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DATE: July 30, 2021
TO: Health Care Providers, Health Care Facilities, Pharmacies, and Local Health Departments
FROM: New York State Department of Health (NYSDOH)

Health Advisory: COVID-19 Vaccine Clinical Considerations for People with a History of Myocarditis or Pericarditis

Please distribute immediately to all personnel conducting medical screening, medical evaluation, vaccine administration, local health departments, pharmacists, specialists, and all primary care providers.

Summary

- On May 28, 2021, the U.S. Centers for Disease Control and Prevention (CDC) alerted healthcare providers to reports of myocarditis and pericarditis following mRNA COVID-19 vaccines.
- On June 23, 2021, after reviewing available evidence including risks of myocarditis, the CDC's Advisory Committee on Immunization Practices (ACIP) determined that the benefits of using mRNA COVID-19 vaccines under the FDA's Emergency Use Authorization (EUA) clearly outweigh the risks in all populations, including adolescents and young adults.
- Myocarditis occurs more commonly in males than in females, and incidence is highest among infants, adolescents, and young adults. Symptoms typically include chest pain, dyspnea, or palpitations, although other symptoms might be present, especially in younger children. Supportive therapy is a mainstay of treatment, with as needed targeted cardiac medications or interventions . Current guidelines from the American Heart Association and American College of Cardiology recommend exercise restriction until the heart recovers.
- Cases of myocarditis following mRNA COVID-19 vaccine predominantly occurred in young men with median onset 3 days after vaccination. Seventy-six percent (76%) of cases occurred after dose 2 of mRNA COVID-19 vaccines. Acute clinical courses were generally mild, and no deaths were reported.
- The FDA has modified the EUA Fact Sheets for Pfizer and Moderna COVID-19 vaccines to include information regarding myocarditis after receipt of mRNA COVID-19 vaccines. To ensure prompt recognition and management, the CDC has developed provider education materials about the possibility of myocarditis and symptoms of concern,.
- Adolescent and young men may receive any age-appropriate COVID-19 vaccine. However, they should be counseled on the rare occurrence of myocarditis after receipt of mRNA COVID-19 vaccines.
- Persons with a history of myocarditis or pericarditis unrelated to COVID-19 vaccine may receive any age-appropriate COVID-19 vaccine after their episode has resolved. However, persons who develop myocarditis or pericarditis after dose 1 of an mRNA COVID-19 vaccine should defer receiving a second dose until additional safety data are available.
- The CDC and the FDA continue to monitor the safety of all COVID-19 vaccines.

Myocarditis and Pericarditis

Myocarditis is an inflammation of the heart muscle; if it is accompanied by pericarditis (inflammation of the thin tissue surrounding the heart), it is referred to as myopericarditis. This advisory will follow the CDC's convention of referring to myocarditis, pericarditis and myopericarditis as "myocarditis" for the sake of succinctness.

Myocarditis occurs more commonly in males than in females, and incidence is highest among infants, adolescents, and young adults. The clinical presentation of myocarditis varies among patients but typically includes chest pain, dyspnea, or palpitations. Younger children may have other symptoms. Diagnostic evaluation might reveal an elevated troponin level or abnormal findings on electrocardiogram, echocardiogram, or cardiac magnetic resonance imaging. Supportive therapy is a mainstay of treatment, with targeted cardiac medications or interventions as needed. Current guidelines from the American Heart Association and American College of Cardiology recommend exercise restriction until the heart recovers.

Between December 29, 2020 through June 11, 2021, the Vaccine Adverse Event Reporting System (VAERS) received 1,226 reports of myocarditis following mRNA COVID-19 vaccination. The highest crude reporting rates (i.e., calculated using confirmed and unconfirmed cases) per million second dose recipients were among males aged 12-17 years and those aged 18-24 years were 62.8 and 50.5 myocarditis cases per million second doses of mRNA COVID-19 vaccine administered, respectively. Crude myocarditis reporting rates among men aged ≥ 30 years, females aged 12-29 years and women aged ≥ 30 years were 2.4, 4.2 and 1.0 cases per million second doses, respectively.

The median age of persons with reported myocarditis after mRNA vaccination was 26 years (range = 12–94 years), with median symptom onset 3 days after vaccination (range = 0–179). Among patients with number of vaccine doses reported, 76% occurred after receipt of dose 2 of mRNA vaccine; cases were reported after both Pfizer-BioNTech and Moderna vaccines.

Of 323 persons age < 30 years that met CDC's case definition, 309 (96%) were hospitalized. Acute clinical courses were generally mild; among 304 hospitalized patients with known clinical outcomes, 95% had been discharged, and none had died at time of review. CDC follow-up is ongoing to identify and understand longer-term outcomes after myocarditis occurring after COVID-19 vaccination.

Additional information on myocarditis and pericarditis is available from the CDC and the American Heart Association and American College of Cardiology.

