

## Sandra Fryhofer, MD, discusses updated booster recs for teens and more

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### Featured topic and speakers

In today's COVID-19 Update, AMA Chief Experience Officer Todd Unger discusses news from the recent meeting of the CDC's Advisory Committee on Immunization Practices, or ACIP, with Sandra Fryhofer, MD, AMA's liaison to ACIP and a member of ACIP's COVID-19 Vaccine Workgroup.

Updates include new COVID booster recommendations for teens, a shorter booster interval after a Pfizer vaccine series, new additional dose recommendations for immunocompromised children, and what you need to know about Pfizer's new COVID vaccine formulation for adults. Also reviewing new data about preventing MIS-C (multisystem inflammatory syndrome) in children, as well as recent decision memos from the CDC director.

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### Speaker

- Sandra Fryhofer, MD, physician, AMA trustee and AMA liaison to CDC's Advisory Committee on Immunization Practices

### Transcript

**Unger:** Hello. This is the American Medical Association's COVID-19 Update video and podcast. Today we're discussing the recent news from the CDC's Advisory Committee on Immunization Practices, or

ACIP, including new COVID booster recommendations for teens, a shorter booster interval after a Pfizer vaccine series, new additional dose recommendations for immunocompromised children and what you need to know about Pfizer's new COVID formulation for adults. We'll also review new data about preventing MIS-C, or multisystem inflammatory syndrome in children.

I'm joined today by Dr. Sandra Fryhofer, AMA's liaison to ACIP and a member of ACIP's COVID-19 Vaccine Work Group. Dr. Fryhofer is also chair-elect of the AMA Board of Trustees. I'm Todd Unger, AMA's chief experience officer, in Chicago. Dr. Fryhofer, welcome back. It seems FDA and ACIP have kicked off the new year with a flurry of announcements. We've got new authorizations from the FDA, decision memos from the CDC director, and now, another emergency meeting from ACIP. What did the ACIP recommend?

**Dr. Fryhofer:** Well, the message from ACIP was clear, concise and strong. Everyone aged 12 and older needs a COVID vaccine booster. With Omicron on the scene, an initial primary vaccine series alone is not enough to protect you. Everyone aged 12 and older should get a booster. No ifs, ands or buts. The CDC director endorsed this new recommendation just hours after our meeting, so it's now official CDC policy. The actual ACIP vote was to expand Pfizer boosters to kids age 12 to 17 at least five months after their primary series. A strong booster recommendation for older age groups was already in place.

**Unger:** So, why was the vote only for Pfizer boosters?

**Dr. Fryhofer:** Well, the vote was Pfizer specific because Pfizer's still the only COVID vaccine currently authorized for those under 18. The age indication for Moderna and Janssen starts at 18. You can still mix and match the boost with age-authorized vaccine types but for those 12 to 17, Pfizer is the only game in town. It's the only vaccine authorized for this age group. CDC now recommends boosters to stay up-to-date with COVID vaccinations.

**Unger:** Well, I noticed that phrase, up to date. Is that a new concept or does that mean that the definition of fully vaccinated has changed?

**Dr. Fryhofer:** Well, up to date is a new way of thinking about COVID vaccination but the technical definition of being fully vaccinated has not changed. It still means you've received the primary vaccine series, which is one Janssen dose or two mRNA vaccine doses. Staying up-to-date means you've also received any additional doses recommended by CDC and this is a phrase I think we'll be hearing again and again. The last sentence of Dr. Walensky's media statement endorsing this latest recommendation encourages all parents to keep their children up-to-date with CDC's COVID-19 vaccine recommendations. I sort of like it, up-to-date. I think it's... I think it's a great way to start the new year.

**Unger:** It's certainly the way that I'm used to hearing about my other vaccines and so, that makes sense to me. You mentioned that the Pfizer booster interval is now five months. It used to be six months after a primary mRNA series. Why and when was the Pfizer booster interval shortened?

**Dr. Fryhofer:** Well, it just happened. FDA authorized a shortened Pfizer booster interval from six months down to five months on January 3 and this shortened time interval was then adopted by the CDC director, Dr. Walensky, in a decision memo. And, you can blame Omicron for the quick change and Israel's real world five-month booster data on safety for making it happen. Two studies from Israel document the effectiveness of a Pfizer booster dose five months after a primary series against severe COVID illness and death due to COVID. Additionally, data from multiple laboratories indicate that a Pfizer booster dose greatly improves antibody response against the Omicron variant.

