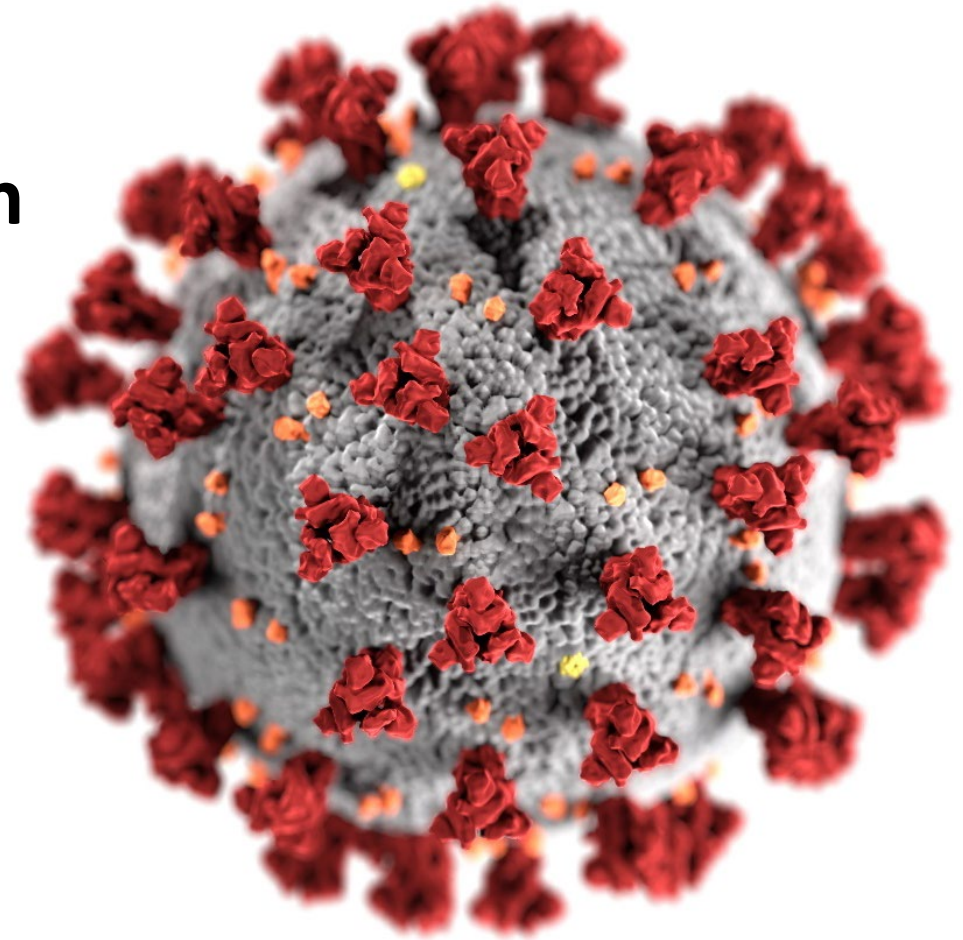


Updates on myocarditis and pericarditis following Moderna COVID-19 vaccination

Advisory Committee on Immunization Practices
February 4, 2022

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cdc.gov/coronavirus

Topics

- Reporting rates of myocarditis following Moderna COVID-19 primary series vaccination in the Vaccine Adverse Event Reporting System (VAERS) among persons ages 18 years and older
- Care and outcomes of persons ages 18 years and older with myocarditis after Moderna COVID-19 primary series vaccination reported to VAERS
- Vaccine Safety Datalink (VSD) subgroup analysis of confirmed myocarditis and pericarditis cases after primary series Moderna COVID-19 vaccination among persons ages 18–39 years



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



VAERS

Vaccine Adverse Event Reporting System

<http://vaers.hhs.gov>



VAERS accepts 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

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



Reporting rates (per 1 million doses administered) of myocarditis among males after Moderna COVID-19 vaccination, days 0–7 after vaccination (through Jan 13, 2022*)

- **76,682,682** total doses of Moderna COVID-19 vaccine administered to males (dose 1 and dose 2)*
- 283 myocarditis case reports in days 0–7 that met CDC case definition
- Reporting rates exceed background incidence[†]
 - After dose 1 (18–39 years)
 - After dose 2 (18–49 years)
- Reporting rates consistently higher after dose 2 vs. dose 1

	Moderna	
	(Males)	
Ages (years)	Dose 1	Dose 2
18–24	5.8	40.0
25–29	2.9	18.3
30–39	3.3	8.4
40–49	0.5	3.5
50–64	0.7	0.9
65+	0.2	0.6



