Andrea Garcia, JD, MPH, discusses vaccines for children 5 and younger

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Featured topic and speakers

In today’s COVID-19 Update, AMA Chief Experience Officer Todd Unger reviews rising COVID-19 case numbers and trending topics related to the pandemic over the past week with AMA Director of Science, Medicine and Public Health Andrea Garcia, JD, MPH. Also covering the FDA’s pivot to wait for more data on vaccines for kids under 5 and what new data from the CDC tells us about booster shots.

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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, thanks for joining us. The big news last week was a pivot by the FDA on the subject of vaccines for kids under five. Tell us more about that and what it means for this last segment of Americans waiting to be vaccinated.

Garcia: Well, thanks for having me back, Todd, and yeah, last week we talked about how Pfizer had submitted an application to the FDA to authorize their two-dose vaccine in children younger than five. And we also mentioned that this was unusual because we know that two-dose series failed to produce that hoped for immune response among that two to four-year-old age group in the clinical
trial. But the hope was to get a head start on vaccinating this group with the hopes that by the time the results from that trial were available that children would be ready for that third dose. That under-five group includes about 18 million children and they are the only segment of the U.S. population, as you mentioned, that is not yet eligible for vaccination. And while we know many of them have serious complications from COVID, many still get very sick and they can spread the virus, of course, to other vulnerable populations. So we do want to make sure that we are able to protect this population.

Unger: So what changed?

Garcia: On Friday, the FDA announced that it would be waiting for the data on the three dose to determine if they were effective in children younger than five before deciding whether or not to authorize that vaccine. In making that decision, they postponed the meeting of their Advisory Committee, which would've been happening right now. They were expected to weigh that evidence and make a recommendation whether to authorize that two-dose vaccine.

Unger: So, I mean, obviously, there was a change midstream and the strategy here you mentioned upfront, the thought was to try to get ahead of this and then the data would catch up. Again, what's behind that change then?

Garcia: So, in the news, we're seeing Pfizer ask for the delay because they discovered that the Omicron wave had led to a far higher rate of infection than the company had previously recorded among children volunteers in their clinical trial. And that new data showed that the Omicron variant was better than the Delta variant at evading the vaccine's protection. So we know that two doses fell short before. Again, we know they're not effective enough in that age group and as a result of that new data, Pfizer and FDA agreed that they should wait on that data on the third dose before moving forward with authorization. And I think many physicians, many pediatric experts agree that this is the right move.

Unger: I'm sure there are a lot of disappointed parents out there that were really looking forward to that chance to vaccinate those young children. Is there any sense of a new timeline associated with this?

Garcia: So in their news release, Pfizer reported that their three dose trial is moving quickly. Their new timetable would allow them to get results in early April over to FDA. We know FDA and its Advisory Committee will have to review that data, as will CDC and their Advisory Committee on Immunization Practices. So it'll be a few weeks after they get that data at least to get that authorization and recommendation in place.
Unger: Well, speaking of a slightly older age group that was in the five- to 11-year-old range, still a lot of work to do there from what I understand in terms of getting that group vaccinated, where do we stand there?

Garcia: Yeah, the uptake of the vaccine in children, including those five to 11, we know they became eligible in early November for the COVID vaccine and that uptake has been extremely low. Only about a third of the 28 million children in that age group have received at least one dose. And I think according to some of the polling we're seeing like such as from the Kaiser Family Foundation, only three in 10 parents of children younger than five now say that they intend to get their child's vaccination as soon as they're available. So I think experts are seeing the younger the child, the more hesitancy we can expect from parents. So we're going to have a lot of work to do in getting kids vaccinated, even those who have been eligible for some time now.

Unger: The CDC also released some new data on boosters. What's behind that?

Garcia: The new data on boosters looked at how long boosters retained their protection and they found that the effectiveness started to wane at about the four-month mark, which, of course, raises the possibility that some Americans, specifically those at high risk of complication and death, may need a fourth dose. The study was specific to the mRNA vaccines, the Moderna and Pfizer, but it does come with some limitations. The analysis didn't include a breakdown by age and it's really difficult in our vaccine data to distinguish between a booster shot and a third dose given to a person who is immunocompromised as a part of the primary series. The study did focus on people who sought medical care for symptoms of COVID, so it's skewed for older adults and those who have weakened immune systems. So the booster shots may have seemed less effective in the general population than they really are.

