AC 1955

Pharmacovigilance Drug Safety Alert

Myocarditis & Pericarditis Following mRNA COVID-19 Vaccination

Since April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults. Onset was typically within several days after mRNA COVID-19 vaccination, and cases have occurred more often after the second dose than the first dose. CDC and its partners are investigating these reports of myocarditis and pericarditis following mRNA COVID-19 vaccination. There has not been a similar reporting pattern observed after receipt of the Janssen COVID-19 Vaccine (Johnson & Johnson).¹

Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the lining outside the heart. In both cases, the body's immune system is causing inflammation in response to an infection or some other trigger. Symptoms can include chest pain, shortness of breath, or palpitations.^{1,2} The severity of cases of myocarditis and pericarditis can vary. For the cases reported after mRNA COVID-19 vaccination, most who presented to medical care have responded well to medications and rest, and had prompt improvement in symptoms.¹

Since April 2021, there have been increased reports to the Vaccine Adverse Event Reporting System (VAERS) of cases of myocarditis and pericarditis happening after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna) in the United States. These reports are rare, given the number of vaccine doses administered, and have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults. CDC and its partners are actively monitoring these reports, by reviewing data and medical records, to learn more about what happened and to see if there is any relationship to COVID-19 vaccination.³

Cases reported to VAERS have occurred:3

- Mostly in male adolescents and young adults age 16 years or older
- More often after getting the second dose of one of these two COVID-19 vaccines than after the first dose
- Typically within several days after COVID-19 vaccination

Recommendations for Clinicians: 1,2

- CDC continues to recommend <u>COVID-19 vaccination</u> for everyone 12 years of age and older given the greater
 risk of other serious complications related to COVID-19, such as hospitalization, multisystem inflammatory
 syndrome in children (MIS-C), or death. The known and potential benefits of COVID-19 vaccination outweigh
 the known and potential risks, including the possible risk of myocarditis or pericarditis.
- Consider myocarditis and pericarditis in adolescents or young adults with acute chest pain, shortness of breath, or
 palpitations. In this younger population, coronary events are less likely to be a source of these symptoms.
- Ask about prior COVID-19 vaccination if you identify these symptoms, as well as relevant other medical, travel, and social history.
- For initial evaluation, consider an ECG, troponin level, and inflammatory markers such as C-reactive protein and
 erythrocyte sedimentation rate. Myocarditis or pericarditis are unlikely in the setting of normal ECG, troponin, and
 inflammatory markers.
- For suspected cases, consider consultation with cardiology for assistance with cardiac evaluation and management. Evaluation and management may vary depending on the patient age, clinical presentation, potential causes, or practice preference of the provider.
- For follow-up of patients with myocarditis, consult the recommendations from the <u>American Heart Association and the American College of Cardiology</u>.
- It is important to rule out other potential causes of myocarditis and pericarditis. Consider consultation with infectious disease and/or rheumatology to assist in this evaluation.
- Where available, evaluate for potential etiologies of myocarditis and pericarditis, particularly acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2 infection (e.g., detection of SARS-CoV-2 nucleocapsid antibodies), and other viral etiologies (e.g., enterovirus PCR and comprehensive respiratory viral pathogen testing).

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Report all cases of myocarditis and pericarditis post COVID-19 vaccination to the VAERS program as described in the Indian Health Manual. Instructions for submitting an AVE can be found on the IHS Pharmacovigilance website. Please ensure that you document "IHS" in field #26 of the form.

References:

- 1. <u>Clinical Considerations: Myocarditis and Pericarditis after receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults, CDC, May 27, 2021.</u>
- 2. NIH materials on myocarditis and pericarditis.
- 3. Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination, CDC, Updated May 27, 2021.