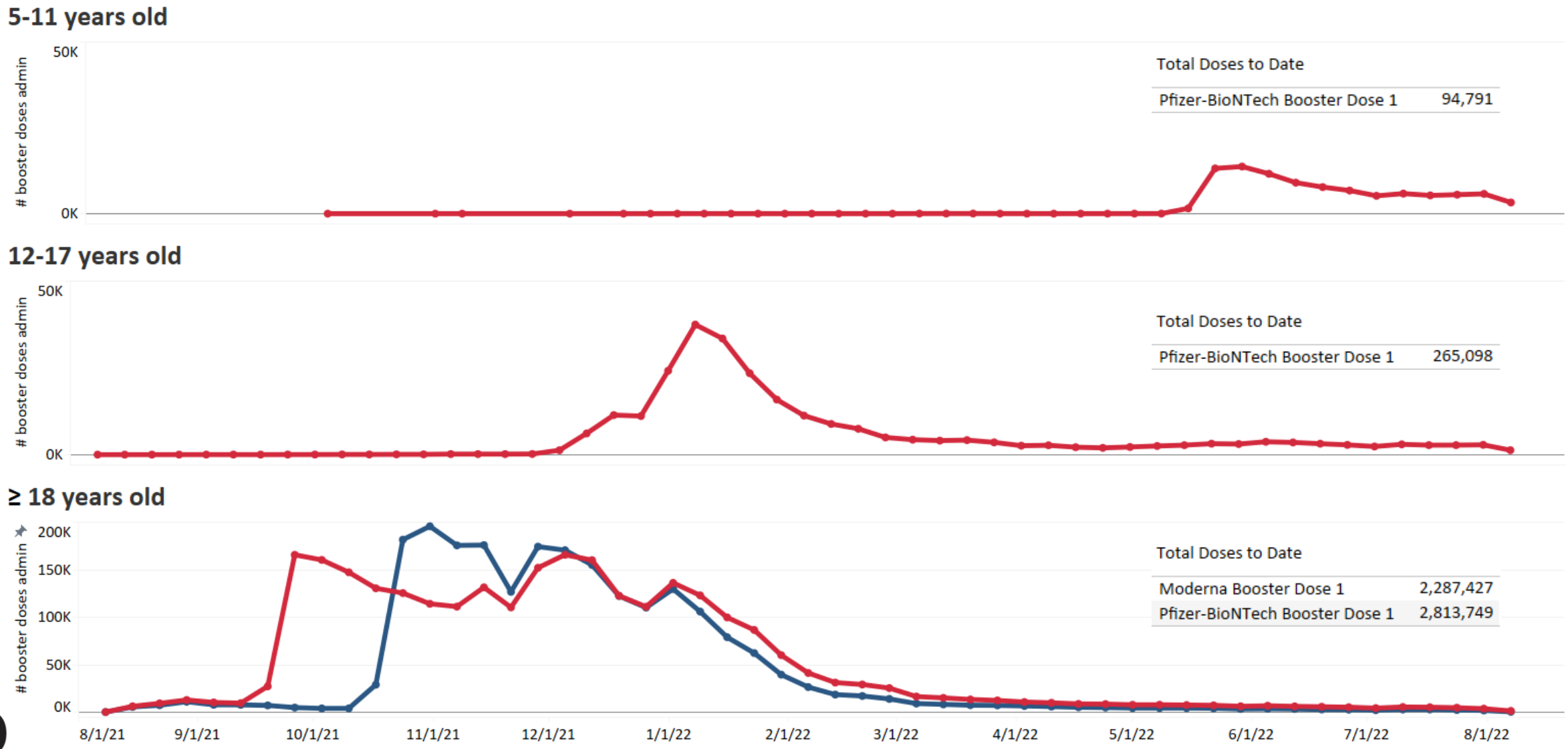
VSD COVID-19 vaccine RCA prespecified surveillance outcomes

EHR = Electronic health record

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 vaccine safety datalink

mRNA COVID-19 booster vaccine doses administered in VSD in people ages 5–11, 12–17, and ≥18 years, over time*



VSD vaccine safety datalink

* Data through Aug 13, 2022

VSD RCA results in children ages 5–11 years for 1st mRNA COVID-19 booster vaccination*

