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In Brief: Myocarditis with the Pfizer/BioNTech and Moderna COVID-19 Vaccines

IN BRIEF

Myocarditis with the Pfizer/BioNTech and Moderna COVID-19 Vaccines

On June 25, 2021, the FDA added a warning to the Fact Sheets for the mRNA-based COVID-19 vaccines manufactured by Pfizer/BioNTech *(Comirnaty)* and Moderna *(Spikevax)* about an increased risk of myocarditis and pericarditis following administration of the vaccines.[1,2]

The warning was issued after a review of reports to the Vaccine Adverse Events Reporting System (VAERS) submitted between December 29, 2020 and June 11, 2021 identified 1226 cases of myocarditis following administration of an mRNA vaccine. Cases occurred most commonly in males (76%), in persons <30 years old (58%), and after administration of the second vaccine dose (76%). Symptoms usually developed within a few days after vaccination. At the time of the review, about 296 million doses of mRNA-based COVID-19 vaccines had been administered in the US, including 52 million doses in persons <30 years old.[3,4]

A CDC analysis of 323 cases of myocarditis following mRNA vaccination in persons 16-29 years old found that 90% of cases were in males and 96% required hospitalization. The median time to symptom onset after vaccination was 2 days. Most cases were mild in severity, and none of the 304 patients with known clinical outcomes died. The CDC estimates that, for every 1 million males 12-29 years old who receive a 2-dose mRNA-based COVID-19 vaccination series, 560 hospitalizations due to COVID-19 would be prevented and 39-47 cases of myocarditis would occur.[4]

The Advisory Committee on Immunization Practices (ACIP) concluded in a June 23, 2021 meeting that the benefits of mRNA-based COVID-19 vaccination still clearly outweigh the risks for all persons ≥12 years old.[5] Adolescents and young adults who experience acute chest pain, shortness of breath, or palpitations after vaccination should be assessed with an ECG, a troponin level, and inflammatory marker testing (e.g., C-reactive protein level, erythrocyte sedimentation rate).[6] Myocarditis has not been associated with use of the adenovirus-based Johnson & Johnson (Janssen) COVID-19 vaccine to date. ■

1. FDA. Fact sheet for health care providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). June 25, 2021. Available at: https://bit.ly/37fX1NG. Accessed July 21, 2021.
2. FDA. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Moderna COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). June 24, 2021. Available at: https://bit.ly/3nosylA. Accessed July 21, 2021.
3. FDA News Release. Coronavirus (COVID-19) update: June 25, 2021. Available at: https://bit.ly/3Bp7TpK. Accessed July 21, 2021.
4. JW Gargano et al. 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. MMWR Morb Mortal Wkly Rep 2021; 70:977.
5. CDC. ACIP live meeting archive – June 2021. Available at: https://bit.ly/3ruraBt. Accessed July 21, 2021.
6. CDC. Clinical considerations: myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines among adolescents and young adults. May 28, 2021. Available at: https://bit.ly/3xZqlmQ. Accessed July 21, 2021.

Online Tables: COVID-19 Treatments and Vaccines

Please check our website for the latest information on COVID-19, including our continuously updated tables: Treatments Considered for COVID-19 and COVID-19 Vaccine Comparison Chart. Available at: www.medicalletter.org/drugs-for-covid-19.

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