Unger: Any other specific things that the data showed?

Garcia: Well, the data was collected from 10 states between August of 2021 and January of 2022. So we know that spans both the Delta and Omicron waves here in the U.S. They looked at emergency department visits, urgent care facility visits and hospitalizations among adults, so this is not looking at mild infections. And what they found was that protection against emergency department and urgent care visits declined 69% within two months of the second dose and that was 37% after five months or more. Good news is that boosters restored those levels to 87%. Bad news, effectiveness of boosters also wanes so that protection against emergency department and urgent care visits dropped to about 66% within four or five months, and then just 31% after five months or more after that third shot. I would just note that we have less data on that population that received that third dose five months or more just because of when those boosters were recommended for our population.

Unger: We'll keep paying attention to that. And also, in the wake of this, the CDC has updated some
of its vaccine guidance as of Friday. We talked in great detail with Dr. Sandra Fryhofer, who is the AMA's Liaison to the ACIP in Monday's episode. But what was the thinking behind these updates and what do physicians need to know at the top level?

**Garcia:** Well, I think the CDC is constantly looking at the data and updating its guidance accordingly to ensure people have optimal protection against both infection, severe illness and death. The CDC said these updates follow that thorough evaluation of the latest safety and effectiveness data and, really, I think these updates mostly impact people who are moderately or severely immunocompromised. So if we think about people who have completed a primary series of a three-dose mRNA vaccine, they're now recommended to receive an mRNA booster dose three months instead of five months after their last primary dose. So that's four doses total. And people who've received a single J&J COVID vaccine should receive one additional dose of an mRNA vaccine, one booster dose, preferably an mRNA. And that's three vaccines total.

**Unger:** So looking at the big picture at this point, look at the news out there about, have we moved past this Omicron surge? We're seeing a lot of states start to drop their indoor mask mandates. I think as of the end of this month here in Chicago that will be the case. And in some cases, vaccine mandates too. So, are we drawing to some conclusion about where we are in this surge?

**Garcia:** Well, we're definitely seeing states move in that direction. Washington, D.C., is the latest to do so. They announced on Monday that people will no longer have to show proof of at least one dose of a COVID vaccine before entering many businesses in the city. On March 1, they'll end their indoor mask mandate for certain locations, so bars, gym, places of worship, restaurants and stores. But masks are still going to be required there in schools, libraries, childcare centers, emergency shelters and public transit. We're seeing this loosening of public health mitigation measures across many states and that is being positioned as a response to the huge drop cases. I think it's important to note, and we're hearing the CDC say, that most of the country is still experiencing high transmission and they're still recommending masks in indoor public settings.

**Unger:** It's interesting, we're a little bit out ahead of this. When you actually look at the numbers in terms of cases, what are we seeing?
Garcia: So, as of last Friday, cases were going down almost everywhere in the country and cases have declined about 75% from their peak in mid-January. We're seeing about 175,000 cases daily. As of Friday, about 100,000 people were hospitalized nationwide. That number has decreased about 30% over the past two weeks. ICUs, also, those numbers have been falling. They're down about 30% as well. Deaths, I think we know they're a lagging indicator. They've leveled off to around 2,400 a day but that decline is only about 6% over the past two weeks and that's still higher than any point of the pandemic except last winter. So we do still have some states, West Virginia, Alabama, Kentucky, where their high numbers of recent hospitalizations per capita in those states align with low vaccination rates well below the national average.

Unger: So still, number one piece of advice, get vaccinated and get boosted. Andrea, thanks so much for taking us through the numbers and all the news on COVID-19 this past week. That's it for today's COVID-19 Update. We'll be back with another segment shortly. In the meantime, for resources on COVID-19 visit ama-assn.org/COVID-19. Thanks for joining us today. Please take care.

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