

Myocarditis and pericarditis following mRNA vaccination



Preliminary myocarditis/pericarditis reports to VAERS following mRNA vaccination with dose number documented (data thru May 31, 2021)

Manufacturer	Myocarditis/pericarditis reports after dose 1	Myocarditis/pericarditis reports after dose 2
Pfizer-BioNTech (488 total reports)	116	372
Moderna (301 total report)	100	201
	216 Total reports after dose 1	573 Total reports after dose 2

- Includes total preliminary reports identified through VAERS database searches for reports with myocarditis/pericarditis MedDRA* codes and pre-screened VAERS reports with signs and symptoms consistent with myocarditis/pericarditis (and with dose number documented)
 - 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/>

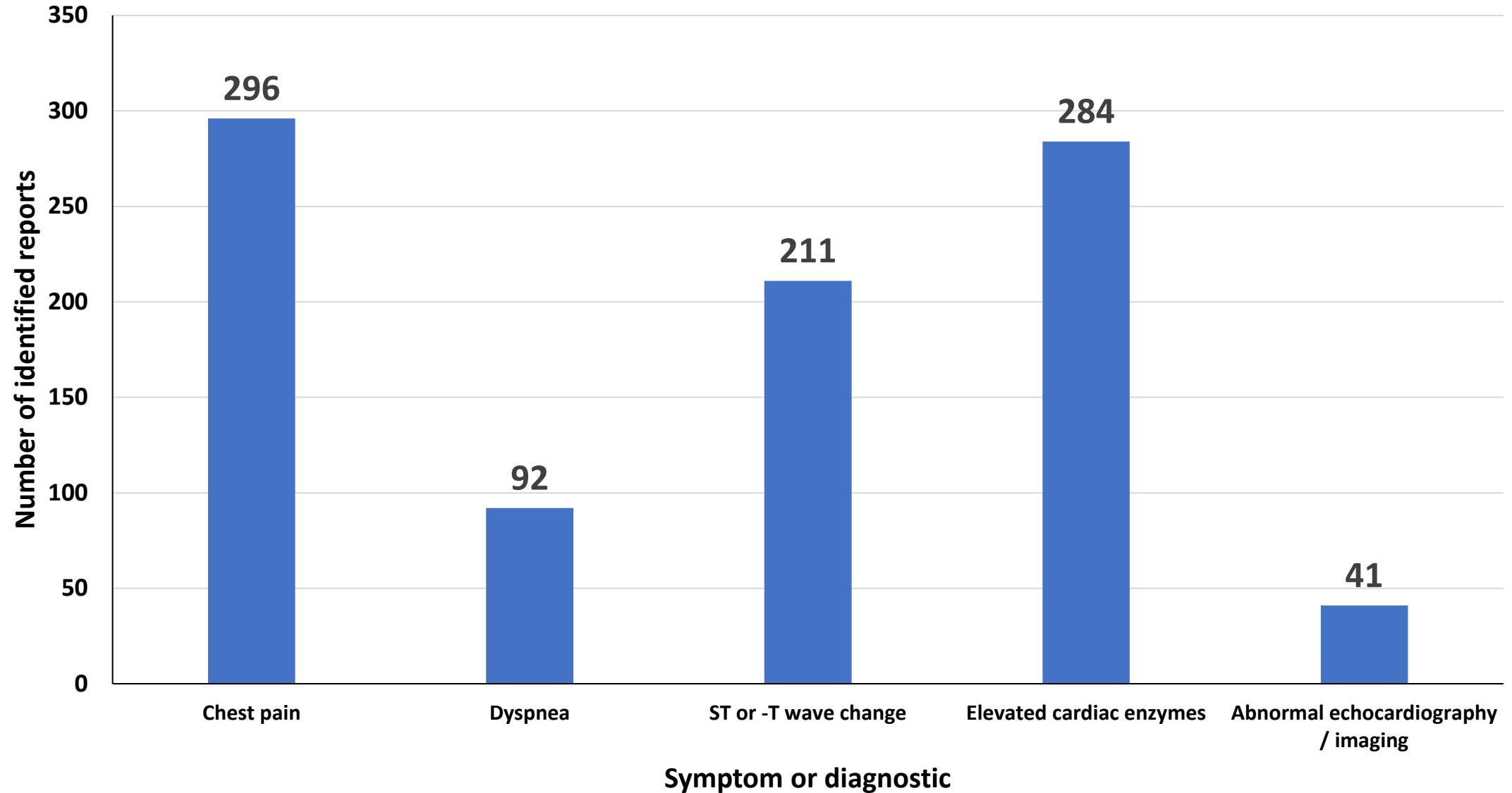
Characteristics of preliminary myocarditis/pericarditis reports to VAERS following mRNA vaccination (data thru May 31, 2021)

Characteristics	Dose 1 (n=216)	Dose 2 (n=573)
Median age, years (range)	30 (12–94)	24 (14–87)
Median time to symptom onset, days (range)	3 (0–33)	2 (0–80)
Sex (%)		
Male	140 (65)	455 (79)
Female	73 (34)	113 (20)
Not reported/not available	3 (1)	5 (1)

* Includes total reports identified through VAERS database searches for reports with myocarditis/pericarditis MedDRA codes and pre-screened VAERS reports with signs and symptoms consistent with myocarditis/pericarditis (and with dose number documented); Follow-up, medical record review, application of CDC working case definition, and adjudication is ongoing or pending



Symptoms and diagnostics of preliminary myocarditis/pericarditis reports under review (limited to ≤30 years old) (N=475)



Outcomes of preliminary myocarditis/pericarditis cases reported to VAERS in persons ≤ 30 years old (N=475) (data thru May 31, 2021)

- 226 (of 475) case reports meet CDC working case definition; follow-up and review are in progress for remaining reports
- 285 (of 475) case reports had known disposition at time of report review
 - 270 discharged; 15 still hospitalized (3 in intensive care unit*)
 - Of 270 discharged
 - 246 (91%) to home
 - 3 to another facility (e.g., rehabilitation facility)
 - 21 did not specify
 - Of 270 discharged, recovery status was known for 221
 - **180 (81%) had full recovery of symptoms**
 - 41 (19%) had ongoing signs or symptoms or unknown status



* One patient with significant comorbidities and BMI>40; one patient with positive stool culture (Campylobacter)

Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. (data thru May 31, 2021)

Age groups	Doses admin	Crude reporting rate*	Expected†,‡ Myocarditis/pericarditis cases	Observed† Myocarditis/pericarditis reports
12–15 yrs	134,041	22.4	0–1	2
16–17 yrs	2,258,932	35.0	2–19	79
18–24 yrs	9,776,719	20.6	8–83	196
25–39 yrs	26,844,601	5.0	23–228	124
40–49 yrs	19,576,875	3.0	17–166	51
50–64 yrs	36,951,538	1.3	31–314	39
65+ yrs	42,124,078	0.9	36–358	26
NR	—	—	—	11

8.8% of doses admin

n=277 reports
52.5% of total reports



* Per million doses administered; † Assumes a 31-day post-vaccination observation window; 528 reports with symptom onset within 30 days of vaccination shown; ‡ Based on Gubernot et al. U.S. Population-Based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14:S0264-410X(21)00578-8.