* As of Jan 13, 2022; 283 of 347 reports of myocarditis among males ages 18 years and older after doses 1 and 2 of Moderna vaccine occurred during days 0–7 after vaccination; 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 day 0–7 risk period, this estimated background is **0.2 to 2.2 per 1 million person 8-day risk period**

Reporting rates (per 1 million doses administered) of myocarditis **among females** after Moderna COVID-19 vaccination, days 0–7 after vaccination (through Jan 13, 2022*)

- **85,729,766** total doses of Moderna COVID-19 vaccine administered to females (dose 1 and dose 2)*
- 76 myocarditis case reports in days 0–7 that met CDC case definition
- Reporting rates exceed background incidence[†]
 - After dose 2 (18–29 years)

	Moderna (Females)	
Ages (years)	Dose 1	Dose 2
18–24	0.5	5.5
25–29	0.3	5.8
30–39	0.6	0.6
40–49	0.8	1.6
50–64	0.8	0.4
65+	0.1	0.5



* As of Jan 13, 2022; 76 of 117 reports of myocarditis among females ages 18 years and older after doses 1 and 2 of mRNA vaccines occurred during days 0–7 after vaccination; 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 day 0–7 risk period, this estimated background is **0.2 to 2.2 per 1 million person 8-day risk period**

Care and outcomes of myocarditis cases reported to VAERS after Moderna COVID-19 primary series vaccination among persons ages 18 years and older, days 0–7 after vaccination (N=359), through Jan 13, 2022*

Of 359 meeting case definition:

- 337 were hospitalized
 - 335 discharged
 - 230 (69%) known to have recovered from symptoms at time of report
 - 2 with disposition under review
- 22 were not hospitalized (seen in emergency department, urgent care, outpatient clinic, not specified)



* As of Jan 13, 2022; 359 reports of myocarditis among persons ages 18 years and older after doses 1 and 2 of Moderna vaccine; reports verified to meet case definition by provider interview or medical record review

