

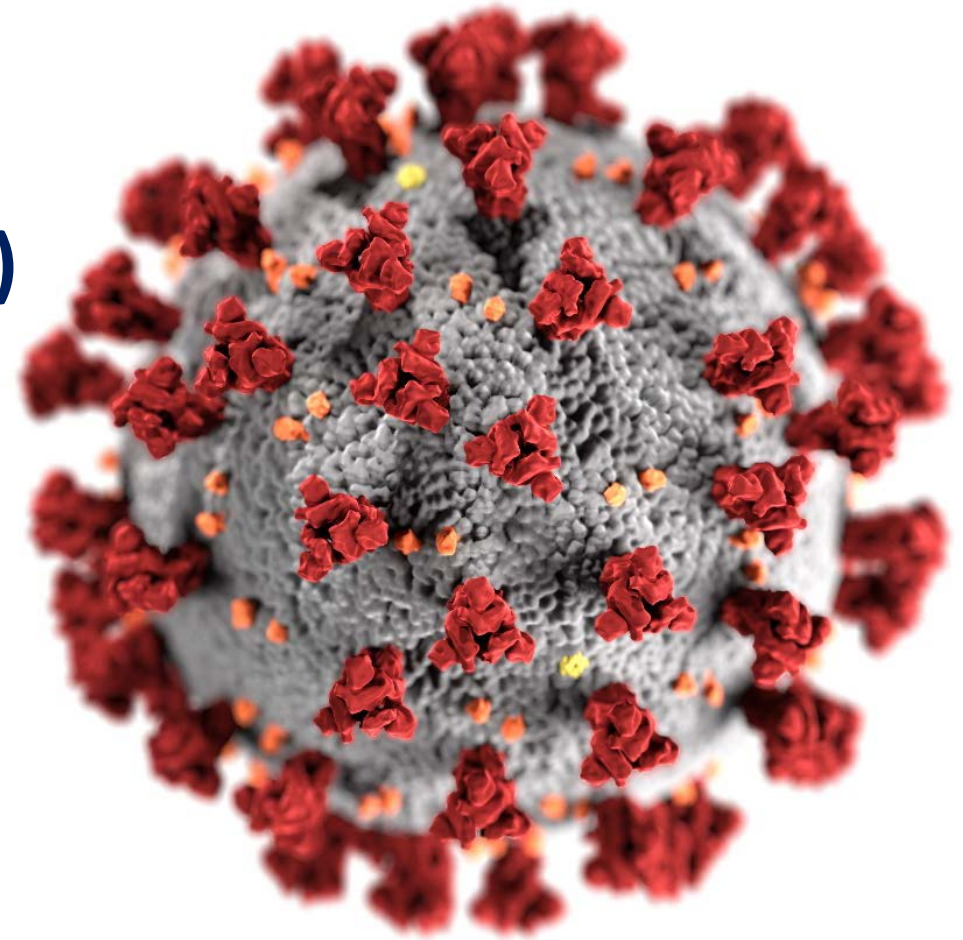
Myopericarditis following COVID-19 vaccination: Updates from the Vaccine Adverse Event Reporting System (VAERS)

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Myopericarditis reports to VAERS



Focusing analysis on reports of myocarditis and myocarditis with pericarditis (myopericarditis) following COVID-19 vaccination

- As of August 18, 2021, total of **2,574** reports in all ages/age groups
 - Myopericarditis: 1,903 reports
 - Pericarditis alone: 671 reports



Preliminary myopericarditis reports to VAERS following COVID-19 vaccination by dose number (data thru Aug 18, 2021)

Manufacturer	Reports after dose 1	Reports after dose 2	Reports after unknown dose
Pfizer-BioNTech (n=1,282)	169	922	191
Moderna (n=557)	133	339	85
Janssen (n=49)	33	1	15
Not reported (n=15)	2	9	4
Total (N=1,903)	337	1,271	295

