

FDA, CDC expand Pfizer & Moderna bivalent vaccines to kids 6 months and up with Sandra Fryhofer, MD

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Featured topic and speakers

In today's AMA Update, bivalent COVID vaccines for young kids authorized by FDA—and recommended by CDC. The latest on Pfizer-BioNTech and Moderna's updated COVID-19 vaccines for children as young as six months old with AMA Board Chair Sandra Fryhofer, MD, who is also the AMA's liaison to the Advisory Committee on Immunization Practices (ACIP) and a member of ACIP's COVID-19 Vaccine Workgroup. AMA Chief Experience Officer Todd Unger hosts.

Speaker

- Sandra Fryhofer, MD, chair, AMA Board of Trustees

Transcript

Unger: Hello and welcome to the AMA Update video and podcast. Today we're discussing how the bivalent COVID vaccines are now recommended for children as young as six-months-old. I'm joined today by Dr. Sandra Fryhofer, chair of the AMA Board of Trustees and the AMA's liaison to the CDC's Advisory Committee on Immunization Practices, or ACIP. Dr. Fryhofer is also a member of the ACIP's COVID vaccine workgroup.

I'm Todd Unger, AMA's chief experience officer in Chicago. Dr. Fryhofer, thanks for joining us today.

Dr. Fryhofer: Well, thank you for having me, Todd.

Unger: Well, we've got some big news here. Let's get right into it and talk about the new CDC recommendation.

Dr. Fryhofer: Bivalent COVID vaccines are now authorized for children as young as six-months-old. This expanded age authorization means more children now have the opportunity to update and broaden their protection against COVID with a bivalent vaccine. The virus continues to mutate. It's changed with time since the original vaccine was developed.

Updated COVID vaccines are critical for ongoing protection. FDA's authorization announcement came on December 8. CDC's directors' endorsement was announced the following day. The CDC website has also been updated. So it's available for these little babies now.

Unger: Are the recommendations the same for both Pfizer and Moderna?

Dr. Fryhofer: While the expanded recommendations vary according to the type of vaccine primary series. And let's start with children who received a Moderna primary series. Children aged six months through four-years-old who completed a two-dose Moderna primary series can now get a Moderna bivalent booster at least two months after their second primary series dose.

But children aged five who completed a two-dose Moderna primary series have a choice of the type of bivalent booster product they receive. They can get either a Pfizer or a Moderna bivalent boost at least two months after completing their two-dose primary series.

The recommendations for little ones who have been getting a Pfizer primary series are a little different. For these little ones, a primary Pfizer series requires three vaccine doses, not two. And for those aged six months through four-years-old getting Pfizer primary series, the new recommendation for them does not call for a booster per se. Instead, it replaces the third dose of their primary series with the Pfizer bivalent dose.

To repeat, for children aged six months through four-years-old receiving Pfizer's COVID vaccine, the first two Pfizer doses remain monovalent. The third Pfizer dose should now be bivalent.

But for children in this young age group, those aged six months through four who already completed their three monovalent Pfizer doses, an additional bivalent boost is not recommended at this time but that may soon change. FDA says data needed to support an updated bivalent booster dose for these children is expected in January 2023, so more to come on that.

Unger: Well, to, I guess, the untrained ear, maybe even others that might—that combinations of age and type of vaccine might be a little confusing. Doesn't the vaccine dose vary according to age? And what happens when children start to age, they get older and the age group recommendations change?

Dr. Fryhofer: Well, those are great questions. And CDC says to give the vaccine product and dose based on the child's age on the day of vaccination. And as you mentioned, as children transition from a younger age group to an older age group, when getting their primary series or when it's time for a booster, it gets a little confusing but they should receive the vaccine product and dosage for the older age group for all subsequent doses.

And it is confusing. CDC realizes that. CDC realizes the nuances of the new authorization are complicated.

For example, for Moderna, when a child goes from age five to age six, the vaccine dose doubles. The same is true with the transition from age 11 to 12. Yet for Pfizer, from age 11 to 12, the vaccine dose triples.

CDC has put together several colorful graphics to help clarify dosing for these age transitions for children and adolescents. There are several different products available that have different colored labels and caps. And in this way, the color on these graphics is extremely helpful.

Unger: It sounds like that will be very, very helpful, indeed. Let's get into the science. Dr. Fryhofer, can you talk about the evidence behind the updated authorization?

Dr. Fryhofer: In expanding Moderna and Pfizer's authorizations to these younger age groups, FDA relied on immune response data comparisons with teens, young adults and older adults. Moderna's safety determination was based on previous safety data from studies of Moderna's investigational original Omicron BA.1 bivalent vaccine. Pfizer's safety assessment was based on data on studies of its investigational bivalent BA.1 booster in older adults and on safety data from clinical trials of primary monovalent vaccination in children six months and older, as well as post-marketing safety data.

Unger: About how many children in this age group does the new recommendation effect?

Dr. Fryhofer: A lot. The vast majority of children in this six-month to five-year-old age group have not received any doses of COVID vaccine and we must continue to increase confidence in COVID vaccines. But I'm so glad that this bivalent booster is now at least available for these little ones.

Unger: Well, they also couldn't be coming at a better time because right now, of course, we're dealing with the triple threat of COVID, the flu and RSV. That's not a great combination. Tell us more about that.

Dr. Fryhofer: Well, at a press conference I participated in last week, CDC director Dr. Rochelle Walensky confirmed high circulating levels of respiratory viruses, including RSV, flu and COVID. There are signs that the numbers of RSV cases may be leveling off.

Flu season started early this year. And I can tell you that from being a practicing doctor. The phone's ringing off the hook. Flu hospitalizations are the highest levels we've seen this time of year in a decade. And at least 14 pediatric deaths from flu have already been recorded. And this is heartbreaking.

There's been a rise in COVID cases and hospitalizations after the Thanksgiving holiday. There is no currently available vaccine for RSV but there are vaccines for flu and for COVID for everyone six months and older, including the updated bivalent COVID vaccines.

A recent study published in MMWR shows updated COVID vaccines help protect against COVID illness and COVID-associated death. Immunity wanes with time. Both flu and COVID vaccines are safe and effective and are specially formulated to protect against the virus strains that are currently circulating.

Unger: Dr. Fryhofer that is amazingly expert information, so important to share. Any final thoughts before we close?

Dr. Fryhofer: The updated bivalent COVID vaccine has now been authorized for everyone aged six months and older. Your best bet to stay well during the holidays is for everyone six months and older to get vaccinated for flu and for COVID and to make sure you're up to date on COVID vaccination, which means getting that Omicron booster when you're eligible.

Unger: Absolutely, want everyone to have a healthy and happy holiday and New Year. Get those vaccines and boosters. That wraps up today's episode.

Dr. Fryhofer, it's always great to see you. Thank you again for this information. We'll be back soon with another AMA Update. In the meantime, you can find all our videos and podcasts at ama-assn.org/podcasts. Thanks for joining us and please take care.

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