Preliminary findings on COVID vaccine for kids under 5 with Andrea Garcia, JD, MPH

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**Featured topic and speakers**

In today’s COVID-19 Update, AMA Chief Experience Officer Todd Unger reviews the latest on vaccines for children ages 6 months through 4 years, as well as boosters for 5-11-year-olds with AMA Director of Science, Medicine and Public Health Andrea Garcia, JD, MPH. Also covering CDC’s recommendation on a second booster shot for people 50 or older and the latest on the monkeypox outbreak.

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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 so much for joining us. We got a lot to talk about today. Boosters, vaccines for kids five and under, and of course, monkeypox. Let's start with big news last week that was about boosters for kids. Tell us what's the latest on that.

**Garcia:** Thanks for having me back, Todd, and yes, last Tuesday we saw the FDA authorize a booster dose of the Pfizer BioNTech COVID vaccine for children in that five to 11 age group. And then following the FDA's authorization, the CDC’s Advisory Committee on Immunization Practices
recommended a booster dose for children, age five to 11. And the CDC director endorsed that ACIP recommendation later that same day. So children in this age group are now eligible and should receive a booster dose, if they receive their last dose at least five months ago.

So this is a third dose for most children in this age group and a fourth dose for some children who are immunocompromised. As a reminder, in November, booster doses were officially recommended for adults and in January, they were recommended for children 12 and older. The thinking behind this latest recommendation is to give kids that extra layer of protection at a time when cases and hospitalizations are again rising nationally. And we know that protection from their primary series may of course be waning depending on when they completed that series.

**Unger:** And the AMA weighed in on that with their own statement. What was the AMA stance on this?

**Garcia:** The AMA released a statement applauding the ACIP for their thoughtful deliberations and their recommendations supporting the booster dose for children in this age group. That statement was attributed to AMA President Dr. Gerald Herman, who said that based on what we know from other age groups, vaccine effectiveness against SARS-CoV-2 infections declines over time and vaccine booster doses have been shown to increase that protection against all outcomes.

So with the highly transmissible Omicron variant, continuing to evolve, strengthen neutralizing antibodies from the booster dose provides that additional layer of protection. And of course, that statement went on to remind people that these vaccines are safe and effective and are especially in preventing hospitalizations and severe disease.

**Unger:** Well, let's talk a little bit about the data part of this. What data was the recommendation based on?

**Garcia:** So that booster recommendation was based on data that Pfizer reported in April. And that data found that for children in that five to 11 group, a third dose generated antibodies both against the Omicron variant and against the original version of the virus. And in that trial, children received a 10 microgram booster dose of the vaccine. We know that's one third of the dose given to adolescents and adults. There were no serious adverse events reported among those trial participants.

The most commonly reported side effects were pain, redness and swelling up the injection site, and aches, chills and fever. I think it's important to note that booster doses are still recommended for children who've had a past infection. As we know, some evidence is suggesting that compared with vaccination protection, following an Omicron upon infection may be weaker and may not last as long.

**Unger:** Well, although the evidence clearly supports that these vaccines are, as you said, safe and effective. We aren't seeing the vaccination numbers we would've hoped for in this age group, even for the primary series, how much are they lagging?
Garcia: Well, it's concerning. Only one-in-three children between the ages of five and 11 have received two doses of the COVID vaccine. And this could be in part because parents believe that kids are at lower risk for severe disease than adults. But if we look at the data that the CDC is shared, Omicron not only sent more children to the hospital in ICU than previous waves but children who were unvaccinated were twice as likely to be hospitalized as those who were vaccinated. So we continue to urge those who are eligible to spate up to date on their COVID vaccinations, including booster doses, obviously, that protects you and it protects your loved ones from severe complications, hospitalization and death. And of course, that includes eligible children.

Unger: Oh, so that is really important to correct misperception out there. And in line with this, the CDC also strengthen its recommendation for second boosters for certain populations. Tell us more.

Garcia: So the CDC is now saying that all people age 50 and older should get a second booster dose if it's at least four months past their first booster. And you may recall that previously the CDC had said that people 50 and older may get that additional shot with the should recommendation previously being reserved for those over 65 or those with underlying medical conditions. So this new guidance was issued by the CDC last Thursday.

It also extends to those who are 12 and older, who are immunocompromised. And we know that while older Americans have the highest coverage of any group of first booster doses, most Americans 50 and older received their last dose of a COVID vaccine more than six months ago. And so the CDC has said, that's leaving many people vulnerable without the protection that they need to prevent severe disease hospitalization, in fact.

Unger: Well, in more Pfizer news, we also received some results from their trial for kids under five. What are the key takeaways there?