- No statistical signals for any pre-specified surveillance outcomes

VSD
vaccine safety datalink

*Results through Aug 13, 2022

VSD signals for pre-specified outcomes in 21-day risk interval after 1st booster in people ages 12 years and older

Results through Aug 13, 2022

* Analyses not yet possible

Primary series with	Pfizer-Pfizer OR Moderna-Moderna	Pfizer-Pfizer	Moderna-Moderna
Signal after 1st booster	Pfizer OR Moderna	Pfizer	Moderna
VSD RCA pre-specified outcomes		**Signal?**	
Acute disseminated encephalomyelitis	No	No	-*
Acute myocardial infarction	No	No	No
Appendicitis	No	No	No
Bell's palsy	No	No	No
Cerebral venous sinus thrombosis	No	No	No
Disseminated intravascular coagulation	No	No	No
Encephalitis / myelitis / encephalomyelitis	No	No	No
Guillain-Barre syndrome	No	No	No
Stroke, hemorrhagic	No	No	No
Stroke, ischemic	No	No	No
Immune thrombocytopenia	No	No	No
Myocarditis / pericarditis	**Yes**	No	No
Seizures	No	No	No
Transverse myelitis	No	No	No
Thrombotic thrombocytopenic purpura	No	No	No
Thrombosis with thrombocytopenia syndrome	No	No	No
Venous thromboembolism	No	No	No
Pulmonary embolism	No	No	No

VSD vaccine safety datalink

Verified myocarditis and pericarditis during the 0–7 risk interval post-vaccination versus the comparison interval 22–42 days post-vaccination with 1st booster dose*

	Primary series	Booster vaccine	Cases in risk interval	Cases in 22–42-day comparison interval	Adjusted rate ratio (95% confidence interval)	2-sided p-value	Events/million doses (95% confidence interval)
12–15-year-olds							
Males	Pfizer – Pfizer	Pfizer	4	1	**18.50 (1.85 – 551.84)**	**0.011**	**61.7 (20.0 – 143.9)****
Females	Pfizer – Pfizer	Pfizer	0	0	NE (NE)	NE	0.0
16–17-year-olds							
Males	Pfizer - Pfizer	Pfizer	8	0	**NE (2.03 - ∞)**	**0.009**	**189.0 (86.4 – 358.8)****
Females	Pfizer - Pfizer	Pfizer	2	3	1.10 (0.11 – 9.49)	0.925	36.6 (4.4 – 132.2)
18–39-year-olds							
Males	Pfizer - Pfizer OR Moderna - Moderna	Pfizer OR Moderna	18	7	**5.34 (2.11 – 14.74)**	**<0.001**	**30.9 (18.3 – 48.9)**
Males	Pfizer - Pfizer	Pfizer	10	3	**8.15 (2.06 – 41.51)**	**0.002**	**31.3 (15.0 – 57.6)**
Males	Moderna - Moderna	Moderna	5	3	3.57 (0.73 – 20.16)	0.116	25.4 (8.3 – 59.3)
Females	Pfizer - Pfizer OR Moderna - Moderna	Pfizer OR Moderna	4	3	2.68 (0.53 – 14.84)	0.227	4.9 (1.3 – 12.6)
Females	Pfizer - Pfizer	Pfizer	1	2	0.99 (0.03 – 13.07)	0.969	2.2 (0.1 – 12.3)
Females	Moderna - Moderna	Moderna	1	1	2.42 (0.06 – 101.49)	0.599	10.7 (2.2 – 31.4)***

*Data through August 20, 2022

** One additional case was in the risk interval but not included because there were no appropriate comparators. These cases are included in the events/million dose calculation.

***Two additional cases were in the risk interval but not included because there were no appropriate comparators. These cases are included in the events/million dose calculation.

