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Volume 67 (Issue 1733)

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COVID-19 UPDATES

mRNA COVID-19 Vaccines and Myocarditis

The FDA has required the manufacturers of the mRNA COVID-19 vaccines *Comirnaty* (Pfizer-BioNTech) and *Spikevax* (Moderna) to revise their labels to include updated information about the risks of myocarditis/pericarditis.

The revised labels state that the risks of myocarditis and pericarditis, with onset of symptoms typically in the first week following vaccination, are highest in males 12-24 years old.¹

The FDA has also required the addition of new cardiovascular safety information based on the estimated incidence of post-vaccination myocarditis and/or pericarditis and one longitudinal retrospective study in hospitalized patients 5-29 years old who were diagnosed with myocarditis following vaccination.

Based on health insurance claims data, the estimated incidence of myocarditis and/or pericarditis 1-7 days post-vaccination with the 2023-2024 formulations of the COVID-19 vaccines in persons 6 months to 64 years old was 8 cases/1 million doses; the incidence was highest in males 12-24 years old (27 cases/1 million doses).¹

In the longitudinal retrospective study, at a median of about 5 months post-vaccination with either mRNA COVID-19 vaccine, persistence of abnormal cardiac MRI findings was common, but the clinical significance of these findings is unknown.² ■

1. FDA. FDA approves required updated warning in labeling of mRNA COVID-19 vaccines regarding myocarditis and pericarditis following vaccination. June 25, 2025. Available at: <https://bit.ly/4ljC1Jg>. Accessed July 2, 2025.
2. SS Jain et al. Cardiac manifestations and outcomes of COVID-19 vaccine-associated myocarditis in the young in the USA: longitudinal results from the Myocarditis After COVID Vaccination (MACiV) multicenter study. *EClinicalMedicine* 2024; 76:102809.

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