Garcia: So many parents have been waiting for this news and on Monday, Pfizer BioNTech reported the preliminary findings of their trial in children younger than five. This data was shared through a news release and the companies announced that a subset of a trial of 1,678 children ages six months through four years, who received that three-dose regimen founded to be 80% effective in preventing infection. So we don't have the supporting data, that was not disclosed.

And the companies did not say how many children were in that subset but a spokeswoman for Pfizer said that the comprehensive results from the trial will be disclosed next month. We expect the company will submit an application for an EUA soon. And following that news on Monday, the FDA announced that VRBPAC, its advisory committee, would be considering both Pfizer's application and Moderna's application for this youngest population on June 15.

Unger: That's good news because I know that a lot of parents out there are anxiously awaiting that EUA. Because if you have mentioned before, cases and hospitalizations are still rising. Let's go into
the numbers.

**Garcia:** According to the New York Times state of the virus this week, the U.S is currently averaging more than a hundred thousand reported cases of COVID per day. That's the first time since February that we've seen cases at this level. Cases are up 46% over the past two weeks. We talked about last week that cases are rising in nearly every state at this point. And we also know that this continues to represent an undercount with many at-home tests going on reported.

Last Wednesday, the CDC warns that one-third of the U.S population now lives in an area with medium to high levels of virus transmission. That was up from one-fourth of the population falling into these risk zones the week before. And then even by Friday, that number had jumped up again with Dr. Walensky, the CDC Director, saying that now more than 45% of Americans live in areas where transmission rates are high enough that people should consider wearing a mask in indoor public settings.

**Unger:** Now we've seen cases up, where are we tracking with hospitalizations?

**Garcia:** Hospitalizations are increasing as well. And that's true in all but five states and territories. Though, the number of patients hospitalized nationwide remains below the peak levels. It has increased by 31% in recent weeks were averaging about 23,800 hospitalizations per day. At a White House briefing last Wednesday, health officials attributed the increases to three main factors that's new and more infectious Omicron sub-variants, waning immunity from vaccines and previous infections, and of course, fewer people are wearing masks.

We know that there are now at least four Omicron sub-variant circulating in the U.S. B.A.2.12.1 is now the dominant Omicron sub-variant. It represents 57.9% of cases. And B.A.2, which was dominant last week has now dropped to about 39.1% of cases. And these new strains appear to be even more infectious than the previous ones. And of course, that is adding to the increase in cases.

**Unger:** Absolutely. It seems like we've heard a lot of this before, maybe with different variants and with slightly different numbers. The World Health Organization recently asked an important question, which is, have we improved our pandemic readiness over the last two years? What was that answer?

**Garcia:** Well, the World Health Organization panel, unfortunately, concluded in a report released last Wednesday that governments around the world are really no better prepared today to address a new global disease threat than they were just before the COVID outbreak began in late 2019. The Independent Panel for Pandemic Preparedness and Response was established in July of 2020. They've tried to overhaul the world's approach to outbreaks, which they consider to be outdated and inadequate, but really it appears that little has changed.
The authors of the new report said that the uneven distribution of vaccines around the world has really been a major challenge that we need to overcome. And this report was released ahead of the WHO's annual policymaking forum, the World Health Assembly, which started this week in Geneva. And these findings echo and other report released late last year that said the world remains dangerously unprepared for the next major disease outbreak.

**Unger:** Well, great segue and big concern because in addition to everything we’ve had on our hands with COVID, is another disease that has a lot of people worried. And that is monkeypox. How concerned do we all need to be? And is this another disease that’s heading our way?

**Garcia:** Well, the CDC issued a health alert on Friday. They’re really urging physicians and health departments to be vigilant for cases of monkeypox. We’re really seeing an unprecedented global spread of the virus. And that of course is raising concerns among public health authorities. That alert came two days after the CDC confirmed a case of monkeypox in Massachusetts. Testing at the CDC on May 18, confirmed that the patient was infected with a West African strain of the monkeypox virus.

The patient was isolated, and the CDC says that they do not pose a risk to the public but there are six additional presumptive monkeypox cases in the U.S at this point, one in New York, one in Washington, two in Utah and two in Florida. Overall, the CDC says that the risk to the population remains low. I think the good news is cases are usually mild. Most people recover from the disease without requiring hospitalization but the CDC is releasing doses of a smallpox vaccine from the Strategic National Stockpile in response to these recent monkeypox cases in the U.S. And that vaccine will be made available to those who are considered high-risk contact to cases.

**Unger:** Well, we will obviously continue to keep an eye on that as things develop. That wraps up today’s COVID-19 Update. Andrea, thanks so much for being here today. We’ll be back soon with another segment next week. For resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us today. Please take care.

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