VSD
vaccine safety datalink

VSD incidence rates of verified myocarditis/pericarditis in the 0–7 days after Pfizer-BioNTech vaccination in people ages 5–39 years, dose 2 and 1st booster*

	Dose 2 primary series Pfizer-BioNTech			1st booster dose Pfizer-BioNTech		
	Cases	Dose 2 admin	Incidence rate/ million doses (95% CI)	Cases	1st boosters admin	Incidence rate/ million doses (95% CI)
5-11 years						
Males	3	207,958	14.4 (3.0 – 42.2)	0	50,415	0.0 (0.0 – 59.4)
Females	0	202,596	0.0 (0.0 – 14.8)	0	49,261	0.0 (0.0 – 60.8)
12–15 years						
Males	31	205,955	150.5 (102.3 – 213.6)	5	81,613	61.3 (19.9 – 143.0)
Females	5	204,074	24.5 (8.0 – 57.2)	0	84,114	0.0 (0.0 – 35.6)
16–17 years						
Males	14	102,091	137.1 (75.0 – 230.1)	9	47,874	188.0 (86.0 – 356.9)
Females	1	107,173	9.3 (0.2 – 52.0)	2	55,004	36.4 (4.4 – 131.3)
18–29 years						
Males	27	331,889	81.4 (53.6 – 118.4)	7	166,973	41.9 (16.9 – 86.4)
Females	2	400,321	5.0 (0.6 – 18.0)	1	240,226	4.2 (0.1 – 23.2)
30–39 years						
Males	5	341,527	14.6 (4.8 – 34.2)	3	197,554	15.2 (3.1 – 44.4)
Females	3	410,713	7.3 (1.5 – 21.3)	1	268,412	3.7 (0.1 – 20.8)

VSD vaccine safety datalink

*Primary series surveillance for people ages ≥18 years ended May 21, 2022, all other data through August 20, 2022.

VSD incidence rates of verified myocarditis/pericarditis in the 0–7 days after Moderna vaccination in people ages 5–39 years, dose 2 and 1st booster*

	Dose 2 primary series Moderna			1st booster dose Moderna		
	Cases	Dose 2 admin	Incidence rate/ million doses (95% CI)	Cases	1st boosters admin	Incidence rate/ million doses (95% CI)
5-11 years**						
Males	N/A	N/A	N/A	N/A	N/A	N/A
Females	N/A	N/A	N/A	N/A	N/A	N/A
12–15 years**						
Males	N/A	N/A	N/A	N/A	N/A	N/A
Females	N/A	N/A	N/A	N/A	N/A	N/A
16–17 years**						
Males	N/A	N/A	N/A	N/A	N/A	N/A
Females	N/A	N/A	N/A	N/A	N/A	N/A
18–29 years						
Males	19	195,809	97.0 (58.4 – 151.5)	7	109,337	64.0 (25.7 – 131.9)
Females	0	243,560	0.0 (0.0 – 12.3)	1	156,707	6.4 (0.2 – 35.6)
30–39 years						
Males	8	216,583	36.9 (15.9 – 72.8)	1	149,468	6.7 (0.2 – 37.3)
Females	1	259,780	3.9 (0.1 – 21.4)	2	191,765	10.4 (1.3 – 37.7)

VSD vaccine safety datalink

*Primary series surveillance for people ages ≥18 years ended May 21, 2022, all other data through August 20, 2022.
**Monitoring ongoing, no data provided if less than 2,500 doses given in a subgroup.

Summary: mRNA COVID-19 vaccine safety of booster doses in people ages 5 years and older

- Safety findings are generally consistent with those observed for primary series vaccination
- Evidence suggests an increased risk for myocarditis following 1st booster dose
  - Myocarditis is a rare event following mRNA COVID-19 booster vaccination
    - CDC has verified 131 myocarditis case reports to VAERS in people ages ≥5 years after 123,362,627 million mRNA COVID-19 booster vaccinations
  - Risk primarily observed in adolescent and young adult males
  - No statistical signal for myocarditis to date in children ages 5–11 years following 1st booster
- In VAERS data, reporting rates of myocarditis are lower following 1st booster dose vs. dose 2 of primary series (and lower following dose 1 vs. dose 2 of primary series)
- In VSD analyses, myocarditis/pericarditis incidence following 1st booster dose and dose 2 of the primary series are similar, though case counts are small and confidence intervals around point estimates are wide

COVID-19 vaccine safety: pregnancy and reproductive health outcomes monitoring

Monitoring systems

- V-safe
- V-safe pregnancy registry
- VSD
- VAERS
- CISA

Outcomes/topics

- Miscarriage
- Stillbirth
- Preterm birth
- Birth defects
- Pregnancy complications
- Pregnancy outcomes
- Infant outcomes
- Neonatal outcomes
- Maternal adverse events and maternal conditions
- Menstrual irregularities
- Post-menopausal bleeding
- Safety of booster doses
- SARS-CoV-2 infection after vaccination
- Co-administration with other vaccines (e.g., influenza)

