



FDA simplifies COVID vaccine dosing; all mRNA vaccines will be bivalent

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Editor's note: For the latest news on COVID-19, visit <http://bit.ly/AAPNewsCOVID19>.

All mRNA COVID-19 vaccines will be bivalent and most unvaccinated people will need only one dose, under [changes authorized by the Food and Drug Administration](#) (FDA) today. However, young children who are unvaccinated will continue to need multiple doses.

The FDA also authorized an additional bivalent booster dose for vaccinated people who are immunocompromised or at least 65 years old.

“COVID-19 continues to be a very real risk for many people,” said Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research. “We are therefore encouraging everyone to consider staying current with vaccination including with a bivalent COVID-19 vaccine. And today’s actions aim to simplify the vaccination process to make it more understandable.”

The changes won’t go into effect unless approved by the Centers for Disease Control and Prevention (CDC) director. The CDC’s Advisory Committee on Immunization Practices (ACIP) is [meeting Wednesday](#).

Earlier this year, vaccine advisors to both the [FDA](#) and [CDC](#) agreed on the need to simplify COVID vaccination with mRNA vaccines from Moderna and Pfizer-BioNTech. The bivalent vaccines that will be used for all doses contain the original SARS-CoV-2 strain and an omicron BA.4/5 strain.

The FDA's updated authorization calls for most unvaccinated children and adults to receive one bivalent dose instead of a multi-dose primary series. Dr. Marks said most people already have some antibodies either from vaccination or infection.

Young children still will need multiple doses. Children under 5 years who are unvaccinated may receive a two-dose series of the bivalent Moderna vaccine or a three-dose series of the bivalent Pfizer-BioNTech vaccine, under the updated authorization. Unvaccinated children who are 5 years of age may receive two doses of the bivalent Moderna vaccine or one dose of the Pfizer-BioNTech bivalent vaccine.

Children 6 months through 5 years who have received one, two or three doses of a monovalent COVID-19 vaccine may receive a bivalent vaccine, but the number of doses will depend on the vaccine and previous doses. Refer to the [Moderna](#) and [Pfizer-BioNTech](#) fact sheets for detailed dosing.

People over 5 years of age who have received one or more monovalent doses are eligible for a single bivalent dose. The FDA did not authorize a second bivalent dose for most people. However, there are several exceptions. People 65 years and older who have received one bivalent dose may receive one more dose at least four months after their initial bivalent dose.

Most people who are immunocompromised and have received a bivalent dose can receive a single additional dose at least two months later and additional doses at the discretion of their health care provider. Eligibility for additional doses for immunocompromised young children will depend on their vaccination history.

Monovalent COVID vaccines from Pfizer-BioNTech and Moderna are no longer authorized. Today's moves did not affect authorization for the COVID-19 vaccines from Novavax and Johnson & Johnson. In June, the FDA's Vaccines and Related Biological Products Advisory Committee will discuss strain composition for the fall and the FDA also will consider whether the general population needs additional doses.

About 69% of the U.S. population has completed a COVID vaccine primary series. That includes about 62% of children ages 12-17 years, 33% of children ages 5-11 years, 6% of children ages 2-4 years and just under 5% of children under 2 years, [according to CDC data](#). Less than 17% of the population has received a bivalent booster dose.

The U.S. Department of Health and Human Services [recently announced](#) that pharmacists, pharmacy interns and pharmacy technicians will continue to be able to administer COVID-19 and influenza vaccines to children ages 3 years and older through 2024. The move extends a policy put in place in 2020 to respond to the COVID-19 pandemic. However, when the public health emergency ends in May, pharmacy personnel will no longer be able to provide routine childhood vaccinations unless state laws allow it.

The AAP encourages children to be vaccinated by a pediatrician who knows their medical history and who can simultaneously provide services like developmental and mental health screenings, counseling about nutrition and injury prevention, and chronic disease management.

Resources

- [FDA press release on COVID-19 vaccine authorization changes](#)
- [Detailed information on changes to the Moderna COVID-19 vaccine authorization](#)
- [Detailed information on changes to the Pfizer-BioNTech COVID-19 vaccine authorization](#)

