The latest from the FDA on second booster shots and more with Susan R. Bailey, MD

Watch the AMA's COVID-19 Update, with insights from AMA leaders and experts about the pandemic.

Featured topic and speakers

In today's COVID-19 Update, AMA Chief Experience Officer Todd Unger chats with AMA's immediate past president, Susan Bailey, MD, about big takeaways from her recent conversation with Peter Marks, MD, PhD, director of the Center for Biologics Evaluation and Research at the FDA. Their talk covered COVID-19 second dose boosters and pediatric vaccines.

Learn more at the AMA COVID-19 resource center.

Speaker

- Susan R. Bailey, MD, immediate past president, AMA

Transcript

Unger: Hello, this is the American Medical Association's COVID-19 Update. Today I'm joined by the AMA's immediate past president, Dr. Susan Bailey, an allergist and immunologist in Fort Worth, Texas, who'll be talking about what she learned in a recent conversation with Dr. Peter Marks, director of the FDA Center for Biologics Evaluation and Research, which largely focused on the first and second boosters and pediatric vaccines. I'm Todd Unger, AMA's chief experience officer in Chicago. Dr. Bailey, you opened this important conversation with some surprising statistics. While two-thirds of eligible Americans are vaccinated, only about 30% of eligible Americans have received a first booster dose, or in most cases, a third shot. What are you hearing from your own patients about that first booster dose? And did Dr. Marks explain why that is so important?

Dr. Bailey: It was a great webinar and the booster issue, I'm hearing from my patients a lot. I am continually surprised that patients that were very anxious to get their first and second shots haven't

thought much about the booster. So I think we can really do a better job encouraging our patients to get that booster shot. And I think some of the confusion is that people don't really understand who's eligible for that third shot. Dr. Marks shared that the booster dose is currently recommended for everyone 12 and over, and will likely be recommended for the five to an 11 age group at some point, too, but that's not official yet.

And the reason that this is so important is that there is good data now from overseas, as well as here in the United States, that third shot really ups the anti. It really increases your level of protection against severe disease, hospitalization and death with the new variants. Of course, the original studies were done on variants that are no longer around and these new variants are more contagious. And the higher your antibody levels are, the more likely you are to be protected. And we need to let our patients know this. We need to help them understand that well, those first two shots were great but that was last year. This is this year and we need to keep going.

Unger: And as we learned from Andrea Garcia in our interview, a couple days ago, particularly important because the numbers, they're going up across the country. So this is a good timing to get that reminder. When you think about kind of roadblocks, obstacles that you're hearing from your patients, are you hearing about potential risks around things like myocarditis that might be affecting decisions, especially around children?

Dr. Bailey: Myocarditis is the one concern that I hear brought up most often now, especially when it pertains to children, adolescents and young adults. And so I explain to folks that the data is showing that the prevalence of myocarditis is highest in adolescents and young adults, mostly in men, but not exclusively. And really it's pretty rare but it's real. But the cases of myocarditis have been mild, have been treatable. And the bottom line is, is that the risk of getting myocarditis and other cardiac problems, clotting problems, strokes, et cetera, if you get COVID is much, much greater than the very small risk of getting myocarditis from the vaccine. The good news is, is that the younger children don't seem to be getting myocarditis like the adolescents are. So they're still obviously collecting the data for the six months to five-year-old age group but the five to 11 group seems to be pretty well protected and tolerates these injections amazingly well.

Unger: That's good news. The conversation then turn to this question around the second booster. Fourth shot if you've received an mRNA vaccine. I think a lot of people are confused about whether to get this or not and if they're eligible, when to get it? What evidence did the FDA use to determine its second booster recommendation?

Dr. Bailey: The most robust data that we have now is from Israel, and the CDC and the FDA have used the Israeli data, looking at three shots versus four shots. And they're finding that the differences were pretty notable. They looked at adults 60 and older and who we know are at risk for severe disease, hospitalization and death. And so since about a third of all adults over the age of 50 have at least one risk factor for severe COVID, the agency has lowered the eligibility age for the fourth

booster, even in healthy individuals to the age of 50. We're not using that 60, 65 cutoff anymore. And again, it's most important to get those first three shots in. If you have any question about whether you should get the fourth shot, ask your doctor, continue that ongoing conversation that hopefully you've been having with your doctor about this over the last year or two. But that fourth booster for over 50 can make a big difference.

