CDC confirms 226 cases of myocarditis after COVID-19 vaccination in people 30 and under
by Melissa Jenco, News Content Editor


Federal health officials have verified 226 cases of myocarditis or pericarditis in people ages 30 and younger who have received an mRNA COVID-19 vaccine and are investigating about 250 more reports.

While rare, the rates for ages 16-24 following a second dose are above what is expected, prompting an emergency meeting of the Centers for Disease Control and Prevention's (CDC’s) Advisory Committee on Immunization Practices (ACIP) next week.

"At that time, we'll update the data, further evaluate myocarditis following mRNA vaccination and assess benefit/risk analysis," said Tom Shimabukuro, M.D., M.P.H., M.B.A., deputy director of the Centers for Disease Control and Prevention's (CDC's) Immunization Safety Office.

Dr. Shimabukuro made a presentation Thursday to the Food and Drug Administration's (FDA’s) vaccine advisory group where he said across all ages, 789 cases of myocarditis/pericarditis have been reported after the Pfizer/BioNTech and Moderna vaccines, most commonly after the second dose. Cases predominantly have been seen in males, and the median age for a case of myocarditis following dose two is 24.

Zeroing in on the 475 people ages 30 and under reporting myocarditis or pericarditis to the Vaccine Adverse Event Reporting System (VAERS), the most common symptoms were chest pain, elevated cardiac enzymes, ST or T wave changes, dyspnea and abnormal echocardiography/imaging.

Among 285 cases with a known outcome, 270 were discharged, most to their homes. About 81% have made a full recovery, and the rest had ongoing symptoms or unknown status. Fifteen are still hospitalized, including three in intensive care.
There were 79 cases of myocarditis/pericarditis reported in teens ages 16 or 17 years after a second dose of vaccine, while the expected number was two to 19 cases, according to Dr. Shimabukuro. There were 196 cases in young adults ages 18-24 years, while eight to 83 were expected. The case rates per million doses for those age groups were 35 and 21, respectively.

"It's a bit of an apples to oranges comparison because again these are preliminary reports," Dr. Shimabukuro said. "Not all of these will turn out to be true myocarditis or pericarditis reports. The expected (cases) are based on published literature."

He noted reports of myocarditis/pericarditis in young people ages 12-24 make up about 53% of the total reports after a second dose. However, these age groups only make up about 9% of the doses administered.

"Clearly, we have an imbalance there," he said.

An analysis of data from another surveillance system, the Vaccine Safety Datalink, found a rate of 16 cases per million second doses in people ages 16-39.

ACIP will hold an emergency meeting on June 18 to discuss myocarditis cases and the AAP will be monitoring the meeting closely. In the meantime, Yvonne A. Maldonado, M.D., FAAP, chair of the AAP Committee on Infectious Diseases, noted there is no recommended change to vaccination of adolescents 12 and older.

The CDC recommends clinicians consider myocarditis and pericarditis in patients who develop acute chest pain, shortness of breath or heart palpitations within a week after vaccination. Initial evaluation may include an ECG, a troponin level and tests for inflammatory markers such as C-reactive protein and erythrocyte sedimentation rate.

Clinicians who suspect myocarditis or pericarditis should consider consulting with a pediatric cardiologist, infectious disease specialist and/or rheumatologist. They should report cases of myocarditis and/or pericarditis after COVID-19 vaccination to VAERS.

Additional safety data presented Thursday looked at adverse events in adolescents ages 12-15, a group that started to receive Pfizer-BioNTech vaccinations under emergency use authorization (EUA) from the FDA in mid-May. The most common adverse events reported to VAERS for this age group have been dizziness, syncope, nausea, pallor, loss of consciousness, headache, hyperhidrosis, vomiting, fatigue and falls.

The new data came on the same day Moderna announced it had requested an EUA for its COVID-19 vaccine in adolescents ages 12-17.

The FDA committee members also spent a significant amount of time discussing the safety data they would like to see in clinical trials involving children under 12 years. There was a range of opinions on how many children should be included in each age group and how long they should be followed.

Some said they would like to see a vaccine for young children soon, since cases might rise if school resumes in person this fall and people move indoors for the winter. Others urged longer studies and full licensure instead of emergency use authorization for these age groups.

The FDA plans to take committee members' opinions into consideration as it provides guidance to manufacturers. Pfizer has said it expects to request an EUA for ages 2-11 in September.
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