Sandra Fryhofer, MD, shares what physicians need to know about boosters

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In today's COVID-19 Update, a discussion about boosters with Sandra Fryhofer, MD, AMA's liaison to the Advisory Committee on Immunization Practices. Learn what physicians need to know about the latest Pfizer booster authorization, including who is eligible, why boosters are needed and what this means for our larger efforts to fight the pandemic.

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Speaker

- Sandra Fryhofer, MD, chair-elect, AMA Board of Trustees; AMA's liaison to the 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 what physicians need to know about the latest Pfizer booster authorization, who's eligible, why boosters are needed and what this means for larger efforts to fight the pandemic. I'm joined today by Dr. Sandra Fryhofer, AMA's liaison to the Advisory Committee on Immunization Practices, or 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, the Pfizer booster authorization seems to travel to a somewhat unusual and somewhat confusing course. So we hope that you can clarify things for us today. Can you start by explaining kind of the chain of events that lead up to ACIP’s initial recommendation?
Dr. Fryhofer: Well, let me first begin with the CDC’s final and official recommendation, and then I'll explain how we got there. In a nutshell, Pfizer boosters only apply to certain adults at least six months after receiving a two-dose Pfizer series. And you must be 65 or have health issues or have high exposure jobs or conditions to qualify.

The journey however, started a month ago with the Biden's administration’s promise of boosters for everyone beginning the week of September 20. I realized it was just an oversight not to acknowledge the role of FDA and ACIP in this process when it was announced but it did ruffle some feathers. VRBPAC, FDA's Independent Advisory Committee met on September 17 to discuss Pfizer's request for full approval of a third dose booster for everyone 16 and older. This request was soundly defeated, unanimously. The elephant in the room is risk of myocarditis after mRNA vaccines, with the highest risk being in young males. Many on the expert panel says, "We need more long-term data about safety, particularly if we're going to be giving this to young people."

The next VRBPAC vote boosters for those 65 and older, and for those at high risk of severe COVID received unanimous approval. And then formal poll also supported booster doses for health care workers and others at high risk for occupational exposure, including teachers. ACIP then used its evidence to recommendations framework, to systematically evaluate and weigh available evidence on the benefits of a booster versus the risk and made its initial recommendations.

Unger: So Dr. Fryhofer, what were the specifics of ACIP's initial recommendation?

Dr. Fryhofer: There were several votes and I'll take them one by one. ACIP voted unanimously in favor of a Pfizer booster for adults 65 and older, as well as for residents of any age in long-term care facilities. ACIP gave another thumbs up for booster doses for those 50 to 64 with underlying medical conditions, as well as for boosters for 18- to 49-year -olds with underlying medical conditions, based on individual benefit and risk.

They voted, no, for giving boosters to those 18 to 64 in occupations or institutional settings where the burden of COVID infection and risk of transmission are high. Now understand, this was a no vote for boosters for health care personnel and teachers. And I must admit, this does not sit well with me.

Unger: Boy, one thing you could take away is, there is a lot of attention on this data. And once that recommendation was made, then it goes to the CDC director for sign-off. But from what I understand, this typically it's a formality but it didn't happen this way, this time around. Can you talk about what happened?

Dr. Fryhofer: Well, the CDC director has to sign off on all ACIP recommendations. That's standard procedure. And as you said, this is usually a formality but it doesn't have to be. Later that evening, CDC director, Dr. Rochelle, Walensky, essentially overruled ACIP's refusal to allow boosters for those

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at occupational risk. This is within her purview as CDC director. She aligned CDC's final policy more closely with FDA's emergency use authorization. She explained that making booster shots available to health care workers, teachers and others who risk contracting disease on the job would best serve the nation's public health needs. And I agree. In my opinion, she showed great leadership in making this decision.

**Unger:** Well then ... So despite the kind of back and forth and very deep and detailed look at all of this data, we now have a direction. Can you take us through the details about who is eligible to receive a third shot right now?

**Dr. Fryhofer:** Well, this third shot booster only applies to those who've already received a two-dose primary series from a Pfizer vaccine. There are shoulds and there are mays. Let's review who should get a booster first.

CDC says, "Those 65 and older and people 18 and older in long-term care settings and people 50 to 64 with underlying medical conditions should receive a Pfizer booster, at least six months after completing a Pfizer two-dose primary series." Now for the mays. And these are the more permissive recommendations. And this is where individual risk benefit analysis kicks in. CDC also says, "People 18 to 49 with underlying medical conditions and people 18 to 64 at increased risk for COVID exposure and transmission because of occupational or institutional setting may also receive a Pfizer booster shot." To repeat, these recommendations only apply to people who previously received a Pfizer two-dose primary series. The time interval for getting the booster, it's at least six months after completing the primary series. So, no mixing and matching of vaccines.

**Unger:** Do you need any kind of a proof, in order to get a booster shot?

**Dr. Fryhofer:** No. It's the honor system. You don't need a prescription. You don't need a doctor's note. People just need to self-request. But I always encourage patients to discuss the benefits and risks with their physician, especially for those that are in the permissive categories.

**Unger:** ACIP's recommendations did take a somewhat narrower view of subgroups eligible for the boosters, than the FDA's authorization. How does the FDA's decision plan in this?
Dr. Fryhofer: Well, the ACIP vote on boosters for occupational risk was very close. It was far from unanimous and it was contrary to FDA's advisory group recommendation. CDC's final and official decision as per the CDC director, is more aligned with FDA's emergency use authorization for the booster. In its news release about the EUA for the Pfizer booster, FDA said this would allow booster doses for health care workers, teachers, daycare staff, grocery workers and those in homeless shelters and prisons who were six months out from a two-dose Pfizer primary series. This decision in essence, addresses not only waning immunity, but also the increased risk of infection for those at high risk of exposure.

