Novavax booster, COVID vaccines in pregnancy and boosters for kids with Sandra Fryhofer, MD

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Featured topic and speakers

In today’s AMA Update, Sandra Fryhofer, MD, the AMA’s liaison to the Advisory Committee on Immunization Practices (ACIP) and chair of the AMA Board of Trustees, shares news from the latest ACIP meeting, including the newest COVID booster from Novavax, more reassuring data on the safety and value of COVID vaccines for pregnant people, their infants and children, and the inclusion of COVID vaccines in the Vaccines for Children Program. AMA Chief Experience Officer Todd Unger hosts.

Speaker

- Sandra Fryhofer, MD, AMA’s liaison, Advisory Committee on Immunization Practices (ACIP); chair, AMA Board of Trustees

Transcript

Unger: Hello and welcome to the AMA Update video and podcast. Today we’re talking about the latest news from the CDC's Advisory Committee on Immunization Practices, or ACIP. I'm joined today by Dr. Sandra Fryhofer, the AMA's liaison to ACIP. Dr. Fryhofer serves on ACIP working on groups for flu, COVID, ebola vaccines, as well as the adult immunization schedule. She's also the chair of the AMA
Board of Trustees.

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

Dr. Fryhofer: Well, Todd, thanks for having me.

Unger: So most of our discussions in regard to the ACIP have been about COVID. Tell me just for starters, what was the focus of the most recent meeting?

Dr. Fryhofer: Well, COVID vaccine updates were on the agenda but this two-day meeting also included updates on a potpourri of other vaccines, including flu, pneumococcal, meningococcal, dengue fever, monkeypox and polio vaccines, as well as progress reports for vaccines under development, including a new vaccine for RSV—that’s respiratory syncytial virus—and a new vaccine for chikungunya virus.

Unger: Well, let’s start with the news on COVID vaccines.

Dr. Fryhofer: Well, there were three main things. A new kind of booster has now been authorized, more reassuring data supporting safety and value of COVID vaccines for pregnant people, their infants and children. And also, COVID vaccines are now part of the vaccines for children program and will be included in ACIP’s child, adolescent and adult immunization schedule. So what do you want me to start with?

Unger: Why don’t we start with the new Novavax booster. What do we need to know there?

Dr. Fryhofer: All right, the Novavax protein subunit monovalent vaccine is now authorized as a booster for those 18 and older with some caveats. It’s only for those either unable or unwilling to get the updated Omicron-specific mRNA bivalent booster. And it can be given until at least six months after a primary series. This announcement was made at our ACIP meeting by an FDA representative. And this Novavax booster is the same product used in the primary Novavax vaccination series.

It’s monovalent, so it doesn’t target BA.5 and BA.4 variants like the Pfizer and Moderna bivalent versions. But for those who can’t or refuse or won’t get a bivalent mRNA boost, it’s great to have this as an option. Now, this CDC recommendation came a few hours later through a decision memo. And CDC interim clinical considerations web page for COVID vaccines has already been updated.

Novavax monovalent COVID booster is now an option for those 18 and older at least six months after their last vaccine dose.

Unger: Dr. Fryhofer, can you tell us about some of the data presented about COVID vaccination for pregnant people, their infants and children?
Dr. Fryhofer: Sure. Well, there are three take home points. COVID can cause severe disease in pregnant people and infants. Vaccination of pregnant people has benefits for mom and for baby. And studies continue to reinforce that COVID vaccination during pregnancy is safe for mom and safe for baby.

Unger: Let's dig in just a little bit more. Can you explain a little bit more about the impact of COVID disease and pregnancy.

Dr. Fryhofer: So people who become pregnant are generally younger and healthier than the general population. But understand, pregnancy is a risk factor for severe COVID illness. A systematic review presented at ACIP showed pregnant people with COVID are more than twice as likely to be admitted to the ICU and more than twice as likely to be put on a ventilator than those with COVID who are not pregnant. They're also more than three and a half times more likely to need ECMO.

This same review also showed COVID associated with increased risk for maternal complications. Pregnant women with COVID are more than six times more likely to die as compared to pregnant women without COVID.

Unger: Wow, those are some really important stats on the infant side. How does getting COVID during pregnancy affect the baby?

Dr. Fryhofer: Well, infants born to people who get COVID during pregnancy are at increased risk of severe outcomes. Pregnant women who got COVID were nearly twice as likely to have a stillbirth and their babies were more than twice as likely to die as compared to those pregnant without COVID.

Unger: How does COVID vaccination then affect pregnancy outcomes?

Dr. Fryhofer: Well, data presented also shows vaccination of pregnant people has benefits for mom and for baby. The V-safe COVID pregnancy registry showed COVID infection in pregnant people who had full vaccination is not associated with increased risk of adverse outcomes. There was no increase in stillbirths and no increase in preterm births for those fully vaccinated.

Infants under six months old are too young to get COVID vaccination. And during the Omicron surge, infants under six months old with COVID had the second highest hospitalization rates. Only those 65 and older had higher hospitalization rates. COVID associated hospitalization rates were highest for infants under six months for American Indian, Alaska Native, Hispanic and Black children. Maternal vaccination is protective for these little ones.

There's evidence that maternal COVID primary series vaccination protected infants under six months old from severe disease and hospitalisations from COVID. However, protection was lower during Omicron as compared to Delta. And this is another reason why getting the new bivalent mRNA
booster when you're eligible is so important.

