New COVID-19 Boosters Target Current Coronavirus Variants

Updated Pfizer-BioNTech and Moderna bivalent boosters contain spike proteins from the original and BA.4 and BA.5 omicron variants.

December 9, 2022 By Liz Highleyman

[UPDATE: On December 8, the Food and Drug Administration authorized the Pfizer-BioNTech and Moderna bivalent COVID-19 vaccines for children ages 6 months and older.]

[UPDATE: On October 12, the Food and Drug Administration authorized, and the Centers for Disease Control and Prevention recommended, the updated Pfizer-BioNTech bivalent COVID-19 vaccine for children ages 5 years and older and the Moderna bivalent vaccine for kids ages 6 years and up.]

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On August 31, the Food and Drug Administration (FDA) authorized updated COVID-19 boosters from Pfizer-BioNTech and Moderna that are a better match for the current circulating coronavirus strains. The Centers for Disease Control and Prevention (CDC) has revised its vaccine recommendations to include the new boosters.

The updated bivalent, or two-target, boosters contain messenger RNA (mRNA) that encodes spike proteins from both the original (Wuhan) SARS-CoV-2 variant and the newer BA.4 and BA.5 omicron variants. BA.5, which emerged in April, is now responsible for most COVID-19 cases in the United States.

“For the first time since December of 2020, these vaccines—our vaccines—have caught up with the virus,” White House COVID-19 response coordinator Ashish Jha, MD, MPH, said at a September 6 media briefing. "[B]arring any new variant curveballs…for a large majority of Americans, we are moving to a point where a single annual COVID shot should provide a high degree of protection against serious illness all year.”

The Pfizer-BioNTech bivalent booster is now available for people ages 12 and older, while the Moderna booster is available for those ages 18 and up. People can get the new boosters at least two months after their last vaccine dose. The bivalent boosters contain a smaller amount of mRNA than the original vaccines, and they are not approved for use as an initial, or primary, vaccine

series. People who originally got the Pfizer-BioNTech, Moderna or Johnson & Johnson vaccines—regardless of how many or which boosters they subsequently received—can get either of the new boosters.

“The updated COVID-19 boosters are formulated to better protect against the most recently circulating COVID-19 variant,” CDC director Rochelle Walensky, MD, PHD, said in a statement. “They can help restore protection that has waned since previous vaccination and were designed to provide broader protection against newer variants. This recommendation followed a comprehensive scientific evaluation and robust scientific discussion.”

> Over 99% of circulating variants in the U.S. are BA.5 or BA.4. Updated #COVID19 vaccines better match variants currently circulating. The addition of #Omicron BA.4 & BA.5 vaccine components may help broaden the spectrum of variants our immune system is ready to respond to. pic.twitter.com/bEDoLng3rl
>
> — Rochelle Walensky, MD, MPH (@CDCDirector)
>
> September 6, 2022

One advantage of the mRNA technology is that new viral sequences can be plugged into the same platform, enabling more rapid development of updated vaccines as the virus evolves. Pfizer-BioNTech and Moderna first developed bivalent boosters containing spike proteins from the original SARS-CoV-2 and the BA.1 variant. These boosters were adopted in the United Kingdom and Canada and are endorsed by the World Health Organization. But at a meeting in June, FDA advisers agreed that it would be better to target the newer BA.4 and BA.5 variants.

“As we head into fall and begin to spend more time indoors, we strongly encourage anyone who is eligible to consider receiving a booster dose with a bivalent COVID-19 vaccine to provide better protection against currently circulating variants,” FDA commissioner Robert Califf, MD, said in a statement.

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. While COVID-19 vaccines lower the risk

for symptomatic disease—and appear to reduce the likelihood of developing long COVID—they do not reliably prevent infection or transmission.

Although the safety and immunogenicity (ability to stimulate antibody production) of the BA.1 bivalent boosters were tested in clinical trials, the BA.4/BA.5 boosters were authorized based on studies showing that they produce a good immune response and provide better protection against infection in mice. This is how annual flu vaccines are developed. Waiting for the results of human trials could give new variants time to take over in the meantime, as happened with the BA.1 booster.

Since they use the same mRNA platform, the BA.4/BA.5 boosters are not expected to present any new safety concerns. The side effects are expected to be similar to those of the original COVID-19 vaccines, most commonly temporary soreness at the injection site and flu-like symptoms, such as fever and fatigue. Myocarditis (heart muscle inflammation) is a rare adverse event most often seen in young men.

“The FDA has been planning for the possibility that the composition of the COVID-19 vaccines would need to be modified to address circulating variants,” said Peter Marks, MD, PhD, director of the FDA’s Center for Biologics Evaluation and Research. “The FDA has extensive experience with strain changes for annual influenza vaccines. We are confident in the evidence supporting these authorizations.”

Experts expressed mixed opinions about the updated boosters. Some think they will shore up waning immunity and provide additional protection against COVID-19. However, others are concerned that the boosters were not tested in humans and argue that because the original recipe vaccines still provide protection against severe disease—especially for healthy young people—the updated boosters may not offer much additional benefit.

There are also questions about booster timing. Although Walensky said, “If you are eligible, there is no bad time to get your COVID-19 booster,” some experts think it’s best to wait about six months after a previous vaccine dose or infection to give the immune system more time to mount a complete response. Canada recommends getting the boosters six months after the most recent dose or infection.

After this round of boosters, COVID-19 vaccines might become an annual affair, like flu shots, federal officials suggested at the White House media briefing.

“It is becoming increasingly clear that, looking forward with the COVID-19 pandemic, in the absence of a dramatically different variant, we likely are moving towards a path with a vaccination cadence similar to that of the annual influenza vaccine, with annual, updated COVID-19 shots matched to the currently circulating strains for most of the population,” said National Institute of Allergy and Infectious Diseases director and White House chief medical adviser Anthony Fauci, MD. However, he added, some vulnerable groups may continue to need more frequent boosters.

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

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