Benefit-Risk Balance for mRNA COVID-19 Vaccines in Adolescents and Young Adults

The ACIP reviewed an individual-level assessment of the benefits of mRNA COVID-19 vaccines in adolescents and young adults compared to the risk of myocarditis onset within 7 days after receipt of a second dose of an mRNA COVID-19 vaccine. The benefit-risk assessment was stratified by age group and sex. The benefits of mRNA COVID-19 vaccines clearly outweighed the risk of myocarditis in all populations for which COVID-19 vaccine is recommended.

Specifically, the ACIP estimated that for every million second doses of mRNA COVID-19 vaccine administered to males aged 12–29 years, 11,000 COVID-19 cases, 560

hospitalizations, 138 ICU admissions, and six deaths due to COVID-19 could be prevented, compared with 39–47 expected myocarditis cases after COVID-19 vaccination. Among males aged ≥30 years, 15,300 COVID-19 cases, 4,598 hospitalizations, 1,242 ICU admissions, and 700 deaths could be prevented, compared with three to four expected myocarditis cases after COVID-19 vaccination. Similar benefits and fewer risks were estimated among females compared to males in each age group reviewed. This analysis did not include the potential benefit of preventing post-COVID-19 conditions and therefore may underestimate the overall benefits of COVID-19 vaccination.

The CDC and FDA will continue to closely monitor reports of myocarditis after receipt of mRNA COVID-19 vaccines and the safety of all COVID-19 vaccines. The benefit-risk analysis may be updated as needed as additional information becomes available.

Clinical Considerations for the Use of mRNA COVID-19 Vaccines

Adolescents and young adults with no history of myocarditis or pericarditis may receive any FDA-authorized COVID-19 vaccine. However, vaccinators should counsel mRNA COVID-19 vaccine recipients, especially males aged 12-29 years, of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek medical attention right away if they develop any of the following symptoms after vaccination:

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

People with a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive any FDA-authorized COVID-19 vaccine after complete resolution of their episode (including resolution of symptoms, no evidence of ongoing heart inflammation or sequelae, and testing to assess cardiac recovery) as determined by the person's clinical team, which may include a cardiologist.

The incidence of myocarditis and pericarditis following mRNA COVID-19 vaccination appears to be higher following the second dose compared to the first dose. It is unclear at present whether people who developed myocarditis or pericarditis after a first dose of mRNA COVID-19 vaccine are at increased risk for further adverse cardiac events following a second dose of the vaccine. Therefore, the CDC recommends that individuals who develop myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine defer receiving the second dose until additional safety data are available.

Administration of the second dose of an mRNA COVID-19 vaccine series following complete resolution of myocarditis or pericarditis (including resolution of symptoms, no evidence of ongoing heart inflammation or sequelae, and testing to assess cardiac recovery) may be considered on a case-by-case basis following a conversation between the patient, their parent, guardian, or caregiver (when relevant), and their clinical team including a cardiologist. Considerations for vaccination may include:

- Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
- Level of COVID-19 community transmission

- Additional data on the risk of myocarditis or pericarditis following an occurrence of either condition after the first dose of an mRNA COVID-19 vaccine
- Additional data on the long-term outcomes of myocarditis or pericarditis that occurred after receipt of an mRNA COVID-19 vaccine
- Timing of any immunomodulatory therapies; ACIP's general best practice guidelines for immunization can be consulted for more information

The CDC is continuing to investigate cases of myocarditis and pericarditis after mRNA COVID-19 vaccination as well as long-term outcomes of such cases. This guidance may be updated as new information is obtained.

All adverse events after receipt of any vaccine, including COVID-19 vaccines, should be reported to VAERS even if it is not known that the vaccine caused the adverse event. Information on reporting to VAERS is available at: https://vaers.hhs.gov/reportevent.html.

Resources:

For questions, call the NYSDOH COVID-19 hotline 1-888-364-3065 or email the NYS Department of Health at immunize@health.ny.gov or the NYC DOHMH at nycimmunize@health.nyc.gov.

- CDC: Morbidity and Mortality Weekly Report (MMWR): Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021: https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm?s_cid=mm7017e4_w
- CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
- Reporting an adverse event to VAERS: https://vaers.hhs.gov/reportevent.html
- NYS COVID-19 Vaccine web page: https://covid19vaccine.health.ny.gov/
- Pfizer COVID-19 Vaccine EUA Fact Sheet for Health Care Providers: https://www.fda.gov/media/144413/download
- Pfizer COVID-19 Vaccine EUA Fact Sheet for Vaccine Recipients: https://www.fda.gov/media/144414/download
- Moderna COVID-19 Vaccine EUA Fact Sheet for Health Care Providers: https://www.fda.gov/media/144637/download
- Moderna COVID-19 Vaccine EUA Fact Sheet for Vaccine Recipients: https://www.fda.gov/media/144638/download