- Includes total preliminary reports identified through VAERS database searches for reports with myopericarditis MedDRA* codes and pre-screened VAERS reports with signs and symptoms consistent with myopericarditis; **excludes reports of solely 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* myopericarditis reports to VAERS following known mRNA COVID-19 vaccination[†] (data thru Aug 18, 2021)

Characteristics	Dose 1 (mRNA only) (n=302) [†]	Dose 2 (n=1,261) [†]
Median age, years (range)	26 (12–94)	20 (11–87)
Median time to symptom onset, days (range)	3 (0–71) [‡]	2 (0–98) [‡]
Sex (%)		
Male	218 (72%)	1,034 (82%)
Female	78 (26%)	220 (17%)
Not reported/not available	6 (2%)	7 (1%)

* Includes reports identified through VAERS database searches for reports with myopericarditis MedDRA codes, with signs and symptoms consistent with myopericarditis, and with dose number documented; and pre-process VAERS reports with follow-up, medical record review, and application of CDC case definition for myopericarditis

[†] Excludes 33 reports after Janssen, and 2 reports that did not specify manufacturer after Dose 1; excludes 1 report after Janssen and 9 reports that did not specify manufacturer after Dose 2

[‡] Four reports after Dose 1 had onset >71 days; five reports after Dose 2 had onset >98 days



Expected vs. Observed reports after mRNA vaccination dose 2, 7-day risk period (N=765)*

Age group, years	Females		Males	
	Cases of myopericarditis, expected	Cases of myopericarditis, observed	Cases of myopericarditis, expected	Cases of myopericarditis, observed
12–15*	0–3	12	1–5	117
16–17*	0–2	15	0–3	121
18–24*	1–8	24	1–11	213
25–29*	1–6	16	1–9	56
30–39	2–21	10	2–19	72
40–49	2–22	22	2–19	45
50–64	4–40	15	4–35	13
65+	4–44	6	4–36	8

* As of Aug 18, 2021; assumes a 7-day observation window, with 765 of 897 reports after mRNA vaccines occurring during Days 0–6 after vaccination; counts among 12–29 years from reports meeting case definition for myopericarditis; expected estimates for females 12–29 years adjusted to reflect reduced incidence in this age group



Expected vs. Observed reports after **Pfizer-BioNTech** dose 2, 7-day risk period (N=549)*

Age group, years	Females		Males	
	Cases of myopericarditis, expected	Cases of myopericarditis, observed	Cases of myopericarditis, expected	Cases of myopericarditis, observed
12–15*	0–3	12	1–5	116
16–17*	0–2	15	0–3	120
18–24*	0–5	11	1–7	134
25–29*	0–4	4	1–5	30
30–39	1–13	7	1–11	40
40–49	1–13	12	1–11	26
50–64	2–22	9	2–19	5
65+	2–22	4	2–18	4

* As of Aug 18, 2021; assumes a 7-day observation window, with 549 of 765 reports after mRNA vaccines occurring during Days 0–6 after vaccination; counts among 12–29 years from reports meeting case definition for myopericarditis; expected estimates for females 12–29 years adjusted to reflect reduced incidence in this age group



Expected vs. Observed reports after **Moderna** dose 2, 7-day risk period (N=216)*

Age group, years	Females		Males	
	Cases of myopericarditis, expected	Cases of myopericarditis, observed	Cases of myopericarditis, expected	Cases of myopericarditis, observed
12–15*	0	0	0	1
16–17*	0	0	0	1
18–24*	0–3	13	0–4	79
25–29*	0–2	12	0–3	26
30–39	1–8	3	1–8	32
40–49	1–9	10	1–8	19
50–64	2–18	6	2–16	8
65+	2–22	2	2–19	4

Moderna vaccine not authorized in 12-17 y/o

* As of Aug 18, 2021; assumes a 7-day observation window, with 216 of 765 reports after mRNA vaccines occurring during Days 0–6 after vaccination; counts among 12–29 years from reports meeting case definition for myopericarditis; expected estimates for females 12–29 years adjusted to reflect reduced incidence in this age group



