New Omicron boosters available from Pfizer and Moderna with Sandra Fryhofer, MD

AMA Update covers a range of health care topics affecting the lives of physicians, residents, medical students and patients. From private practice and health system leaders to scientists and public health officials, hear from the experts in medicine on COVID-19, monkeypox, medical education, advocacy issues, burnout, vaccines and more.

Featured topic and speakers

In today’s AMA Update, bivalent boosters authorized by FDA: the latest on Pfizer-BioNTech and Moderna's updated COVID-19 vaccines for fall with Sandra Fryhofer, MD, chair, AMA Board of Trustees and AMA liaison to the Advisory Committee on Immunization Practices (ACIP). AMA Chief Experience Officer Todd Unger hosts.

Speaker

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

Transcript

Unger: Hello and welcome to the AMA Update video and podcast, an ongoing series covering a range of health care topics affecting the lives of physicians and patients. Today’s topic—the latest from ACIP, the CDC Advisory Committee on Immunization Practices, including what you need to know about the new Omicron COVID vaccine booster.

I'm joined today by Dr. Sandra Fryhofer, chair of the AMA Board of Trustees and our vaccine subject matter expert and AMA’s liaison to ACIP. I'm Todd Unger, AMA’s chief experience officer in Chicago. Dr. Fryhofer, welcome back.
Dr. Fryhofer: Well, Todd, thanks for having me.

Unger: Well, we've got very exciting news to talk about today. Tell us about the new booster and who should get it.

Dr. Fryhofer: Well, Todd, a new updated Omicron-specific COVID booster has arrived. It's finally here. It's bivalent, and it's been tweaked to better match Omicron BA.4 and BA.5 strains, which are currently circulating. FDA authorized it.

ACIP now recommends it for everyone aged 12 and older but there's a catch. You must have already completed a primary COVID vaccine series to be eligible but it can be with any COVID vaccine product. "Bivalent" means it's half original strain, and half Omicron BA.4, BA.5.

The only bivalent boosters currently authorized are mRNA versions—one by Pfizer, another by Moderna—and this is the first time these mRNA vaccines have been updated.

Unger: That is great news. And you said about age-specific—let's just get the details there. What's it mean and how soon can you get it?

Dr. Fryhofer: Pfizer's bivalent booster is authorized for those 12 and older. For Moderna, authorization starts at age 18. Booster recommendations for expanded ages and other vaccines may follow but this is what we have for now. And children aged 5 to 11 who received a primary Pfizer series should still receive the original monovalent booster.

The timing depends on when you got your last vaccine dose. The time between last COVID vaccine dose and getting a bivalent boost is at least two months. Now, understand that most people eligible for a booster are at least six months from their last COVID vaccine dose.

Unger: Now, a lot of people have the question, what if I've already had COVID? Do you still need to get a booster?

Dr. Fryhofer: Yes, if you've already had COVID, you still should get it but not until you've recovered from the acute illness and you're out of isolation, of course. But CDC guidance says it's probably best to wait at least three months after a COVID infection to get the booster. But again, you must have completed a primary COVID vaccine series to be eligible.

Unger: Small math question—you said, bivalent. I'm thinking two. But you said it's half original strain, half BA.4 and BA.5. That's three strains altogether, I think, if that. How does that work?

Dr. Fryhofer: Well, remember that mRNA COVID vaccines trigger antibodies to spike protein. BA.4 and BA.5 are different Omicron subvariants and have different mutations but their spike protein just happens to be the same. So that's why this new bivalent vaccine targets both BA.4 and BA.5.
Remember, Omicron first appeared in early December. It's still dominant but it keeps changing. It's evolved through several sublineages, BA.1, 2, 3, 4. BA.5 now makes up nearly 90% of all circulating COVID strains and FDA is hoping this new bivalent booster will be a good match against circulating strains.

**Unger:** I've seen headlines that talk about the fact that the bivalent boosters weren't yet tested on people. Is that true?

