FDA and CDC back COVID vaccines for youngest kids with Andrea Garcia, JD, MPH [Podcast]
In today's COVID-19 Update, AMA Chief Experience Officer Todd Unger discusses the latest on COVID vaccines for kids under 5 with AMA Director of Science, Medicine and Public Health Andrea Garcia, JD, MPH. Also covering progress on Moderna's and Pfizer's EUAs, and identifying questions parents might have for physicians about getting their kids vaccinated.

Learn more at the AMA COVID-19 resource center.

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. Big news? The parents have been waiting for, for a long time. It's finally come through. What's the latest on COVID vaccines for kids under five.

Garcia: Well, thanks for having me back. And yeah, so we talked last week. FDA's vaccine advisory committee, VRBPAC, had just unanimously voted to recommend EUAs for both Moderna and Pfizer vaccines for the youngest kids. In the days that followed, we saw FDA grant those EUAs. And then
over the weekend, ACIP, the CDC's advisory committee, voted to recommend the vaccines on Saturday. And later that same day, we saw the CDC officially recommend vaccinating the youngest children in the final step of what we all know has been a very long wait for parents of kids in this age group. In a recent statement, Dr. Rochelle Walensky, the CDC director said all children six months and older, including those who have already had COVID, should get a COVID vaccine.

**Unger:** And the AMA released a statement on that, about the authorization. Can you give us a summary of the AMA's stance on this issue?

**Garcia:** So that statement was attributed to our new AMA president, Dr. Jack Resneck, calling it a vital step in protecting many more children from COVID-19. That statement went on to say that many parents across the U.S. have anxiously awaited a safe and effective COVID-19 vaccine for their children, having to forgo normal daily activities for the past several years to protect their youngest children from the virus. And parents will breathe a sigh of relief knowing that these vaccines will very soon be available. It also points out how this decision was based on a rigorous review of the scientific data and that COVID-19 is a leading cause of death among children ages zero to 19 years. Since the beginning of the pandemic, children in the U.S., aged six months to four years, have had more than two million cases of COVID-19. More than 20,000 kids have been hospitalized and more than 200 deaths in this age group.

**Unger:** Well, despite those numbers, the evidence points to we know that some parents are going to be hesitant and have questions. How does the AMA address this part?

**Garcia:** Well, the AMA is urging parents to get their children vaccinated against COVID-19 as soon as they're eligible. But we certainly understand that even with this review of the scientific evidence and the unanimous votes from, both the FDA and the CDC advisory committees, many parents and families are going to have questions. And we encourage parents to speak with their child's physician, and to review trusted resources, such as getvaccineanswers.org, to get the information that they need to make informed decisions. We're also encouraging the use of v-safe, which is a smartphone-based tool that helps the CDC monitor COVID-19 vaccine safety.

**Unger:** Well, talking to your pediatrician is always a good idea. Why don't we just start getting into a few of the details? Let's just start with a reminder of the difference between the EUAs.

**Garcia:** Yeah. Moderna's EUA is a two-dose series. It's spaced four weeks apart and that's for children six months through five-years-old. And Pfizer's EUA is a three-dose series for children six months through four-years-old, with the first two shots spaced three weeks apart and the third shot given at least eight weeks later. I think it's important to note that this third shot is not a booster but it is a part of the original series, the primary series. So you really need those three doses to get the protection. There is a good chance, however, that we could see FDA, down the road, authorize actual booster doses for both of these options at a later date. We know that both of these vaccines are at a
lower dose than the vaccine given to older kids and adults.

**Unger:** Now, we know certainly everyone, and particularly parents, are always concerned about potential side effects. What should physicians be telling parents to watch out for as they get their initial doses?

**Garcia:** Well, the data so far suggests that the side effects in younger kids are milder than those in older kids. Physicians suspect this is likely due to the lower dose of the vaccines that are being given. The side effects are very similar to other childhood vaccines that are routinely given. So if we think about increased fussiness, sleepiness, pain at the injection site, that's what we would expect to see. The good news is that no children in either of the vaccine trials developed heart issues, like myocarditis, but these were small sample sizes and they may not be large enough to detect the very rare side effects. With that being said, myocarditis is not expected in the under fives, as that is something we typically see more frequently in teenagers and young adults rather than younger kids. But it's also important to remember that the chance of having myocarditis remains much higher among kids who catch COVID than it is among those who get vaccinated, which is important for physicians to remind concerned parents about.

**Unger:** Well, I'm going to guess that parents are wondering which of the two options is better. How should the pediatricians be answering that particular question?

