Andrea Garcia, JD, MPH, discusses vaccine authorization for 5-11-year-olds

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Featured topic and speakers

In today's COVID-19 Update, a discussion with AMA's Director of Science, Medicine & Public Health, Andrea Garcia, JD, MPH, on COVID-19 vaccine numbers and trending topics related to the pandemic over the past week. Also covering booster news and current vaccine timeline for the 5 to 11-year-old age group.

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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 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, this week's news, all about boosters and potential vaccine authorizations for children. Yesterday, we took a deep dive into boosters with what physicians need to know about them with AMA's ACIP liaison, Dr. Sandra Fryhofer.

And so today, I'd like to begin with vaccines for children. Let's talk about timing and questions onmany parents' minds, how soon can we expect an authorization for a vaccine for the five to 11-year-old age group?

Garcia: Thanks for having me back. And yeah, this is definitely on the minds of parents. On Sunday, Dr. Fauci suggested that kids aged five to 11 could begin getting vaccinated in early November. That means children in this age group could be fully immunized by the holidays.

Today, the FDA's advisory committee is meeting to review the data supporting Pfizer's application for emergency use for the vaccine in this age group. That vote will happen later today but obviously hasn't taken place yet.

Once that vote happens, the FDA will consider the recommendations made by their advisory committee. If the FDA rules in favor of an EUA for this age group, we'll go through that same process with CDC and ACIP, determining if they want to recommend use for this population. If that happens, then 28 million children in that age group could be eligible soon for the vaccine.

Unger: And that would be big. And we will touch base again with Dr. Sandra Fryhofer with that next week, if there is an update there.

Let's talk about what we know about effectiveness of the vaccines. First, let's start with Pfizer. What do we know about the effectiveness of the Pfizer vaccine with this age group?

Garcia: So according to the Pfizer-BioNTech study, the children who were vaccinated in their clinical trial, they received doses that were one-third of the size of the adult doses. And they developed a robust immune response after receiving the regimen. The regimen was similar. It's two shots three weeks apart to the adult dose. The difference there really being the dose size. The company said the vaccine in children reduced the risk of developing a symptomatic infection by 91%. Yeah.

And then the FDA also analyzed that data. And on Friday, they made available their analysis. They indicated that the benefits of staving off COVID with the Pfizer vaccine generally outweighed the risks of the most worrisome possible side effects, which we know is myocarditis in that age group.

Unger: Any other side effects of note or pretty standard fare for what we've seen before?

Garcia: So if we look at the data from the clinical trial, the most common side effects in children were fatigue, headache, muscle pain and chills. So all of those things that we experienced in older populations. According to the FDA, the data that was submitted by Pfizer on the clinical trial indicated there were no cases of myocarditis in that group, which is inflammation of the heart muscle. And there were no cases of pericarditis, which is inflammation of the outer lining of the heart. Both are rare

complications that we've seen in young boys and men receiving the vaccine.

Unger: That's good news. At this point, we are also hearing new findings for Moderna's vaccine with this age group. What is the news there?

Garcia: So on Monday, Moderna announced that its COVID-19 vaccine is safe. It produces a powerful immune response in children age six through 11. One month after the immunization was complete, the children in Moderna's trial had antibody levels that were 1.5 times higher than those seen in young adults.

They did not release the full data and the data is not published in a peer review journal. We do know that the company tested two shots of the vaccine 28 days apart in 4,753 children. The dose for the kids was 50 micrograms of the vaccine, so that's half of the size of the adult dose.

We also know that Moderna has submitted study results for the vaccine for using adolescents age 12 through 17 to the FDA. They did that in June but FDA has not yet announced a decision for that age group. So it could be a little while before we see an authorization of this vaccine in even younger age groups.

Unger: So the Biden administration appears to be ready should an authorization for this group come through. Can you share details from the plan that they announced last week?

Garcia: I believe the headlines read, "Small Needles, Short Lines." So the administration is really trying to outline plans to get this vaccine into arms. So on Wednesday, they said they plan to ensure some 25,000 pediatric or primary care offices, thousands of pharmacies and hundreds of school and rural health clinics will be ready to administer the shots if and when, of course, the FDA and the CDC act, so if the vaccine is authorized and recommended for use in this population.

