

FDA authorizes Novavax vaccine for kids ages 12-17 with Andrea Garcia, JD, MPH

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Featured topic and speakers

In today's COVID-19 Update, AMA Director of Science, Medicine and Public Health Andrea Garcia, JD, MPH, shares news on the Novavax vaccine from the FDA—as well as updates on COVID boosters for fall, monkeypox vaccines, TPOXX treatments, and Dr. Anthony Fauci's announcement on stepping down from the National Institute of Allergy and Infectious Diseases (NIAID). AMA Chief Experience Officer Todd Unger hosts.

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Speaker

- Andrea Garcia, JD, MPH, director of science, medicine & public health, American Medical Association

Transcript

Unger: Hello, this is the American Medical Association's COVID-19 Update video and podcast. Today we have our weekly look at the numbers, trends and latest news about COVID-19 with the AMA's Director of Science, Medicine and Public Health, Andrea Garcia in Chicago.

I'm Todd Unger, AMA's chief experience officer also in Chicago. Andrea, nationwide, we've seen COVID-19 case numbers decreasing, thankfully, over the past few weeks. Are we continuing? Can we call it a trend?

Garcia: Yeah, I think that we can at this point. The downward trend continues. Reported daily cases have fallen to below 100,000 per day nationally. And according to *The New York Times*, there are about 95,000 reported cases, which is about 19% lower than two weeks ago. And the good news is we're seeing this declining cases in almost every state.

Unger: Are we seeing hospitalizations, deaths still on the rise as kind of lagging indicators or not?

Garcia: Well, there's actually good news on both of those fronts. As the number of hospitalized patients with COVID is continuing to decline, we're around 40,000 patients hospitalized, which is down more than 6% nationally over the past two weeks.

With that being said, some states haven't turned the corner yet. About half of states are still seeing either increasing or flat hospitalization numbers. The number of deaths have also started to reverse course. If you're looking at the numbers nationally, fewer than 500 COVID deaths are being reported each day.

The daily average is around 460 deaths per day. And of course, that's still more than we would like to see. But it represents a 7% decrease over the past two weeks. So it's good to see those numbers starting to come down.

Unger: Indeed. Are we getting updates on the vaccine front, specifically Novavax vaccine? Tell us more about what we heard.

Garcia: Now, the FDA authorized the Novavax COVID-19 vaccine late last week for emergency use in adolescents between the ages of 12 and 17. The vaccine is authorized as a two-dose primary series. And then we saw the CDC director sign a decision memo on Monday allowing the Novavax COVID vaccine to be used as a primary series option in this adolescent population.

As we noted previously, the Novavax vaccine was authorized for emergency use by the FDA and recommended by the CDC for use in adult 18 of age—age 18 and over. And that happened back in July. Again, with another vaccine option available for children and one that is based on more traditional protein-based technology, the hope is that vaccination rates will increase, especially as we head into that back-to-school season.

The other news around Novavax is they're working on an updated version of their vaccine that specifically targets the Omicron variant and its variants. And the company could request authorization of that vaccine later this year.

Unger: What's the data behind the decision to expand age group there?

Garcia: Well, remember that the standard for an EUA is that the known and potential benefits of the vaccine outweigh the known and potential risks. So if you look at the trial, it showed that the vaccine had nearly 80% efficacy overall at the time. The Delta variant was the predominant one circulating in the U.S.

And then if we look at the safety data from the pediatric trial, it showed the vaccine to be generally well-tolerated. Serious and severe adverse reactions were low. And most reactions were mild to moderate in severity and only lasted two days.

Unger: Well, looking at fall, which is right around the corner, what do we see in terms of fall booster shots?

Garcia: Well, White House COVID Coordinator Dr. Ashish Jha said last week that the newly updated COVID boosters will be available to teens and adults in a few short weeks. And he indicated that he believes every American over the age of 12 will be eligible for it.

Dr. Jha's timeline is really the most specific estimate that we've heard to date. Of course, we've in previous months heard of health officials throw out dates between September or October. That booster dose, of course, will have to up, undergo review by the FDA and the CDC.

