

Why immunocompromised patients should get third mRNA COVID-19 shot

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What's the news: The Food and Drug Administration (FDA) on Thursday authorized third doses of Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines for some people who are immunocompromised. The action was followed on Friday by a unanimous vote of the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommending the three-dose regimen for patients with weakened immune systems who did not adequately respond to the two-dose regimen from the Pfizer and Moderna COVID-19 vaccines.

The FDA has updated the existing emergency use authorization (EUA) for the two mRNA vaccines. It does not apply to the one-dose Johnson & Johnson vaccine because there is not yet sufficient data to show an improved immune response following an additional dose. The additional dose of the mRNA COVID-19 vaccines applies to people who received solid-organ transplants and others with similarly compromised immune systems. These patients should also be counseled to maintain physical precautions to help prevent COVID-19.

The amended EUA notes that the third dose of either mRNA vaccine should be administered at least 28 days after the second shot in the mRNA vaccine series. It was noted that patients will be able to self-attest that they are immunocompromised, though specific guidance on the implementation of this recommendation is not yet available.

"This recommendation will allow physicians and other vaccine providers to offer an additional dose of mRNA vaccines for their most vulnerable patients, who are at high risk for severe outcomes from COVID-19," said AMA President Gerald E. Harmon, MD, a family physician who practices in South Carolina.

Read the CDC's updated guidance, "Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States."

Visit the AMA COVID-19 vaccine resource guide to find out more about SARS-CoV-2 vaccine developments.

Why it's important: Immunocompromised people account for at least 2.7% of U.S. adults—as many as 6 million people.

The third dose is for people, according to ACIP, with moderate to severe immune compromise may include those with:

- Active or recent treatment for solid tumor and hematologic malignancies.
- Receipt of solid-organ or recent hematopoietic stem cell transplants.
- Severe primary immunodeficiency.
- Advanced or untreated HIV infection.
- Active treatment with high-dose corticosteroids, alkylating agents, antimetabolites, tumor-necrosis blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Physicians who treat immunocompromised patients have been advocating that these patients be given an additional dose of a COVID-19 vaccine. This has been especially important in the face of the rapidly spreading and dangerous Delta variant of SARS-CoV-2.

Approval of a third dose comes amid growing evidence that people with weakened immune systems do not get adequate protection from the normal two-dose regimen of Pfizer and Moderna COVID-19 vaccines. This makes immunocompromised people especially susceptible to breakthrough COVID-19 infections.

Read more from the CDC about talking with patients who are immunocompromised about an additional dose of an mRNA COVID-19 vaccine.

The third dose is not for other people without compromised immune systems and who are fully vaccinated do not need an additional dose because they remain adequately protected at this time. ACIP continues to monitor the need for a booster dose, or a dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned.

Learn more: This news comes the same week that the CDC recommended that pregnant people get vaccinated against COVID-19. With less than one-quarter of pregnant women vaccinated, the new guidance moves the CDC from its previously neutral stance and comes two days after more than 20 health organizations urged vaccinations for those who are pregnant, have recently been pregnant and plan to become pregnant. The CDC's guidance was updated after finding no increased risk of miscarriage among those who have been immunized.

“The AMA strongly urges everyone who is eligible for COVID-19 vaccines, including pregnant women, to get vaccinated as soon as possible to protect themselves and their loved ones from severe COVID-19 complications, hospitalization and death,” Dr. Harmon said.

“We encourage anyone with questions about the vaccines to speak with their physician and review trusted resources, including [getvaccineanswers.org](https://www.getvaccineanswers.org),” Dr. Harmon said. “We also encourage the public to heed the CDC’s updated recommendations calling for mask wearing in areas of high or substantial COVID-19 transmission and in K–12 schools, to help reduce transmission of the virus. Wearing a mask is a simple, but important protective measure that can help us all stay safer.”

The AMA recently announced the Current Procedural Terminology (CPT[®]) code set has been updated by the CPT Editorial Panel. The update to the COVID-19 CPT codes now includes a new administration code unique to a third dose of the current shot offered by Pfizer.