Unger: On a more general front, any news about vaccine safety? Were there any kind of vaccine safety updates that were discussed?

Dr. Fryhofer: Safety of COVID vaccination during pregnancy continues to be extensively studied. And no safety signal concerns have been identified. The V-safe COVID pregnancy registry has followed pregnant people vaccinated during pregnancy. There has been no increased risk of spontaneous abortion and no increased risk of major birth defects linked to COVID vaccination during pregnancy.

In summary, COVID can cause severe disease in pregnant people and infants. Studies clearly show vaccination of pregnant people is safe and has benefits for mom and for baby. However, many moms and their babies are missing out on these benefits by not getting vaccinated.

Data from VSD, which is CDCs Vaccine Safety Datalink showed only 43% of pregnant people have been vaccinated and boosted. This means that overall, 57% of pregnant people are either unvaccinated or under-vaccinated.

Unger: Again, important statistics. Where are we now with COVID vaccine and booster recommendations for children?

Dr. Fryhofer: COVID vaccines were authorized for children as young as age six months in June of 2022. And from March 2020 to October 2022, children age six months to four years old had the highest hospitalization rates among those now eligible for vaccination. Bivalent boosters starting at age five were authorized this month, October 22. These booster doses achieved higher antibody levels than after a primary series.

Reactogenicity symptoms were similar. Rates of myocarditis after a primary series in children age 5 to 11 are considerably lower than rates seen in adolescents.

Unger: Well, on that topic of myocarditis, I know that it's a big concern for parents. How common is that?

Dr. Fryhofer: Myocarditis risk is rare. And it's been primarily observed in adolescent and young adult males within the first week after the second dose or a booster dose of mRNA COVID vaccine. An interval of eight weeks between vaccine doses may further lower myocarditis risk. However, rates of myocarditis in those 5 to 11 is much lower than rates in adolescents. Again, the biggest risk is for adolescent and young males.

And so far, there's been no evidence of increased risk for myocarditis following mRNA vaccines in the youngest age groups. Those children that are six months to five years old. Now, most patients with
vaccine-related myocarditis have fully recovered at follow-up. The bottom line, getting vaccinated is safer for your heart than getting COVID disease. Risk of adverse cardiac outcomes where 1.8 to 5.6 times higher after COVID infection than after COVID vaccination.

The benefits of COVID vaccination far outweigh the known and potential risks, including the small risk of myocarditis and pericarditis. Safety monitoring continues. COVID vaccines continue to undergo the most comprehensive and intense safety monitoring in U.S. history.

Unger: Well, given all of those benefits that you outlined and the safety profile that you just discussed, what kind of uptick are we seeing for kids with the vaccine?

Dr. Fryhofer: Unfortunately, we’re seeing lower vaccine coverage in the pediatric age group than for any other age group. Overall, about 30 million children and adolescents have received at least one COVID vaccine dose. For children aged six months to four years old, only 6.9% have received at least one dose. For those age 5 to 11, only 38.6% have received at least one dose, only 15.6% have been boosted.

For adolescents age 12 to 17, 71.1% have received at least one dose. But only 29.3% have been boosted. So we have much work to do to get these children protected.

Unger: Indeed. And how soon can children get boosters?

Dr. Fryhofer: So for children age six months through age four, boosters are not authorized yet. The bivalent mRNA boosters are recommended starting at age 5. And at least two months after the last vaccine dose children, five years and older can receive a bivalent mRNA booster starting at age 5 for Pfizer and age 6 for Moderna. But remember, the new Novavax booster is only authorized for those 18 and older.

However, a primary series of Novavax can be given to those age 12 and older.

Unger: Now, I heard that ACIP also voted to include COVID vaccines in the VFC, Vaccines For Children program. Why is that so important?

Dr. Fryhofer: Well, VFC, which is the Vaccines For Children program is a federally funded program that provides no cost vaccines to children who otherwise might not be able to get vaccinated. So being part of VFC means COVID vaccines will be available for free for uninsured and underinsured children. Now, this does not mean COVID vaccines are now going to be required for school entry. That type of decision is made on the state and local level.

For everyone, COVID vaccines are free for now. But that may soon change. The federal government now pays about $30 per Pfizer dose. But news reports say that Pfizer plans to quadruple the list price.
up to $110 to $130 a dose when it hits the private market. So that's another reason to go ahead and get boosted now while the boost is free.

**Unger:** Dr. Fryhofer, any final thoughts?

**Dr. Fryhofer:** We're starting flu season and a possible winter surge of COVID is on the horizon. We're also seeing a surge in RSV—respiratory syncytial virus in younger children. And there's not a vaccine for RSV yet. Now's the time for everyone to make sure you and your loved ones are up to date on vaccinations, including both flu and COVID vaccination for those six months and older.

New updated bivalent mRNA COVID vaccine boosters are now authorized for everyone age 5 and older. These bivalent boosters offer unique protection because they target the original strain of the virus, as well as the Omicron BA.5 variant that's now dominant. I urge everyone who's eligible to get vaccinated.

COVID vaccination and flu vaccination is the best way to protect us from serious illness over the next few months.

**Unger:** Dr. Fryhofer, as usual, so much great information. Thank you so much for being here and giving us those updates. And we'll have to have you back for additional updates for other vaccines.

**Dr. Fryhofer:** I'd love that.

**Unger:** Excellent. Well, that wraps up our segment for today. Again, thanks Dr. Fryhofer for being here and sharing this important 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 being here today. Please take care.

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