Unger: What did Dr. Marks have to say about the timing of that fourth shot? I know some people in the eligible age group are tempted to wait until the fall when we might have another surge or even a different shot that might target new variants. What do you think about timing?

Dr. Bailey: I'm hearing patients ask me, "Well, I'm going to wait to get my fourth booster until fall because cases tend to go up in the wintertime." So I asked that specifically to Dr. Marks during the webinar and he said, if you're eligible for a fourth shot now, don't wait. We never know what new variants are going to pop up. We are going to probably need to push real hard for boosters in the fall but there's no reason to wait on them. And so basically if you've recently had COVID, it's reasonable to wait. Unfortunately, many have gotten breakthrough infections. Fortunately, the overwhelming majority of those infections have been mild but you probably are going to have some natural immunity for about three months or so after a natural infection.

And in terms of boosters for new variants, they're looking at that but at this stage of the game, they don't have anything definitely outlined. And if there is one, it's probably not going to be available till October anyway. So the bottom line was if you're eligible, go ahead and get that booster now.

Unger: All right. That is very clear advice. The other topic that you discussed was where we are on a vaccine for kids under five. Did Dr. Marks have any sort of timeframe or explanation on why it's taking so long?

Dr. Bailey: Yes. Really the topic of pediatric COVID vaccines has been the one issue that I think I've heard the most about from my colleagues and from families. And there's a real split. There are a number of families who are incredibly ready and anxious to get their under fives immunized. And then there are many that are not convinced that the risk of the vaccine isn't greater than the risk of getting COVID.

Dr. Marks in his presentation reviewed the overall safety data, the efficacy data, but the data for the youngest age groups has been complicated by the emergence of new variants during the studies. And so that's kind of made things challenging for them. There are also concerns about exactly what dose do you give? How long should you wait between the doses, the follow up? And of course, always looking at the benefit, risk considerations. For example, pediatricians and parents are concerned when young children develop high fevers very suddenly because they can be at risk for febrile seizures and that's not seen in the adult population. So they're really, really careful with that. So they're looking at the pediatric data with a stronger microscope, if you will, to make sure that they're really doing the right

thing when these things get approved.

Right now, they're thinking late June for approval but I pushed him on that and said, "Listen, is there any way that we can get this sooner? Please hurry. There are people that are really desperate out there." And he said that if they do get finished analyzing the data soon, they might have an advisory committee meeting before that.

Unger: Any other kind of key takeaways from your conversation you want to share with physicians right now?

Dr. Bailey: I just think it's important for us to step back and remember that we've lost a million Americans to COVID-19. We've also given hundreds of millions of vaccines to COVID-19. The data that we have now generated for this vaccine is probably greater than any vaccine in history, in terms of safety and efficacy. We've got lots of good information to fight disinformation and misinformation with. And so I urge all of my colleagues to continue to be very proactive about having those vaccine conversations with their patients. This isn't over. We still have a lot of work to do but there might be good news in the future in terms of being able to combine this with the flu vaccine or things like that in the future. Patients and doctors just need to keep talking about this as time goes on.

Unger: Well, Dr. Bailey, I just want to say thank you to you and to Dr. Marks. The series of conversations that you've had throughout the pandemic, they've been incredibly valuable and they have so much information for physicians. There's a lot more in this last conversation that you had with Dr. Marks that we obviously haven't had a chance to discuss here. If you want to view the webinar in full, make sure to visit the AMA's YouTube channel, where you can see the complete webinar. That's it for today's COVID-19 Update. We'll be back soon with another segment. For resources on COVID-19, visit ama-assn.org/COVID-19. Dr. Bailey, thanks for being here. Thanks to everyone out there for watching. Stay safe, be well.