Unger: Dr. Fryhofer, obviously there're a lot of pieces of data supporting the decision to authorize boosters. Can you take us through some of the key data?

Dr. Fryhofer: First off, we have three safe and highly effective COVID vaccines. COVID vaccines continue to maintain high protection against severe disease, hospitalization and death. However, a CDC study published in MMWR the same day as FDA's advisory committee meeting shows Pfizer's vaccine effectiveness declined significantly from 91% down to 77%, and more than four months after the second vaccine dose. To me, this is sort of a wake-up call.

Pfizer data presented showed waning immunity with time at six to eight months after the second vaccine dose, based on neutralization titers. They use data from a Kaiser Permanente study to show waning immune effectiveness was not due to the Delta variant escaping vaccine protection. Data from Israel's third dose booster program with boosters given at least five months after the second dose, showed more than 10 fold, improved protection against confirmed infection and severe COVID.

Israel's data on those 60 and older has been published in the New England Journal of Medicine. At the ACIP meeting, safety and vaccine effectiveness data from many, many sources was reviewed. There were no new safety surprises. Vaccine safety surveillance will continue.

There were significant declines in VE, vaccine effectiveness, against infection in individuals 65 and older for mRNA vaccines in the Delta period. There was smaller declines in VE against hospitalization in individuals 65 and older but the declines in older patients were more substantial than in younger populations. Among younger adults, those under 65 vaccines remain effective in preventing hospitalization and severe disease. But vaccines may be less effective in preventing infection or symptomatic illness, due to waning immunity over time and the Delta variant.

Unger: So it's interesting. I mean, I think people are not used to just this continuing amount of data coming in, as we learn our way through this pandemic. You mentioned the things that you have seen and we're supporting this. Is there any data that's lacking? What don't we know right now?

Dr. Fryhofer: There's a whole lot we don't know and the data keeps rolling in. We still don't have a
correlate of protection, when it comes to antibody levels. We still don't know about mixing and matching different vaccine platforms and brands. FDA has authorized the Pfizer booster under EUA, Emergency Use Authorization. The booster recommendation only applies to Pfizer and only for those who received an initial Pfizer two-dose primary series. We still don't have booster guidance from Moderna or Janssen.

These are interim ACIP recommendations. Safety surveillance is still ongoing. These authorizations can be revoked at any time, so they're not set in stone. Recommendations could change and likely will change in the future, based on new evidence.

Unger: Let me just ask you to clarify one thing in what you just talked about. Obviously, for people who received the Janssen or the Moderna vaccine, can they get a booster now?

Dr. Fryhofer: Well for Moderna, the only way you can get a booster right now, is if you're immunocompromised. So you can't get a Moderna booster, unless you are immunocompromised or you should not. On August 12, FDA authorized an additional COVID vaccine dose for certain immunocompromised people. And for immunocompromised persons, ACIP recommends an additional dose of either Pfizer for those 12 and older or Moderna for those 18 and older, following our primary mRNA vaccine series. You get that additional dose at least one month after the primary series. And you need to try to get the same type of additional dose as the original series, if you can. There are still no recommendations for additional doses or for boosters for those who received Janssen’s single dose viral vector vaccine.

Unger: Do you have any sense of timing on boosters for Moderna and J&J?

Dr. Fryhofer: Well again, this booster recommendation we talked about today, only applies to Pfizer, for those who received a Pfizer primary series. This does not apply to those who received two doses of Moderna or one dose of Janssen. Moderna's booster data has been submitted to FDA. Janssen's one dose may soon become two. News headlines from the company, say, "A two-dose version with shots given two months apart is 94% effective." That's their company news release. We don't have publication of that data yet. Janssen has not yet submitted this data to FDA.

Unger: So obviously, the Delta variant continues to kind of wreak havoc here in the states. How to boosters help with our larger efforts in fighting the Delta variant and eventually turning the corner on this pandemic?
Dr. Fryhofer: This debate boiled down to whether booster should be given, even though the vaccines are still offering high protection against severe disease, possibly in the hopes of blocking milder breakthrough infections among those fully vaccinated. And as Dr. Walensky said, "Making booster shots available to health care personnel, teachers and others who risk contracting disease on the job would best serve the nation's public health needs."

Frontline workers, including health care personnel and teachers, and others now have access to Pfizer boosters to strengthen their protection against COVID infection. We need to keep these frontline workers protected well and able to work. Our teachers need to be able to teach our health care workforce needs to stay well so they can care for our patients. But most of all, we still need to get everyone vaccinated.

Unger: Absolutely. And on that note, any final thoughts regarding kind of where we are and where we're headed?

Dr. Fryhofer: Well, the definition of being fully vaccinated has not changed. For public health purposes, it's still two weeks after two mRNA vaccine doses or after a single Janssen dose. But even with all this talk about boosters, the top priority is still, we need to vaccinate those not vaccinated. And as of September 14, only 63.1% of those eligible have been fully vaccinated. So, we still have much work to do.

Unger: We absolutely do well. Dr. Fryhofer, Thank you so much for bringing some clarity. Maybe folks out there should just tune in to our COVID-19 Update to get the scoop here. I appreciate you giving us the details and your perspective. That's it for today's COVID-19 Update video and podcast. We'll be back with another segment soon. Thanks again, Dr. Fryhofer. In the meantime, for resources on COVID-19, visit ama-assn.org/COVID-19. Take care.

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