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Health Advisory

Update on Myocarditis and Pericarditis after mRNA COVID-19 Vaccination July 12, 2021

The Centers for Disease Control and Prevention (CDC) has issued updates on heart inflammation (myocarditis and pericarditis) occurring after mRNA COVID-19 vaccination in the United States. These include both Pfizer-BioNTech and Moderna COVID-19 vaccines. Myocarditis is inflammation of the heart muscle and pericarditis is inflammation of the tissue lining the outside of the heart.

An elevated risk for myocarditis has been observed after mRNA COVID-19 vaccination, particuarly in males aged 12-29 years. Cases typically occured within a few days after vaccination and more often after the second dose. Clinical courses were generally mild and many patients had resolution of symptoms with conservative treatment. There were no associated deaths. Overall, cases remain rare. Follow-up to understand long-term outcomes is ongoing.

SUMMARY POINTS

- Rare cases of heart inflammation (myocarditis and pericarditis) have been detected after mRNA COVID-19 vaccination through vaccine safety monitoring systems.
- The cases have mostly occurred in younger males within a few days after the second dose and were mild.
- The ACIP concluded that the benefits of mRNA COVID-19 vaccines continue to outweigh the risks. COVID-19 vaccination continues to be recommended for all persons aged ≥12 years.
- Cases of myocarditis or pericarditis occurring after vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).
- Guidelines have been published on considerations for mRNA COVID-19 vaccination in persons with a history of myocarditis or pericarditis.

The CDC's Advisory Committee on Immunization Practices (ACIP) has concluded that the benefits of COVID-19 vaccination in preventing COVID-19 associated morbidity and mortality clearly outweighed the risk of myocarditis and pericarditis. This applied to all recommended age groups, including adolescents and young adults, both at the individual and population level. This analysis has been published in a CDC MMWR report.

COVID-19 vaccination continues to be recommended for all persons aged ≥ 12 years. Emergency Use Authorization (EUA) Fact Sheets have been modified to include information about myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines, including when to seek medical care, and should be provided before vaccination. Additional patient and provider education materials have been developed to guide recognition and management. All cases of myocarditis or pericarditis after COVID-19 vaccination should be reported promptly to the Vaccine Adverse Event Reporting System (VAERS).

Additionally, guidelines have been published on considerations for a second vaccine dose in persons who develop myocarditis or pericarditis after the first dose of an mRNA COVID-19 vaccine series and those with a history of myocarditis or pericarditis prior to COVID-19 vaccination. Healthcare professionals can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project if they have complex COVID-19 vaccine safety questions.

The CDC and Food and Drug Administration (FDA) are continuing to closely monitor reports of myocarditis and pericarditis after COVID-19 vaccination and will bring additional data to the ACIP to consider and update the risk-benefit analysis as needed.

Resources

- Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory <u>Committee on Immunization Practices — United States, June 2021 | MMWR (cdc.gov)</u>
- <u>Clinical Considerations: Myocarditis after mRNA COVID-19 Vaccines | CDC</u>
- Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination | CDC
- <u>Vaccine Adverse Event Reporting System (VAERS)</u>
- <u>Clinical Immunization Safety Assessment (CISA) Project | CISA | Monitoring | Ensuring Safety | Vaccine Safety | CDC</u>
- <u>ACIP Live Meeting Archive June 2021 (cdc.gov)</u>
- ACIP June 2021 Presentation Slides | Immunization Practices | CDC