COVID-19 vaccine safety: pregnancy and reproductive health outcomes monitoring

- To date, for outcomes studied, there have been no concerning findings for pregnancy and reproductive health outcomes following COVID-19 vaccination
- Data on COVID-19 vaccine safety during pregnancy and reproductive health outcomes following vaccination will be presented at a future ACIP meeting

v-safe after vaccination health checker

VSD vaccine safety datalink

CDC + FDA VAERS

CISA clinical immunization safety assessment project

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- VAERS Team
- V-safe Team
- Clinical Immunization Safety Assessment (CISA) Project
- Vaccine Safety Datalink (VSD) Team
- CDC Immunization Safety Office
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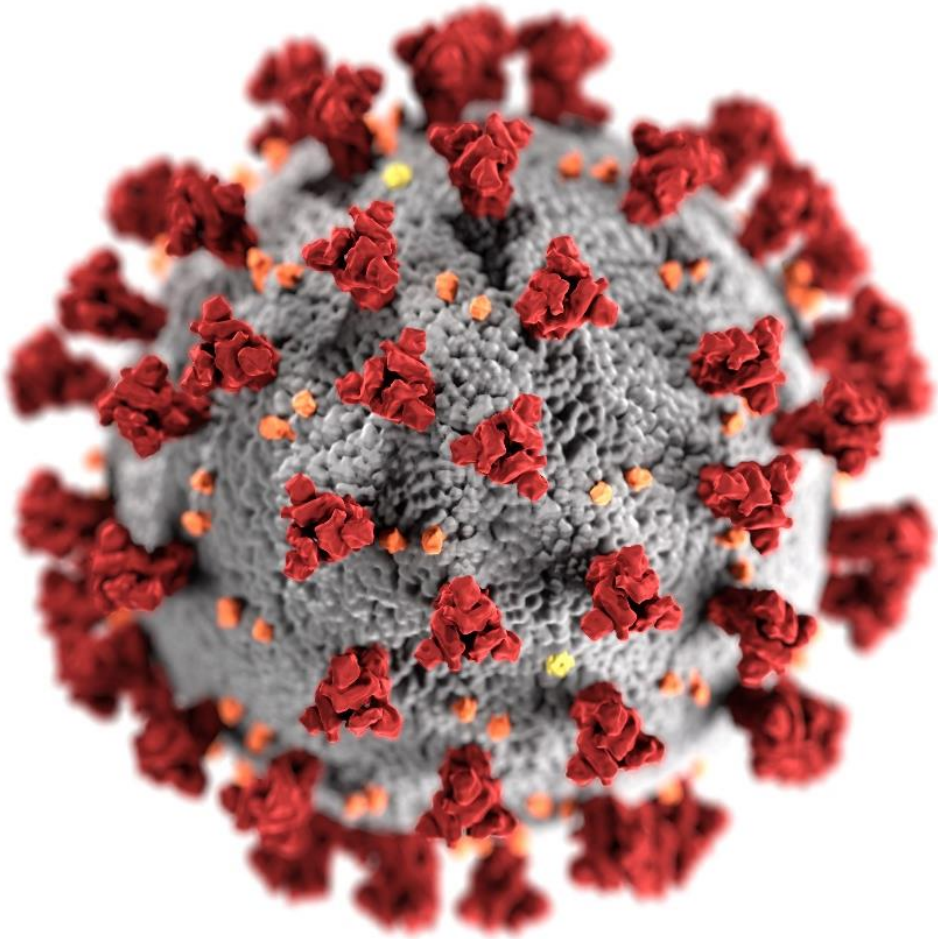
- Kaiser Permanente Northern California (VSD)
- Marshfield Clinic Research Institute (VSD)
- VSD sites
  - HealthPartners Institute, Minneapolis, MN
  - Kaiser Permanente Colorado, Denver, CO
  - Kaiser Permanente Northwest, Portland, OR
  - Kaiser Permanente Southern California, Los Angeles, CA
  - 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
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