**Garcia:** It's important to point out that either vaccine is far better than none. And the FDA and the CDC are not recommending one of the vaccines over the other. Some parents may opt for Moderna, simply because bringing children into a pediatrician for two shots is easier than arranging for three. And also, you get that protection faster than you would with three doses. We do expect uptick to be slow in surveys conducted by the CDC about half of parents set in February that they would vaccinate their children but by May, that number was around one-third of parents saying that they're intending to do so. For those children, who've already had COVID, doctors should remind parents that vaccinations are still needed to protect children, including from future variants. And parents may also be more willing to opt for either COVID vaccine if it's offered with routine immunizations.

**Unger:** Well, along those lines, what will this roll-out of vaccines to this age group look like? And how many children is it going to impact?

**Garcia:** These latest EUAS make vaccines available to an additional 19 million young children. We know doses began shipping on Friday. They've started to arrive in pediatrician offices and pharmacies on Monday. Although, it may take a little time to get up and running. Parents should be able to get children vaccinated at pop-up clinics, at children's museums, at libraries, at childcare sites, which is all part of making these vaccines accessible to anyone who wants them.
Unger: Well, we'll keep an eye out on that roll-out from a national and state level over the next few weeks. In the meantime, how are we doing with cases? I know that cases have come down here in Chicago, has the rest of the country seen a similar trend?

Garcia: According to the New York Times' state of the virus, we're still seeing around 100,000 cases per day. That number has stayed pretty consistent through the month of June. Cases are going down in about half of the states, particularly in the Northeast, in the Midwest. As you noted, that's the case here in Chicago. And we're not alone. In the past two weeks, parts of New England have seen cases fall by about 30%. But in the south and the west, cases are increasing substantially daily. New infections have nearly doubled. This month, in Arkansas and in Kentucky and also in Wyoming, they are four times as high as they were two weeks ago.

Unger: What about hospitalizations? Are we seeing that continuation of lower rates relative to the cases?

Garcia: Yeah. More than 30,000 people are hospitalized nationwide with COVID, that's a slight increase since the beginning of the month. I think the good news is hospitalizations are decreasing in more than a dozen states. However, in states like California and Florida, they're very popular states, their increases have led to an overall increase at the national level. Deaths have been more difficult to determine in recent weeks. We know they're a lagging indicator but we've also seen delays in reporting after Memorial Day. Reports of new deaths are remaining around 350 each day. That's, of course, down from more than 2,600 a day at the height of the Omicron surge.

Unger: That's a pretty significant change, isn't it? The fact that even with the rising cases, that deaths have remained at that level, relative, at least, to where they were before?

Garcia: Yeah. In the past, we've seen death rates increase substantially following an increase in infections. And we haven't seen that play out with this surge. The pattern has changed. Dusts are going up slowly in the Northeast, where the latest wave began, and they're likely to do the same nationally as the surge moves across other areas. But we're not seeing that huge increase that we once were. Of course, that could be in part because most Americans now carry some immune protection, whether that's from vaccine or prior infection or both. We no longer have huge pockets of people who are unvaccinated and haven't been exposed to the virus at all. And likely, because of this, as well as that therapeutics that we now have available, the average case of COVID is becoming milder.

Unger: Well, I guess we could take that as a bit of good news, which we haven't had a lot of lately. What does it mean for the pandemic overall, do you think?

Garcia: I think it's good news for some of us who may get the virus but not become as seriously ill. However, as has been the case throughout the pandemic, some groups are getting left behind. And
we've seen older people make up a larger share of COVID deaths than they did last year. Those with weakened immune systems, we know they continue to face greater risks. And we also still see deaths in unvaccinated people at much higher rates than vaccinated people. Even though we know many of those who are unvaccinated, do have some prior protection from prior infection. I think to put this in perspective, the New York Times reported that the virus is still killing more than twice as many Americans every day as suicide or car crashes are. And many of those who survived the virus are debilitated, some of them for long after their infections

**Unger:** Still continues to be so important to be vaccinated and boosted in that regard. What do we take away from all of this news that you’ve brought us today?

**Garcia:** It’s a good reminder to stay up to date on vaccines and get booster shots. Once you’re eligible. Look at what we’ve seen with Omicron. We’ve learned that people who were infected by an earlier Omicron version could still be susceptible to an infection from later sub-variants, like BA.4 or BA.5, not long after they recover. However, the combination of vaccinations and an earlier Omicron infection provides more durable protection than an infection alone. And waning immunity won’t help if we’re faced with a new variant on the road.

**Unger:** Well, those are all good reminders. That wraps up today's episode. Thanks so much for being here, Andrea. And we'll be back with another COVID-19 Update video and podcast next week. For resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us today. Please take care.

**Disclaimer:** The viewpoints expressed in this podcast are those of the participants and/or do not necessarily reflect the views and policies of the AMA.