Care and outcomes



Care and outcomes of preliminary myopericarditis cases reported to VAERS after COVID-19 vaccination in persons ≤ 29 years old (N=1,339) (data thru Aug 18, 2021)

1,339 total preliminary reports

- 742 met CDC case definition* of myocarditis or myopericarditis
- 494 under review

Of 742 meeting case definition:

- 701 were hospitalized
 - 667 discharged
 - 515 (77%) known to have recovered from symptoms at time of report
 - 18 still hospitalized (5 in ICU)
 - 16 with unknown disposition
- 27 were not hospitalized (seen in emergency dept., urgent care, outpatient clinic, not specified)

* Included in: Gargano et al. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021. MMWR Morb Mortal Wkly Rep 2021;70:977–982.

<https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7027e2-H.pdf>



Reporting rates



Reporting rates of myopericarditis (per million doses administered), by manufacturer, sex, and dose number, 7-day risk period* (as of Aug 18, 2021)

Ages [†] (yrs)	Pfizer			Moderna		Janssen	Pfizer		Moderna		Janssen	Pfizer		Moderna		Janssen
	(All)			(All)		(All)	(Males)		(Males)		(Males)	(Females)		(Females)		(Females)
	Dose 1	Dose 2		Dose 1	Dose 2	Dose 1	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1
12–15	2.6	20.9		0.0	not calc.	0.0	4.8	42.6	0.0	not calc.	0.0	0.5	4.3	0.0	0.0	0.0
16–17	2.5	34.0		0.0	14.6	0.0	5.2	71.5	0.0	31.2	0.0	0.0	8.1	0.0	0.0	0.0
18–24	1.1	18.5		2.7	20.2	2.7	2.4	37.1	5.1	37.7	3.0	0.0	2.6	0.7	5.3	1.6
25–29	1.0	7.2		1.7	10.3	1.9	1.8	11.1	3.2	14.9	2.0	0.3	1.3	0.4	6.3	0.0
30–39	0.8	3.4		1.0	4.2	0.4	1.1	6.8	1.6	8.0	0.0	0.6	1.0	0.4	0.7	1.0
40–49	0.4	2.8		0.5	3.2	1.2	0.7	4.4	0.6	4.6	2.2	0.1	1.8	0.4	2.1	0.0
50–64	0.2	0.5		0.6	0.8	0.2	0.2	0.5	0.4	1.0	0.0	0.3	0.8	0.8	0.7	0.5
65+	0.2	0.3		0.2	0.3	1.0	0.2	0.4	0.4	0.4	1.0	0.2	0.4	0.1	0.2	0.9

* Reports with time to symptom onset within 7 days of vaccination

† Reports among persons 12–29 years of age were verified by provider interview of medical record review



Investigating myocarditis health effects after COVID-19 vaccination



Enhanced surveillance for myocarditis outcomes after mRNA COVID-19 vaccination in VAERS case reports*

- Assess long-term functional status and clinical outcomes among individuals reported to have developed myocarditis after mRNA COVID-19 vaccination (among reports that met CDC case definition)
- A two-component survey intended to assess outcomes at least 90 days after onset of myocarditis symptoms
 - Patient survey: Ascertains functional status, clinical symptoms, quality of life, and need for medication or other medical treatment
 - Healthcare provider (e.g., cardiologist): Gather data on cardiac health and functional status
- Timeline: data collection ~ August 2021-November 2021



* <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myo-outcomes.html>

Enhanced surveillance for myocarditis outcomes after mRNA COVID-19 vaccination in VAERS case reports* (cont.)

