FDA and CDC Change COVID Vaccine Recommendations

People 65 and older and immunocompromised people can get a second bivalent booster; most unvaccinated people now need only one initial shot.

April 28, 2023 By Liz Highleyman

UPDATE: On April 28, the Food and Drug Administration authorized the Pfizer-BioNTech bivalent booster as a fourth vaccine dose for children ages 6 months to 4 years who have certain immunocompromising conditions. Additional doses may be administered at the discretion of health care provider.

On April 18, the Food and Drug Administration (FDA) amended its emergency use authorization for COVID-19 vaccines from Pfizer-BioNTech and Moderna. Today, a Centers for Disease Control and Prevention (CDC) advisory committee and CDC director Rochelle Walensky, MD, MPH, endorsed corresponding changes to its vaccine and booster recommendations. The aim, the agencies say, is to simplify the vaccination schedule for most people.

The Pfizer-BioNTech and Moderna bivalent vaccines, which contain blueprints for spike proteins from both the original (Wuhan) SARS-CoV-2 variant and newer omicron variants, are now the only authorized messenger RNA (mRNA) options. Previously, the original monovalent vaccine was used for the initial two-shot series, and the bivalent version was used as a booster. Now, the monovalent vaccine is no longer authorized.

Today, FDA amended the EUAs of the Pfizer-BioNTech and Moderna COVID-19 bivalent mRNA vaccines to simplify the vaccination schedule for most individuals.

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pic.twitter.com/9394LP1HvR

— U.S. FDA (@US_FDA) April 18, 2023

The FDA also changed the initial vaccine regimen. A single dose of the bivalent vaccine—rather than two doses of the original monovalent version—is now considered sufficient for adults and children ages 5 and older. Most unvaccinated people have already been exposed to the coronavirus, so a single initial dose will confer hybrid immunity. The initial vaccine regimen for children ages 6 months to 5 years is more complicated and varies according to age and prior vaccination history. Children younger than 6 months are not eligible for vaccination.

The FDA and CDC did not make changes for the Novavax and Johnson & Johnson vaccines. The Novavax vaccine may be used as an initial two-dose series or as a first booster (but not for people who have already received a prior booster). The J&J vaccine was initially touted as a "one and done" option, but the CDC now recommends a bivalent mRNA booster two months later. The availability of both these vaccines is limited.

"At this stage of the pandemic, data support simplifying the use of the authorized mRNA bivalent COVID-19 vaccines and the agency believes that this approach will help encourage future vaccination," Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research, said in a press statement. "Evidence is now available that most of the U.S. population 5 years of age and older has antibodies to SARS-CoV-2, the virus that causes COVID-19, either from vaccination or infection, that can serve as a foundation for the protection provided by the bivalent vaccines."

"COVID-19 continues to be a very real risk for many people, and we encourage individuals to consider staying current with vaccination, including with a bivalent COVID-19 vaccine," Marks added. "The available data continue to demonstrate that vaccines prevent the most serious outcomes of COVID-19, which are severe illness, hospitalization and death."

The FDA summarizes the evidence for its decision here.

Some Can Get Second Bivalent Boosters

Many people who received the bivalent booster, which was first authorized last September, have been wondering when they would be eligible for another dose.

Boosters temporarily raise levels of antibodies against SARS-CoV-2, but these typically wane after a few months. However, the vaccines also stimulate memory B-cell and T-cell responses, which provide longer-lasting protection against severe disease.

This week, the FDA authorized a second bivalent booster four or more months after the previous

dose for people ages 65 and older. Studies have shown that immunity wanes faster in this population, but additional vaccine doses can restore it temporarily.

Immunocompromised adults and children ages 5 and up can receive a second bivalent booster two months after the first one. They may also receive additional doses at the discretion of their health care providers. For younger immunocompromised children, eligibility depends on age and which vaccines they previously received.

This group includes cancer patients (especially those on active treatment), people with advanced or untreated HIV, organ transplant recipients and people who have various other chronic conditions or are taking medications that impair immune function. Such individuals may not produce enough antibodies, or their antibodies may wane rapidly. Data for immunocompromised people are varied, and the change is intended to provide "maximum flexibility," Marks told Jeremy Faust, MD, for Inside Medicine. Speaking at a media briefing, Marks suggested that professional organizations (for example, those representing oncologists or HIV experts) could develop standards for specific patient groups.

However, people younger than 65 with normal immune function are not eligible for a second bivalent booster at this time. These individuals may receive a single bivalent booster if they haven't already gotten one. The FDA said it intends to make decisions about future vaccination after receiving recommendations at a meeting in June about which SARS-CoV-2 strains are expected to circulate in the fall. Administration officials have indicated that they expect COVID-19 vaccines to become an annual affair, like flu shots.

Experts expressed mixed opinions about the latest changes. Many concur that older and immunocompromised people will benefit from an additional bivalent booster, but that's where the agreement ends. Some feel that everyone should be able to get a second bivalent booster to reduce their risk for acute illness and long COVID. Others feel the evidence is not sufficient to recommend even a single booster for healthy young people.

In related news, the White House announced a program to continue funding COVID vaccines for people without health insurance. Many feared that cost would be a barrier to vaccination once the COVID public health emergency expires on May 11. Last week, President Joe Biden signed Republican legislation ending a separate COVID national emergency. But that doesn't mean COVID is over.

"The new, streamlined vaccination schedule provides clear, actionable guidance that the public along with their health care professionals can use to make decisions about vaccination for themselves and their loved ones, including children, older adults and people who are immunocompromised," Infectious Diseases Society of America president Carlos del Rio, MD, said in a statement. "Today's announcement is intended to eliminate any confusion over frequency and eligibility and help bridge the gap to more people getting boosted against COVID-19. Getting vaccinated and boosted remains the best way to protect oneself against serious illness, hospitalization and death, and helps protect young children and those who are

immunocompromised against COVID-19.”

Click here for the CDC’s latest vaccine and booster recommendations.
Click here for the CDC’s recommendations for immunocompromised people.

Click here for more news about COVID-19 vaccines.
