

## Medical News &amp; Perspectives

## Updated COVID-19 Vaccine Now Available in US, Recommended for Everyone Older Than 6 Months

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The US Centers for Disease Control and Prevention (CDC) on September 12 recommended that everyone 6 months or older get a new COVID-19 monovalent vaccine targeting the Omicron subvariant XBB.1.5.

The CDC's move came the day after the US Food and Drug Administration (FDA) approved Moderna's and Pfizer-BioNTech's updated COVID-19 messenger RNA (mRNA)

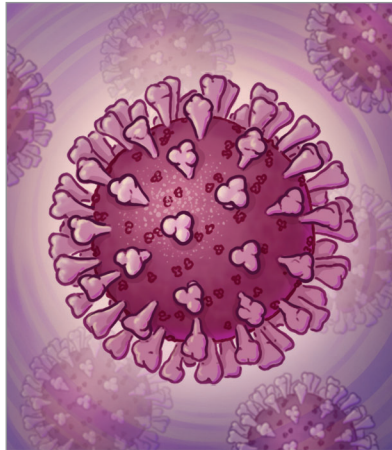
vaccines for people 12 years or older and authorized the shots for emergency use in children 6 months through 11 years of age.

"The public can be assured that these updated vaccines have met the agency's rigorous scientific standards for safety, effectiveness, and manufacturing quality," Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research, said in a statement.

Although the FDA greenlit the XBB vaccines for everyone 6 months or older, the CDC could have recommended it only for people at the greatest risk of severe COVID-19, such as those who are 65 years or older, pregnant, or immunocompromised.

But, as Jeffrey Duchin, MD, pointed out September 13 at an Infectious Diseases Society of America media briefing, "many people who think they're at low risk may not really be at low risk." High-risk groups stand to gain the most from getting immunized, but "the vaccine can offer some benefit for everyone," said Duchin, Seattle and King County health officer for public health.

When the FDA okayed the XBB.1.5 vaccines, it also withdrew the Emergency Use



Authorization for the companies' bivalent COVID-19 vaccines, which had been available for a year and included antigens from the ancestral SARS-CoV-2 virus and Omicron subvariants BA.4 and BA.5, whose spike proteins are identical. Those SARS-CoV-2 viruses have long been out of circulation, leading to the FDA's Vaccine and Related Biological Products Advisory Committee in June to unanimously recommend updating the vaccine to target the XBB lineage.

By September 2, the CDC estimated that XBB.1.5 represented only 3.1% of circulating SARS-CoV-2, compared with 30.3% in the 2-week period ending June 24, during which time the FDA advised vaccine manufacturers to target that subvariant in monovalent COVID-19 vaccines this fall. However, the agency noted in June, the spike proteins of XBB subvariants—which now represent more than 90% of circulating SARS-CoV-2 in the US—are similar, so a vaccine targeting one of them should be effective against the others.

And at the September 12 meeting of the CDC's Advisory Committee on Immunization Practices, both Moderna and Pfizer presented data showing that their XBB.1.5 vaccines were also immunogenic against EG.5.1, the most common subvariant of EG.5, representing an estimated 21.5% of circulating variants in the US, and BA.2.86, which, as of September 8, had been identified in cases from 9 states and in wastewater in 2 more. The US classified BA.2.86 as a "variant being monitored" on September 1.

On the same day that the FDA approved the 2 mRNA vaccines, Novavax announced that doses of its updated protein-based vaccine had arrived in the US, although the agency hasn't yet authorized their use. Novavax said it is seeking Emergency Use Authorization from the FDA for people 12 years or older.

Because distribution of COVID-19 vaccines has transitioned from the government to the commercial market, the US Department of Health and Human Services in April launched the "Bridge Access Program." Administered by the CDC, the \$1 billion program is providing free COVID-19 vaccines for an estimated 25 million to 30 million uninsured or underinsured adults 18 years or older through their local pharmacies, clinicians, and health centers. Free vaccines are available to children and teens younger than 18 years through the federally funded Vaccines for Children program. ■

**Published Online:** September 18, 2023.  
doi:10.1001/jama.2023.19759

**Conflict of Interest Disclosures:** None reported.

**Note:** Source references are available through embedded hyperlinks in the article text online.