- Preliminary implementation data
 - As of August 18, 2021, VAERS has received 742 reports of myocarditis or myopericarditis after COVID-19 vaccination that met case definition
 - Of these, 253 patients are at least 90 days post-myocarditis diagnosis
 - Data collection is currently underway



* <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myo-outcomes.html>

Summary



Summary

- 2,574 reports of myopericarditis or pericarditis to VAERS (as of August 18, 2021)
 - 1,903 myopericarditis, 671 pericarditis
- Epidemiology of myopericarditis following COVID-19 vaccination similar to previously reported updates
 - Primarily in younger males, after dose 2 mRNA vaccination, symptom onset clustering within several days of vaccination,
- Limited follow-up information in VAERS case reports suggests most patients (77%) recovered from symptoms at time of report or follow-up
- Observed vs. Expected analysis with VAERS reports
 - Males: Observed > Expected in age groups through 49 years
 - Females: Observed > Expected in age groups through 29 years
- Enhanced surveillance for myocarditis outcomes after mRNA COVID-19 vaccination in VAERS case reports is ongoing



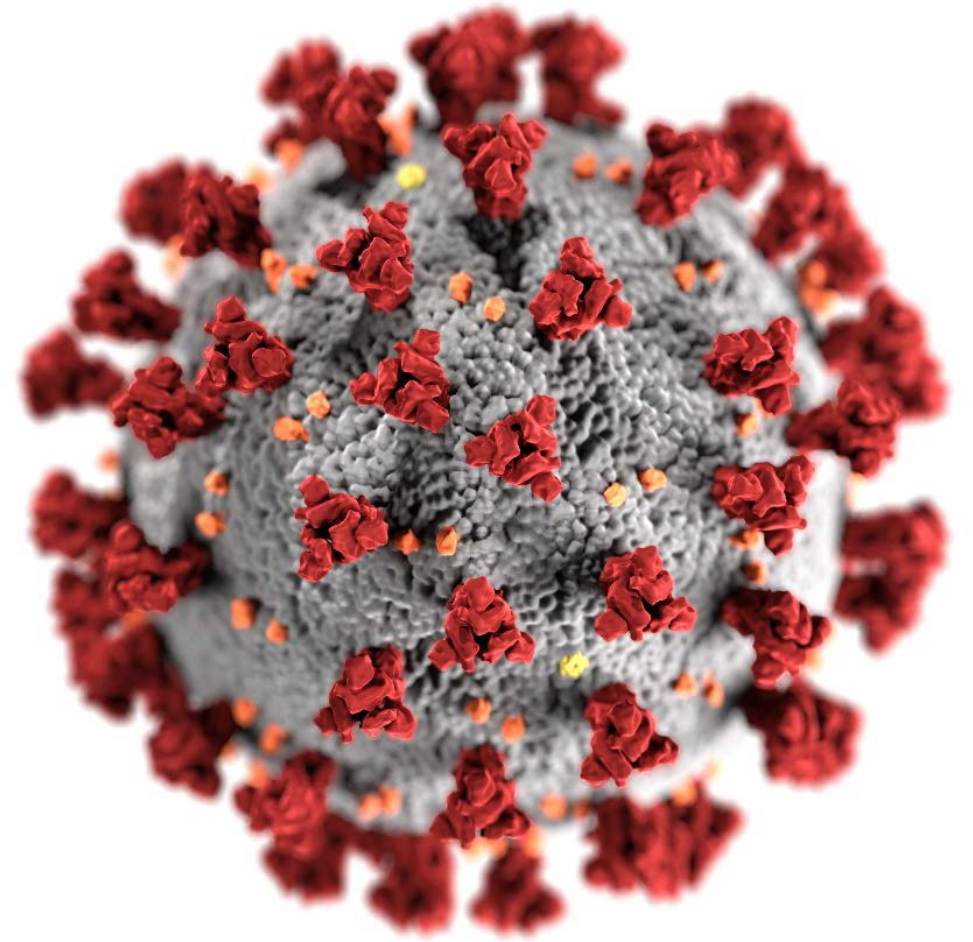
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 - VAERS Data team
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- **FDA/Center for Biologics Evaluation and Research**



Thank you!



For more information, contact CDC
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