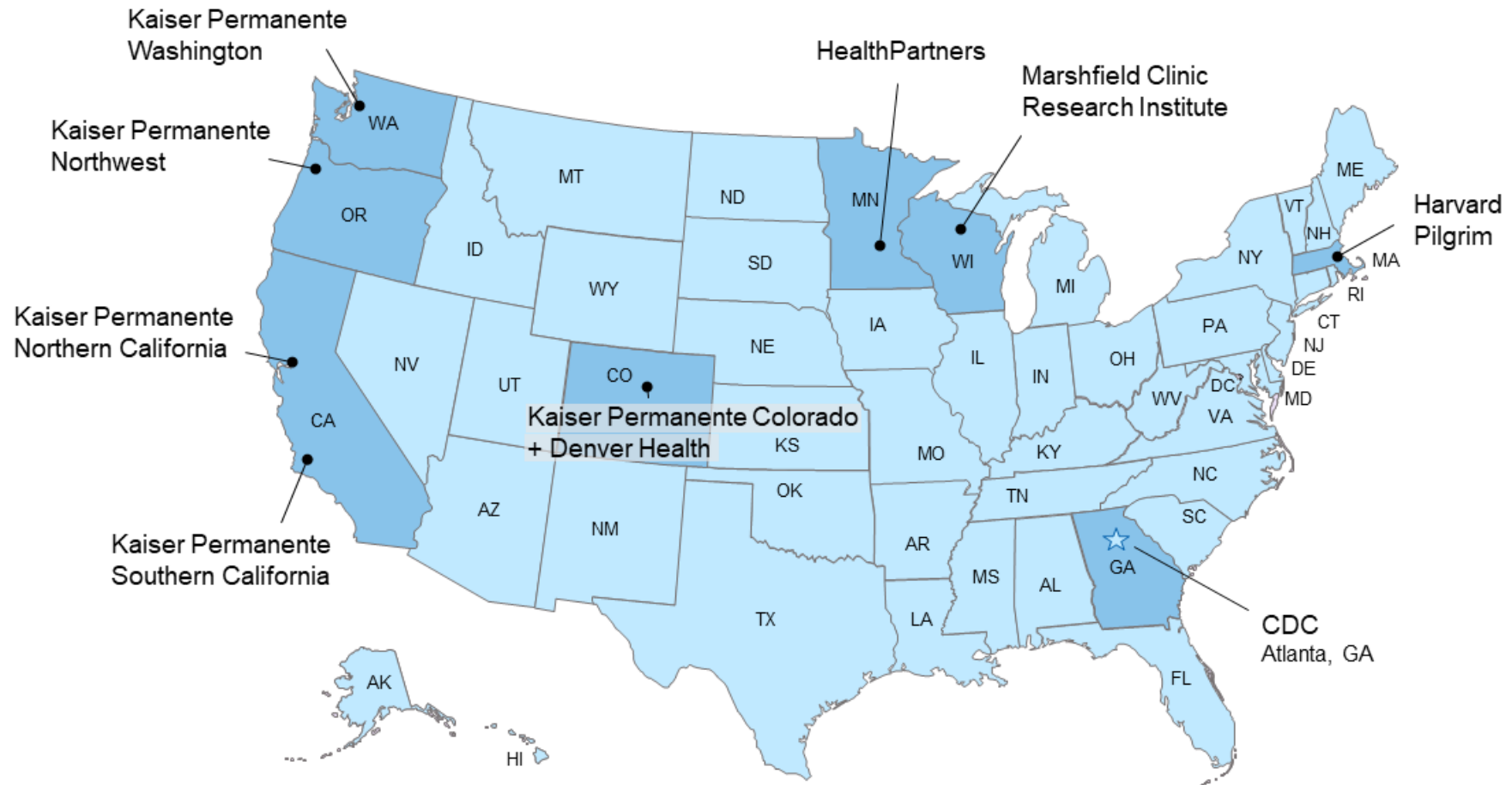
Summary of VAERS findings

- 164 million total doses of Moderna COVID-19 vaccine (doses 1 and 2) administered to persons ages 18 years and older (as of Jan 13, 2022)*
 - 359 total reports of myocarditis to VAERS in the 0–7 days following vaccination that met CDC case definition
 - Reporting rates of myocarditis exceed background rates for males (18–49 years, depending upon dose) and females (18–29 years, after dose 2)
 - Reporting rates of myocarditis were generally higher following dose 2 vs. dose 1, especially in males
 - Most myocarditis patients were hospitalized, and most were discharged home
 - Most discharged patients (69%) had recovered from symptoms at time of discharge



* 76,682,682 in males, 85,729,766 in females, 1,588,270 sex unknown or not reported

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

Safety monitoring began in December 2020



VSD COVID-19 vaccine RCA prespecified surveillance outcomes

Prespecified outcomes	Settings
Acute disseminated encephalomyelitis	Emergency dept, Inpatient
Acute myocardial infarction – First Ever	Emergency dept, Inpatient
Acute respiratory distress syndrome	Emergency dept, Inpatient
Anaphylaxis – First in 7 days	Emergency dept, Inpatient
Appendicitis	Emergency dept, Inpatient
Bell’s palsy – First Ever	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	Emergency dept, Inpatient
Narcolepsy / cataplexy	Emergency dept, Inpatient, Outpatient
Pulmonary embolism – First Ever	Emergency dept, Inpatient
Seizures	Emergency dept, Inpatient
Stroke, hemorrhagic	Emergency dept, Inpatient
Stroke, ischemic	Emergency dept, Inpatient
Thrombosis with thrombocytopenia syndrome – First Ever	Emergency dept, Inpatient
Thrombotic thrombocytopenic purpura	Emergency dept, Inpatient
Transverse myelitis	Emergency dept, Inpatient
Venous thromboembolism – First Ever	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
- Expected counts were 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



Myocarditis and pericarditis electronic case identification

- Electronic case identification using ICD-10 codes 
- Followed by chart review and adjudication by clinical subject matter experts using CDC case definitions

