

Summary of VAERS Reports of myocarditis, pericarditis and myopericarditis following vaccination with mRNA COVID-19 vaccines

Background:

This memo responds to questions posed from the Israeli Ministry of Health to the FDA and CDC. They are investigating a safety signal of myocarditis /myopericarditis in a younger population (16 -30 years old) following administration of Pfizer-BioNTech Covid-19 vaccine. The Ministry of Health stated they received reports of around 40 cases of this adverse event. They did not provide additional details about these cases.

Questions Posed by Israeli Ministry of Health:

1. How many doses of the vaccine were administered to this age group?

CDC to provide this data

2. How many cases of myocarditis / peri-myocarditis were reported in your country?

A search of the U.S. Vaccine Adverse Event Reporting System (VAERS) conducted on February 23, 2021 revealed 27 cases (6 cases of myocarditis, 7 cases of myopericarditis, 14 cases pericarditis).

The following Medical Dictionary for Regulatory Activities (MedDRA) preferred terms were used to conduct the search: myocarditis; eosinophilic myocarditis; hypersensitivity myocarditis; pericarditis; pericarditis adhesive; pericarditis constrictive; pleuropericarditis; pericardial disease; pericardial effusion; pericardial rub; myopericarditis. Reports with sufficient information were reviewed and categorized based on case definitions previously used for surveillance of myopericarditis after smallpox vaccine (<https://www.cdc.gov/mmwr/PDF/wk/mm5221.pdf>).

Reports were included if they contained a diagnosis by of myocarditis, pericarditis or myopericarditis. Reports with pericardial effusion and no other signs of myopericarditis were excluded. If the diagnosis in the narrative was pericarditis but the patient also had elevated troponin they were categorized as myopericarditis.

3. Could you elaborate details on these AE cases (time of diagnosis from the vaccine, first/second dose, risk factors, etc.) ?

Twelve cases occurred after dose 1, 7 cases after dose 2, and the dose was not reported for 8 cases. Four patients had comorbid conditions that could suggest alternate etiologies for the adverse event. These included:

- One patient with subacute pericarditis noted on cardiac MRI. The clinical impression was this pre-dated vaccination
- One patient had a history of recurrent pericarditis
- One patient had recent SARS CoV-2 infection
- One patient had psoriatic arthritis and was on Adalimumab

None of the cases reported other risk factors or causes such as preceding viral infections or other vaccines administered concurrently. However, due to the nature of passive surveillance reports, it is not possible to completely exclude these due to potential incompleteness of reports.

The following table displays additional information about the cases of myopericarditis.

Characteristics	Reports of Myopericarditis/Myocarditis/Pericarditis (N = 27)
Median age, years (range)*	36 (21–84)
Female (%)	10(37)
Male (%)	16 (59)
Gender not reported (%)	1(4)
Median Time to Onset in Days (range)	3 (0-20)

4. Have you assessed the causality between the AE and the vaccine for each of the cases?

During this analysis period the reporting rate of myopericarditis following administration of the mRNA COVID-19 vaccines was low and estimated to be 0.7 per million doses of vaccine administered. However, the limitations of passive surveillance such as under-reporting, lack of a control group, missing and incomplete data make it challenging to assess causation. Thus, FDA has not made a final determination regarding the causality between myopericarditis and the mRNA COVID-19 vaccines. We will continue to monitor this outcome in active and passive surveillance.