According to the White House, distribution efforts for kids will look different, right? It is not going to look the way it did for adults. They are going to be relying on physician offices, on clinics and on pharmacies instead of on mass vaccination sites. So pediatricians, family physicians are going to be enlisted to help work with parents. We know that jurisdictions through their public health agencies are really working to increase enrollment of primary care physicians to help improve access to the vaccine in this population.

And really, this plan is designed to capture lessons learned from the rollout of the vaccine in older age groups. The vials will be smaller. The needles to administer the doses will be smaller. The packaging configuration is going to be 10 dose vials in cartons of 10 vials each, so 100 doses total. That's more manageable for physician practices. And we know that the vaccine for kids can also be stored for up to 10 weeks at standard refrigeration temperature, so it doesn't require that ultra cold storage. All these things are more friendly to physician offices.

The main goal, obviously, getting vaccines in settings where parents and kids are familiar and to have that trust with the vaccine provider.

Unger: That's really great to see that learning put to use. And I know that's been something the AMA has been a vocal advocate for, is getting the physician more involved. And so good to see that change is being made to facilitate that for this next wave of vaccinations. Speaking of which, where do we stand right now on vaccinations? Are they still inching up slowly?

Garcia: Yes, increasing, but slowly, I think is the way I would characterize it. According to the CDC, 220.5 million Americans have received one dose. That's about 66.4% of the total population. And of those, 190.7 million are fully vaccinated, so 57.4% of the population.

So far, the CDC is estimating that 13.3 million people received a booster dose. I think we're going to expect to see those numbers jump again next week with the new recommendations around J&J and Moderna.

Unger: Absolutely. Where do we stand with cases and hospitalizations right now? We've had three weeks running where we've been talking about a downward trend. Are we seeing that continue?

Garcia: The country is averaging about 75,000 new cases a day. That's fewer than half as many that were, than were reported in early September, but it's still five times more as many than were being identified in June before Delta had been spreading widely.

Death and hospitalizations are also declining. More than 50,000 COVID patients are hospitalized nationwide. And 1,500 deaths are being reported each day.

Cases and just numbers in general have remained persistently high in many of the Western states. So when we look at Alaska, Montana, Wyoming and Idaho, they're really leading the country in cases per capita but only three states Vermont, New Hampshire and Colorado are averaging more cases now than they were two weeks ago.

The good news is, is the situation in the South continues to improve. Florida, which we know they were averaging about 20,000 cases a day during much of August, are now reporting around 2,200

new infections daily. So they are now one of the lowest per capita rates in the nation.

Unger: That is good news. And still high levels here. One question that never really got answered when we were in the worst of the Delta wave was whether or not the variant caused more serious disease or whether it was just more transmissible? We now seem to have some supporting data to answer that question. Can you tell us more about that?

Garcia: Yes. A limited CDC study found no significant change in hospitalization outcomes during the U.S. Delta wave. So on Friday, scientists from the CDC said that, "There is no significant difference in the course of hospitalized patients' illness during the Delta wave compared to earlier in the pandemic."

With that being said, larger and more detailed studies from a number of other countries have found that Delta infections were considerably more likely to be hospitalized in the first place. And that's a trend that the CDC study was unable to assess due to limitations of the data.

The CDC study also showed that the proportion of older hospitalized patients needing intensive care or dying had shown some signs of increasing during the Delta wave.

With all that being said, it was a small sample size, about 7,600 COVID hospitalization. So we really can't draw significant conclusions from that and more research is definitely needed to figure this out.

Unger: Well, just in closing, some messages from the AMA for folks to hear this week, one, about booster recommendations, for instance.

Garcia: Yeah, the AMA released a statement in support of the new booster recommendations. It read that, "We believe the FDA's authorization and the CDC's recommendations in support of booster doses, including the flexibility to mix and match products, will help provide continued protection against COVID-19 for those who need it most. The balance and benefit of risks for booster doses varies. And we encourage those who have questions to reach out to their physician or a vaccine provider. Of course, the number one priority remains getting those who are unvaccinated vaccinated, so we continue to urge those who've not yet been vaccinated and who are eligible, including pregnant people, to get vaccinated as soon as possible. And if you have questions, talk to your physician and review trusted resources, including getvaccineanswers.org."

Unger: All right. And again, that website getvaccineanswers.org. Andrea, thanks so much for being with us here today and sharing your perspective.

That's it for today's COVID-19 Update. We'll be back soon with another COVID-19 Update video and podcast. In the meantime, for updated resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us. Please take care.