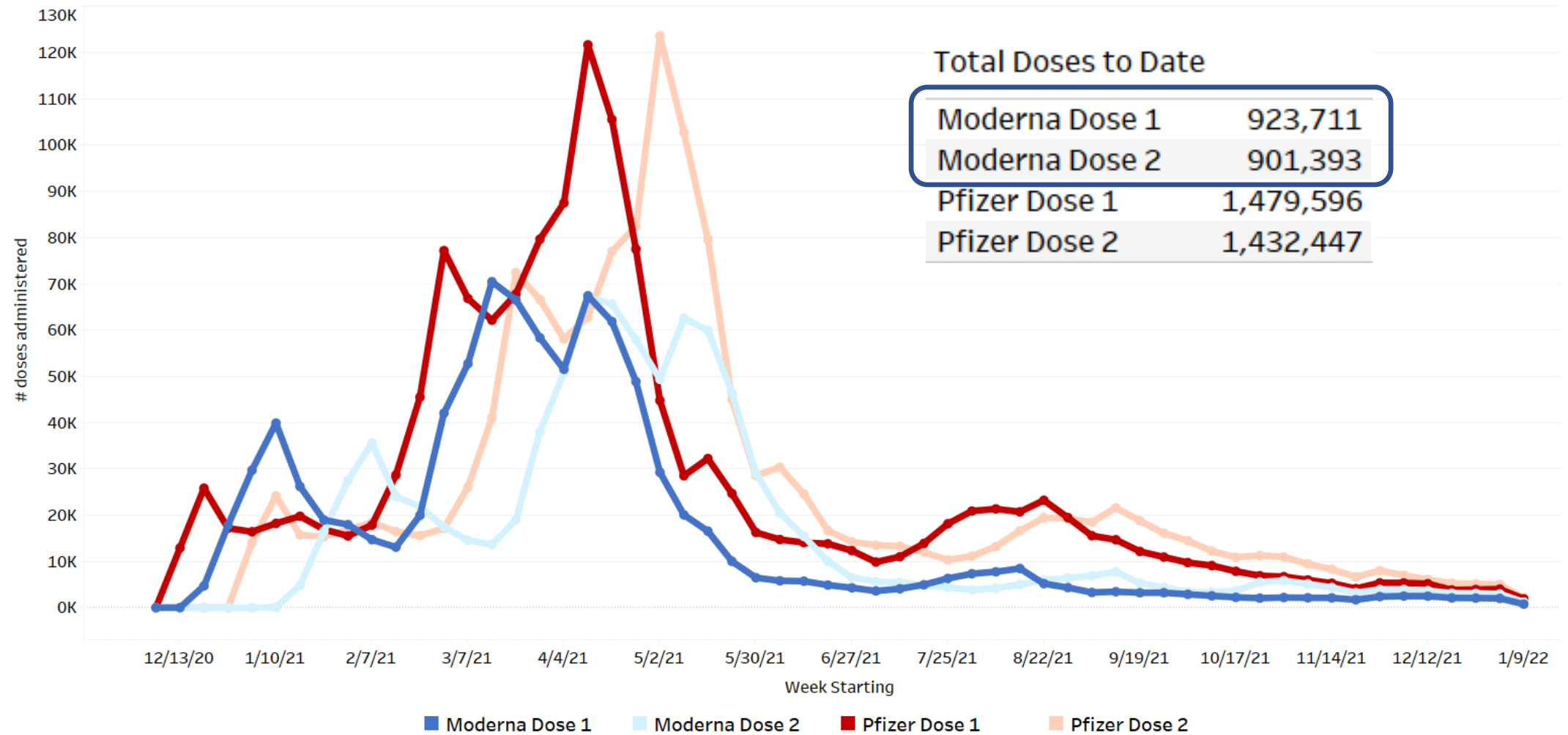
Code list

B33.22 Viral myocarditis
B33.23 Viral pericarditis
I30.* Acute pericarditis
I40.* Acute myocarditis
I51.4 Myocarditis, unspecified
I31.9 Disease of the pericardium, unspecified



* Includes all additional character codes

VSD mRNA COVID-19 vaccine totals in persons ages 18–39 years



Confirmed myocarditis and pericarditis in the 0–7-day risk interval among persons ages 18–39 years compared with outcome events in vaccinated comparators on the same calendar days for Moderna COVID-19 vaccination (thru Jan 15, 2022)

Moderna COVID-19 vaccine	Events in risk interval, 0–7d* (per million doses)	Events in comparison interval, 22–42d*	Adjusted rate ratio [†] (95% CI)	2-sided P-value	Excess cases in risk interval (per million doses)
Both doses	38 (21.1)	7	9.18 (4.12 – 22.89)	<0.001	18.8
Dose 1	9 (9.7)	7	3.46 (1.12 – 11.07)	0.031	6.9
Dose 2	29 (33.0)	4	18.75 (6.73 – 64.94)	<0.001	31.2
Dose 2 males	26 (65.7)	4	16.96 (6.02 – 59.17)	<0.001	61.8
Dose 2 females	3 (6.2)	0	NE [‡] (0.93 – ∞)	0.056	6.2



* Risk interval is 0–7 days after either dose, comparison interval is 22–42 days after either dose