**Dr. Fryhofer:** Bivalent vaccines have been tested. We have human data on bivalent COVID vaccines with beta and with Omicron and more than 1,700 individuals from the manufacturers and from NIH. Omicron-specific bivalent COVID vaccines were studied in more than 1,400 of those individuals but those human studies targeted BA.1.

And now, BA.1 is no longer circulating. That's why FDA directed the manufacturers to make a booster targeting the BA.4, BA.5 spike protein. Changing the strains for a vaccine that's already been studied is not new.

We do this for flu vaccine every year. We don't give last year's flu vaccine for this year's flu season. FDA allows changes in flu vaccine as the flu virus evolves without requiring a full efficacy trial. This is the same type thing.

These BA.4, BA.5 boosters have been studying in animals. Those antibody comparison titers are encouraging and reassuring but you're right. There's no clinical trial data specifically for bivalent BA.4, BA.5 boosters in humans yet but there will be.

**Unger:** How well are the current vaccines and antibody treatments working right now?

**Dr. Fryhofer:** We know that primary vaccination and boosting saves lives. Currently, authorized vaccines offer dramatic protection against severe illness and death. Studies also show that protection wanes with time and the majority of people are now more than six months since receiving their last vaccine dose.

Omicron is more transmissible. Our current vaccines don't work as well against it. Neither do many monoclonal antibody treatments. And that's why this new bivalent Omicron-specific booster is so important.

**Unger:** Can you tell us more about the Omicron booster study, specifically, that had been done? What's the evidence behind the booster and how well did it work in clinical studies?

**Dr. Fryhofer:** The Omicron BA.1 bivalent studies found adding a second COVID virus to the original vaccine broadens the antibody response. There were higher antibody titers, not only for Omicron.
variants but also higher antibody titers against other COVID variants as well. And the resulting antibody titers were as high or higher than for vaccines containing only the original vaccine strain.

The studies also included people who had prior COVID infections. Bivalent COVID vaccines administered to those with prior COVID infection resulted in the highest antibody titers.

**Unger:** Excellent. Let's turn our attention now to the kind of safety and side-effect profiles. What do we know about this? And any surprises?

**Dr. Fryhofer:** No surprises. And no cases of myocarditis or pericarditis were observed in the studies. Side effects were as expected. Like other COVID vaccines, bivalent vaccines are reactogenic.

The most common side effects include fatigue, headache, muscle aches, joint aches, chills, nausea, vomiting and some fever. There are some subtle differences in mutations between BA.1 and the BA.4, BA.5 spike protein sequences. However, experts do not anticipate any differences in safety or reactogenicity, based on these limited mutations.

**Unger:** You said that there hadn't been any observed myocarditis cases as yet. Do you think, going forward, that that's a concern, especially with young men?

**Dr. Fryhofer:** Right. We don't know for sure. The potential risk of myocarditis, specifically with these new bivalent boosters, is still unknown and will be studied. But here's what we do know so far about myocarditis risk after COVID vaccines.

The risk is rare, and it's been primarily observed in adolescent and young adult males. Most individuals with myocarditis have fully recovered at followup. The risk of heart problems after COVID infection is higher than after mRNA COVID vaccinations. Studies also show a longer interval of at least eight weeks between vaccine doses may further lower myocarditis risk.

**Unger:** Now, Dr. Fryhofer, you mentioned the flu shot earlier when we were talking about different kind of vaccines. I'm obviously going to get both my booster for COVID and I want to get my flu shot. Can someone like me get those at the same time or should they be given together or not?

**Dr. Fryhofer:** It's fine to give a flu shot along with any COVID vaccine at the same visit. In fact, since both flu and COVID and ... will be circulating, CDC encourages it. It's also fine to give COVID vaccines, including these new bivalent boosters, with other needed vaccines, with one exception—monkeypox.
As you know, we're in the midst of a monkeypox outbreak. ACAM2000 and JYNNEOS are the two vaccines available for orthopox viruses. ACAM2000 has been linked to myocarditis. We don't know about risk of myocarditis for JYNNEOS.