This week, Pfizer did ask FDA to authorize its Omicron COVID booster. I think it's worth noting here that the company's indicated in a press release that a clinical study investigating the safety, tolerability and immunogenicity of the vaccine is expected to start this month.

So that means that data is not going to be available for the FDA to consider that this new booster does target the Omicron's variants BA.4 and BA.5, as well as the original strain of the virus.

Unger: That's good news. And with the potential for the new vaccine boosters becoming available next month, should patients who are eligible wait for the new booster shots? Or should they get one now?

Garcia: I think even though we're anticipating the new boosters will be available for those 12 and older, I think we need to consider that they may roll out first to groups that are higher risk of severe outcomes from COVID such as older populations or immunocompromised people before they're made available to others.

According to Dr. Jha, if you're eligible for a second booster dose but haven't received it yet, his advice is get it now rather than holding off in anticipation of an updated booster. He said that his general feeling is that there's no reason to wait. Go get it. Even if we're only a few weeks away, he said that

people who get boosted now will still be able to get the BA.5 shot in a few months when their immunity from the booster wanes.

Unger: Well, turning our attention from COVID to monkeypox and the vaccine front, there is also news from the administration on the shortage on the vaccines. What's the update there?

Garcia: So the Biden administration announced last week that they would accelerate access to the vaccines and treatments for monkeypox. They made 1.8 million additional doses of the two-dose JYNNEOS vaccine available to states and local governments for ordering starting this week. Those doses are being made available ahead of schedule. And that's to encourage rapid distribution of the vaccine to individuals who are at high risk.

Jurisdictions that are adopting the intradermal administration of the vaccine and who have used 90% of their current supply of the vaccine are eligible to order those additional doses. And just as a reminder, FDA issued an EUA allowing that intradermal injection of the JYNNEOS vaccine using one-fifth of a dose.

Unger: And there was also news of a targeted vaccine program. What do we need to on that front?

Garcia: The Biden administration officials announced the vaccination program targeted to people attending large LGBTQ events saying that they are going to set aside about 50,000 vaccine doses in a pilot initiative to cover high-risk individuals who are attending those events.

The administration also said they're going to make 50,000 courses of TPOXX which is the antiviral being used to treat the disease more readily available to clinicians and patients this week. This allocation of TPOXX is in addition to the over 20,000 courses that we know have already been deployed to jurisdictions from the Strategic National Stockpile.

Unger: Well, that's good news because the monkeypox case numbers continue to go up. What are we seeing on that front?

Garcia: Yeah, those case numbers continue to surge. And according to the CDC, we're now at over 15,000 confirmed cases of monkeypox nationwide. We know that every state now has reported at least one case after Wyoming became the last state to confirm a case. And that's about double the number of cases in the last two weeks. California, Florida, Georgia, Illinois and New York, as well as Texas, are among the states with the highest number of cases.

Unger: And final news. A big announcement this week from someone who's played an incredibly important role in the COVID pandemic and other pandemics. That's Dr. Anthony Fauci. What would the AMA like us to hear on that front?

Garcia: Well, he obviously made news this week when he announced he'd be stepping down in December as President Biden's top medical advisor and as the director of the National Institute of Allergy and Infectious Diseases. That's a position he's held for many years. And according to The New York Times, this wasn't entirely unexpected.

He's been hinting at this for some time. And it was almost certain he would retire before 2025. The AMA issued a statement in response to this news and recognized him as a strong and steady voice for science and data-driven responses to some of the biggest health challenges of our time, including the HIV/AIDS crisis, Ebola, Zika, and of course, the nearly three years of the COVID-19 global pandemic.

As the statement reads during that time, Dr. Fauci has not only provided sage advice and counsel to presidents of both parties but he's smartly leveraged modern media to deliver clear, direct guidance and information to the American people. And he'll also likely be remembered for his simple human actions, like hugging a Dallas nurse who survived Ebola to destigmatize the disease. And he certainly had a remarkable career. And we wish him well in his next chapter.

Unger: Absolutely remarkable career. If there's anybody that deserves some good old fashioned R&R, I have to say it's Dr. Fauci. Andrea, thanks so much for being here today with us. 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 being with us here today and take care.

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