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COVID-19 Vaccination Provider Partners,

Federal health agencies have updated COVID-19 vaccine resources for vaccine providers and vaccine recipients to include information about the risk of rare cases of myocarditis/pericarditis following mRNA COVID-19 vaccination, particularly in adolescents and young adults.

The **U.S. Food & Drug Administration** (FDA) has updated COVID-19 Vaccine Emergency Use Authorization (EUA) fact sheets for the <u>Pfizer</u> and <u>Moderna</u> vaccines for patients and providers to include the risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue surrounding the heart) following vaccination. In addition, the **Centers for Disease Control and Prevention** (CDC) has updated for providers its <u>clinical considerations regarding myocarditis and pericarditis</u>.

These updates follow a review of information and a discussion by the CDC's Advisory Committee on Immunization Practices (ACIP) last week. The FDA and CDC will continue to monitor reports, collect more information, and follow up to assess longer-term outcomes over several months.

The CDC continues to recommend COVID-19 vaccination for individuals 12 years of age and older, given the risk of COVID-19 illness and related, possibly severe complications such as long-term health problems, hospitalization, and death.

"Thanks to the extensive safety monitoring systems in the U.S., we can have confidence that we have the systems in place to identify this risk. These discussions are an example of the vaccine safety system working exactly as it should," said Dr. Bruce Vanderhoff, Chief Medical Officer, Ohio Department of Health.

UPDATED RESOURCES FOR VACCINE PROVIDERS, VACCINE RECIPIENTS

For each vaccine, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) has been revised to include a warning about myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers has been revised to include information about the risk of myocarditis and pericarditis and recommendations for providers.

The warning to vaccine recipients states:

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Pfizer or Moderna COVID-19 Vaccine.
- In most of these people, symptoms began within a few days following receipt of the second dose of the vaccine.
- The chance of having this occur is very low.
- Vaccine recipients should seek medical attention right away if they have any of the following symptoms after receiving the vaccine:

- Chest pain.
- Shortness of breath.
- Feelings of having a fast-beating, fluttering, or pounding heart.

Recommendations for vaccine providers:

- Report all cases of myocarditis and pericarditis post COVID-19 vaccination to the <u>Vaccine</u> <u>Adverse Event Reporting System</u> (VAERS).
- 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. In the setting of normal ECG, troponin, and inflammatory markers, myocarditis or pericarditis are unlikely.
- 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</u> Heart Association and the American College of Cardiology.
- It is important to rule out other potential causes of myocarditis and pericarditis. Consider consultation with infectious disease and/or rheumatology specialists to assist in this evaluation.
 - Where available, evaluate for potential causes 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).

MORE INFORMATION

- FDA: Pfizer Fact Sheet for Recipients and Caregivers
- FDA: Pfizer Fact Sheet for Healthcare Providers Administering Vaccine
- FDA: Moderna Fact Sheet for Recipients and Caregivers
- FDA: Moderna Fact Sheet for Healthcare Providers Administering Vaccine
- CDC: <u>Clinical Considerations</u>: <u>Myocarditis and Pericarditis after Receipt of mRNA COVID-19</u>
 <u>Vaccines Among Adolescents and Young Adults</u>
- CDC: Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination

BACKGROUND: MYOCARDITIS/PERICARDITIS REPORTS

Since April 2021, there have been more than 1,000 reports to the Vaccine Adverse Event Reporting System (VAERS) of cases of myocarditis and pericarditis after mRNA COVID-19 vaccination (i.e., Pfizer-BioNTech, Moderna) in the United States. However, not all cases have been verified. The CDC is evaluating 484 total reported cases, 323 of which meet the CDC working case definition for myocarditis or pericarditis. All of these cases were among vaccine recipients younger than 30.

CDC notes that these reports are rare given the millions of COVID-19 vaccine doses administered. Confirmed cases have occurred:

- Mostly in male adolescents and young adults age 16 years or older.
- More often following the second dose (vs. the first dose) of an mRNA COVID-19 vaccine.
- Typically, within several days after COVID-19 vaccination.
- Most patients who received care responded well to treatment and rest and quickly felt better.
 Patients can usually return to normal daily activities after symptoms improve, but they should talk with their doctor about returning to exercise or sports.

JOINT STATEMENT

The American Academy of Pediatrics, the American Academy of Family Physicians, the American Medical Association, the American College of Physicians, the American Heart Association, and several other organizations have joined the CDC in issuing a joint statement on COVID-19 vaccination and myocarditis/pericarditis.

"The facts are clear: this is an extremely rare side effect, and only an exceedingly small number of people will experience it after vaccination. Importantly, for the young people who do, most cases are mild, and individuals recover often on their own or with minimal treatment. In addition, we know that myocarditis and pericarditis are much more common if you get COVID-19, and the risks to the heart from COVID-19 infection can be more severe," according to the statement.

If you have any questions, please call the ODH Provider Call Center between 8 a.m. and 7 p.m. Monday through Friday, at 1-844-90DHVAX (1-844-963-4829) or email COVIDVACCINE@odh.ohio.gov.

Sincerely,

COVID-19 Vaccine Provider Relations Team