**Unger:** That's good news. When you mentioned safety, I know one of the main concerns is about a risk of myocarditis. Talk about that a little bit more.

**Dr. Fryhofer:** Well, myocarditis risk is the elephant in the room and the Israeli data for boosters in the 12- to 15-year-old age group is very reassuring. After administration of more than 6,300 third dose boosters to 12- to 15-year-olds, there were no cases of myocarditis. At our ACIP meeting, an Israeli public health official actually shared a live update of this, the latest on their five-month booster safety data, and after administration of more than 40,000 vaccine booster doses, there were only two cases of myocarditis in this age group.

We also know that myocarditis rates among 12- to 15-year-olds who received a primary series are lower than rates among 16- and 17-year-olds and in older age groups, rates of myocarditis after a third dose are lower than after a second dose. We also have encouraging data from the U.K. showing an mRNA booster dose in those 18 and older increases vaccine efficacy in the setting of Omicron. And, remember, the myocarditis risk concern is not just for vaccines. COVID disease itself can also cause myocarditis.

**Unger:** Beyond myocarditis, are there any other safety concerns?

**Dr. Fryhofer:** There's a special ACIP work group called VAST that reviews all the safety data and VAST reviewed the most recent data from three U.S. safety monitoring systems. This review included safety data after a primary vaccine series in 12- to 15-year-olds as well as safety data for booster doses in 16- to 24-year-olds. This is the youngest group for which boosters were previously authorized. And the news is good. No new safety signals were identified.

**Unger:** That is great news. Let's talk a little bit about MISC or the multisystem inflammatory syndrome in children. Are there any updates on how to prevent this?

**Dr. Fryhofer:** MISC is a nightmare potential complication of COVID infection. It's serious and can be deadly. And, there was some very exciting data presented at ACIP. A study of 12- to 18-year-olds shows a two-dose series of Pfizer vaccine is 91% effective at preventing MISC. In this study, 95% of those hospitalized with MISC had not been vaccinated. 39% of unvaccinated children with MISC required respiratory or cardiovascular life support. None of the vaccinated children did. Now, this data will be published in an upcoming MMWR.

**Unger:** Just more reasons to get vaccinated. What about the CDC's decision memo endorsing an additional dose for immunocompromised children five to 11? What's new there?

**Dr. Fryhofer:** This decision memo was also triggered by a new FDA emergency authorization amendment. We know that vaccine effectiveness is lower among patients with immunocompromising conditions and this is the group for whom the two-dose primary series was not adequate. CDC already recommends an additional mRNA vaccine dose as part of an augmented primary series for those moderately and severely immunocompromised aged 12 and older. So, now, children that are younger, those age five to 11 with immunocompromising conditions, can get a third dose to complete their primary augmented series. This only applies to that same narrow group of moderately and severely immunocompromised patients, as for adults. For example, those who have gone through solid organ transplantation or have an equivalent level of immunocompromise. Children five to 11 who are not immunocompromised do not need a third dose at this time. A booster dose is also not recommended for five- to 11-year-olds at this time.

**Unger:** All right. Well, of course, the big news continues to be about Omicron in all of the headlines. Can you give us an update on just how bad it is?

**Dr. Fryhofer:** It's so contagious. The Omicron surge has magnified the intensity of the pandemic for everyone. The seven-day average daily case count is at a record high of nearly 500,000. Delta's still around but barely. Omicron now represents over 95% of new COVID cases. Again, it's so contagious. We've seen a substantial increase in COVID cases over the last month. Some of the highest incidence rates are in adolescents. There's been a slight increase in hospitalization rates in pediatric groups since the summer but fortunately, overall it's steady. But, that could change. Vaccination matters. There's a marked difference in incident rates in 12- to 17-year-olds by vaccination status. COVID cases are seven times higher and COVID hospitalizations are 11 times higher in unvaccinated adolescents as compared to those who have been vaccinated.

Now, we've been talking a lot about boosters but you can't boost until you get your primary vaccine series and we have to keep encouraging everyone to get vaccinated. The road to protection begins with that first shot.

**Unger:** Yes, it does. And, speaking of vaccinations, where do we stand right now with vaccination coverage in terms of the numbers for adults and adolescents?