But if you've received a dose of either of them, CDC suggests waiting for four weeks to get a COVID vaccine dose. However, if you've already received a COVID vaccine dose and you're now at risk of monkeypox due to exposure, no need to wait. Go ahead and get the monkeypox vaccine dose as soon as you can.

And remember that COVID vaccines, including bivalent boosters, are reactogenic. Shingles vaccine is also very reactogenic. So you might want to think twice about giving both shingles vaccine and a COVID vaccine on the same day.

Unger: All right. For those physicians out there thinking about the kind of storage administration side of these new boosters, what advice do you have for them?

Dr. Fryhofer: Storage rules remain the same as for the original vaccine products. Pfizer still has to be stored in those super-cold freezers until expiration but can be stored at regular refrigerator temperatures for up to 10 weeks. Moderna can be stored in regular freezers until expiration and up to 30 days at regular refrigerator temperatures. Beyond use date for both products is 12 hours.

Both manufacturers—for both of these manufacturers, the products that are bivalent clearly say so on the label. But unfortunately, the color coding and other information on the labels is confusing and misleading. So vaccinator, beware. Make sure you understand which age-appropriate product you have, what you use it for and who you can give it to. Very important there.

Unger: Do you think that there's going to be kind of an over-demand for these? Are there enough vaccine doses to go around at this point?

Dr. Fryhofer: Well, I hope there's a lot of demand for this booster, because I think it's very important. CDC says over 200 million people are now eligible for a bivalent COVID vaccine booster. Remember, most people are now at least six months out from their last vaccine dose and we require that two-month interval between last vaccine dose and getting this booster.

The government has purchased 171 million bivalent vaccine booster doses—66 million from Moderna, 105 million from Pfizer. These vaccines are free, at least for now. Both Moderna and Pfizer agreements include options for more doses but this would require more funding from Congress.

Unger: Now, the new booster has been updated to provide better protection against new variants, like Omicron. The new booster campaign is about to begin. How much interest does there seem to be from the public?
That's a really key question. Have you heard anything out there about acceptability? Or what are they predicting in terms of demand?

**Dr. Fryhofer:** Well, several surveys were presented at ACIP. Nearly 75% say they're likely to get this new booster. Two-thirds said they'd be willing to get both the booster and a flu shot at the same time.

Another survey reinforced the value of the patient-physician relationship. Physician recommendation is so important in the decision to get vaccinated. We physicians must continue to promote the importance of getting a dose of one of these updated bivalent COVID vaccine boosters when they are indicated and available.

**Unger:** Any final thoughts? This has been a good-news episode, in terms of another tool in the arsenal. Can you summarize at this point where we are, Dr. Fryhofer?

**Dr. Fryhofer:** COVID vaccines have dramatically reduced COVID hospitalizations and deaths. However, the virus continues to mutate. Omicron bivalent vaccines have been studied in over 1,400 individuals.

This new bivalent vaccine specifically targets BA.4 and BA.5 variants that are here, now and circulating. The bivalent vaccine broadens antibody response. It triggers higher antibody titers for variants and also for other COVID variants.

I strongly urge everyone to stay up to date on COVID vaccines, including recommended booster doses, to protect yourself and your loved ones from severe complications, hospitalization and death. Now is our chance to get ahead of this virus. And I got my booster over the weekend.

**Unger:** That's fantastic. The first thing I did when I found out we were going to be talking today was call my mom and told her to get her appointment. And I'll be shortly behind her.

That wraps up today's episode, Dr. Fryhofer. Thanks so much for being with us and sharing this important news. We'll be back soon with another episode. In the meantime, you can find all our videos and podcasts at ama-assn.org/podcasts. Thanks for joining us today. Please take care.

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