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

[‡] NE = not estimable

Summary of VSD findings*

- 923,711 dose 1 and 901,393 dose 2 Moderna COVID-19 vaccinations have been administered in VSD
- VSD analyses with vaccinated concurrent comparators indicate that Moderna COVID-19 vaccination is associated with increased risk of myocarditis and pericarditis in persons ages 18–39 years
 - Increased risk observed after both dose 1 and dose 2 in the 0–7-day risk interval, with risk greater following dose 2
 - Dose 2 adjusted rate ratio=18.75 vs. Dose 1 adjusted rate ratio=3.46
 - Highest excess cases per million doses administered observed after dose 2
 - 31.2 excess cases in 0–7-day risk interval per million doses administered in both males and females
 - 61.8 excess cases in 0–7-day risk interval per million doses administered to males



* Through Jan 15, 2022

Acknowledgments

- VAERS Team
- Clinical Immunization Safety Assessment Project
- COVID-19 Vaccine Task Force Data Monitoring and Reporting Group
- CDC Immunization Safety Office
- FDA/Center for Biologics Evaluation and Research
- Kaiser Permanente Northern California
- Marshfield Clinic Research Institute
- VSD Sites
 - HealthPartners Institute, Minneapolis, Minnesota
 - Kaiser Permanente Colorado, Denver, Colorado
 - Kaiser Permanente Northwest, Portland, Oregon
 - Kaiser Permanente Southern California, Los Angeles, California
 - Kaiser Permanente Washington, Seattle, Washington
 - Denver Health, Denver, Colorado

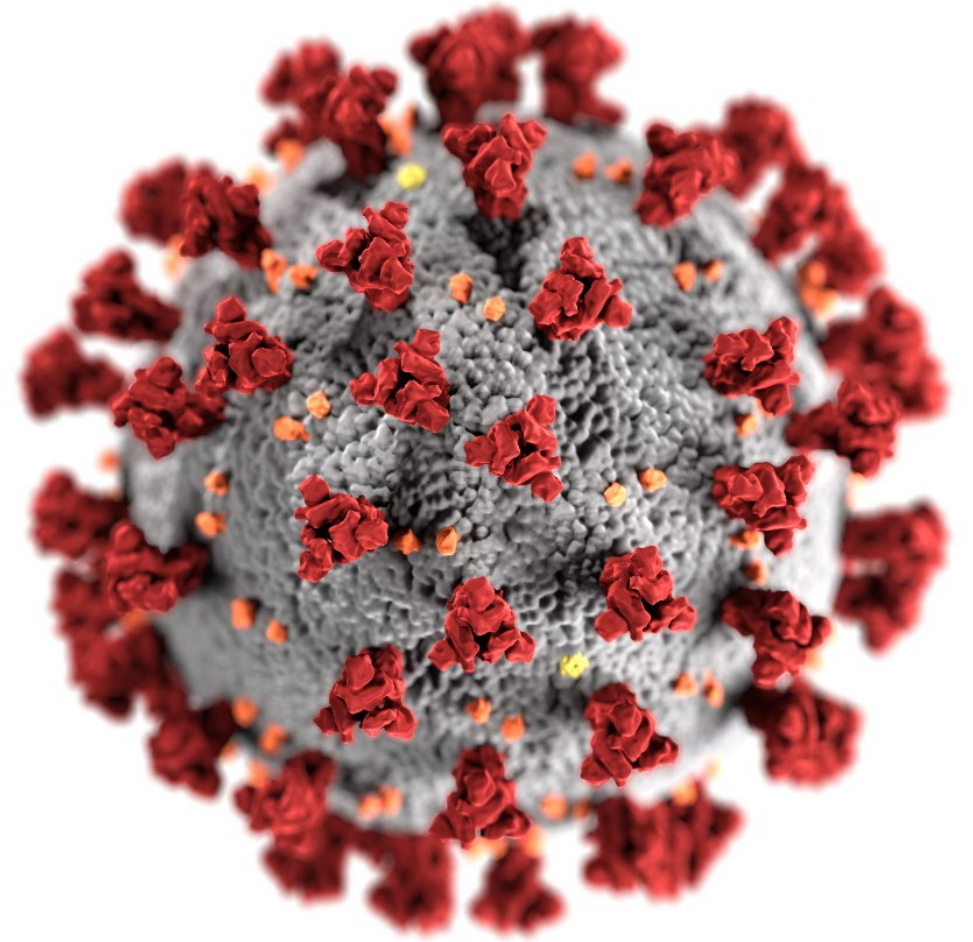


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Thank you!



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