**Dr. Fryhofer:** Well, here's the update we heard at ACIP. For adults 18 and older, 73%. That's about three-fourths are fully vaccinated. But, only 38% of them have received a booster. For adolescents aged 16 to 17, 57%. That's about two-thirds are fully vaccinated. But, only 6% have received a booster. There are 16.7 million adolescents aged 12 to 15 in the U.S. Only about half of them, 8.6 million, have been fully vaccinated. With this new age-expanded booster recommendation for everyone 12 and older, about five million children aged 12 to 15 are now eligible for a booster.

We are so fortunate that vaccine supply is not an issue. There's plenty of vaccine and Pfizer's new gray top formulation for those 12 and older should make vaccination administration a lot easier.

**Unger:** So, gray top formulation. What...? What is that and what makes it so special?

**Dr. Fryhofer:** Well, it's more user-friendly. Pfizer's gray top formulation for those 12 and older was just released on December 23, just in time for the holidays, and it has several advantages over the original purple top version, which is also for those age 12 and older. The gray top contains six doses per vial but no dilution is necessary. It can be stored in a regular refrigerator for up to 10 weeks, which is more than twice as long as the purple top version. It can be kept at room temperature for up to 12 hours prior to first puncture, including thaw time, and once punctured, you have twice as long to use it, 12 hours as compared to six hours after puncture for the purple top version.

So, no big surprise. The purple top version will soon be phased out. I sort of like the color purple. The orange top version is still the one for kids aged five through 11. Remember, they get the 10 microgram kiddie dose rather than the 30 microgram adult dose and they're still working on a vaccine version for toddlers. We should expect some new data about a baby dose, three shot series, in late March, early April.

**Unger:** Well, that's good news about that gray top formulation. I know there have been some practical implications there of the other version. Earlier in our conversation, you mentioned decision memos from the CDC director. Talk about these. Are these new? What are they?

**Dr. Fryhofer:** Well, I think they are new. This is the first time I've seen them mentioned at ACIP and I've been an ACIP liaison for about 20 years. I anticipate we'll probably be seeing more of them. As CDC's Dr. Amanda Cohn explained at the meeting, COVID has not gone away. We're now going into year three of the pandemic. ACIP usually meets three times a year and those meetings are scheduled well in advance so participants have time to reserve and plan for them on their schedules. ACIP met 24 days last year in 2021.

**Unger:** Wow.

**Dr. Fryhofer:** Not including the many, many hours of work group meetings. And, there have been so many emergency ACIP meetings called at the last minute. So, looking forward, CDC's trying to

determine the best way for ACIP to continue its independent oversight. There's so much happening in this space in real time, including modifications of FDA emergency use authorization and biologics license applications that require prompt attention. These will require policy changes that must happen quickly. The new plan is for the CDC director to approve such changes based on CDC's subject matter expert opinions. CDC and ACIP are hoping for a more feasible, sustainable approach to meetings and we'll have to see how that goes. We have to make sure that transparency remains intact to ensure public trust and confidence in the process.

**Unger:** Well, Dr. Fryhofer, there's been so much news and the emergence of Omicron has really scrambled everything here. Do you have any final thoughts to sum up where things stand now or additional information for folks?

**Dr. Fryhofer:** Well, during the discussion at ACIP, many expressed great concern about the psychosocial impact of COVID on children during the pandemic. Children are being affected in large numbers, both physically and emotionally. Children have been through so much. They've been isolated socially. This can trigger depression and anxiety. COVID has affected kids in college. They can't be around their friends. They can't go to school if they test positive. Some parents can't go to work due to child care challenges. Booster doses may help decrease transmission and could help us get through Omicron and help kids and keep kids in school and keep our country going.

Boosters may not totally eliminate transmission but hopefully they'll help. We also need to enhance our protection by wearing masks. One liaison member said that this meeting was an example of real world, real time, real tough decision making. ACIP's message was clear, concise and strong. Everyone who's eligible needs to get vaccinated and everyone 12 and older who's completed their primary series needs a booster.

**Unger:** Real world, real time, real tough. I think that about sums up everything that we've been through and the just continuing developments that we need to stay abreast. Dr. Fryhofer, thanks so much for joining us today. That wraps up today's COVID-19 Update video and podcast. We'll be back soon with another segment. For updated resources on COVID-19, visit [ama-assn.org/COVID-19](https://ama-assn.org/COVID-19). Thanks for joining us. Stay well.

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