COVID-19 vaccines for kids under 5 still pending with Andrea Garcia, JD, MPH

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In today's COVID-19 Update, AMA Chief Experience Officer Todd Unger reviews the timeline for COVID vaccines for kids under five with AMA Director of Science, Medicine and Public Health Andrea Garcia, JD, MPH. Also covering COVID case numbers, what to expect this summer, how and why you should report positive at-home tests, as well as an increase in monkeypox cases in the U.S.

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Learn more at the Monkeypox resource center.

Speaker

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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 again for joining us this week. The big headlines this week are about something that has yet to happen but much anticipated, the authorization of COVID vaccines for kids under five. What is the latest news here?

Garcia: Well, thanks for having me on, Todd, and yeah, that is definitely making headlines. I think that's because last Thursday during the White House briefing, Dr. Ashish Jha, the President's COVID
Response coordinator, shared the potential timeline for vaccine distribution for those doses for children under five and that's, of course, in anticipation of the FDA authorizing and CDC recommending use of those vaccines in mid-June. He indicated that those first doses could be administered as early as June 21 and that states and pharmacies and community health centers could start ordering doses as soon as last Friday.

This is, of course, the most concrete timeline that parents of young children have been given yet but Dr. Jha did caution that this distribution and the preparations are all contingent on the FDA's authorization and that recommendation from the CDC. We know CDC usually follows the recommendations of the ACIP. That group is scheduled to meet for two days on June 17 and June 18. Dr. Jha did say that no doses will be shipped until both the FDA and the CDC sign off.

**Unger:** Well, obviously this is potentially very exciting news for parents who have been waiting for a long time to get their youngest children vaccinated. Are pediatricians being included in the distribution effort should those authorizations come through?

**Garcia:** Yeah. Dr. Jha did say that the administration has been working closely with local health departments, with pediatricians and with family doctors, and they've asked states to distribute those early doses to children's hospitals, which we know serve the most vulnerable children. They're also prioritizing sites in those neighborhoods that have been hardest hit by the pandemic. I think that it's clear that it may take time for vaccines to become broadly available to everyone but the White House expects that within weeks of the authorization, every parent who wants their child to get vaccinated will be able to get an appointment.

**Unger:** That's a question because even with all these preparations, we know not every parent is going to rush out to get their children vaccinated. Witness the five- to 11-year-old age group, which has had an authorized vaccine available for quite a while and it does serve as a relatively good predictor of vaccine acceptance. Where do we stand for that particular group? What are we learning there?

**Garcia:** Yeah, so the latest data still show that only around 29% of five- to 11-year-olds are fully vaccinated and that's even though, as you said, that group has been eligible since November. A survey by the Kaiser Family Foundation reported that just about 18% of parents with children under five said that they would get their kids vaccinated right away. The largest group, 38%, put themselves in that wait-and-see category and 27% said that they would definitely not be getting their children vaccinated.

**Unger:** Oh, which is interesting because the science does show that the vaccine could be very beneficial to this age group. Can you quickly review what we know about the data and the pending applications right now?
Garcia: Yeah, so according to reports, Pfizer and BioNTech said that preliminary findings from their clinical trial had shown their three-dose COVID vaccine had been 80% effective in preventing symptomatic infection in a subset of participants who were six months to four-years-old. Last Wednesday, the company reported that they had completed their application for an emergency use authorization. Moderna's request to authorize its vaccine for children under six has been pending since April. That vaccine is two doses given four weeks apart and the company said the vaccine was 51% effective against infection in children six months to two years and 37% effective against infection and children ages two through five.

The Moderna does is a quarter of the dose given to adults. Pfizer is a tenth of the dose strength for adults, and keep in mind, Moderna has also applied for an EUA for its vaccine for children ages six to 17. The FDA's Advisory Committee will meet to discuss that application on June 14. Just as a reminder, as of now, Pfizer's vaccine is the only one that is currently authorized for children five and older.

Unger: Well, potentially exciting news, then, for young children but separately, we could also see the authorization of another vaccine for adults, one that takes a more traditional approach. Tell us a little bit more about that.

Garcia: At the time of this filming, advisors to the FDA are meeting to discuss the safety and efficacy of a more traditional protein-based vaccine developed by Maryland biotech company, Novavax. The protein-based technology's been used to make vaccines for decades and if authorized is an alternative to the mRNA vaccines that are now available. That's important for people who are allergic to the ingredients in the mRNA vaccines or for those who are choosing not to get the existing vaccines for other reasons.

We know that the FDA has said based on their review of the clinical trial data that the vaccine is likely to afford meaningful protection against Omicron, especially against severe disease but they're also going to be closely looking at the four cases of myocarditis in the trial. Novavax was part of the race to develop a COVID vaccine in 2020 but the company reportedly faced manufacturing hurdles that ultimately delayed authorization, but we should have more news on the outcome of the VRBPAC conversation to discuss next week.

Unger: A lot of potential vaccine news coming out. Let's go back, though, and talk about cases this week. Is the news getting any better than what we talked about last week?

Garcia: A little bit. According to The New York Times State of the Virus, we're currently seeing more than a hundred thousand COVID cases each day but, obviously, we always talk about the caveat to those numbers being on reported cases because of home tests but current figures are also likely lower because of reporting delays from Memorial Day weekend. Overall, cases are still increasing in many states but there are signs of improvement in the Northeast and in the Midwest, which is good news.
Reports of new cases have fallen by more than 20% since mid-May in Michigan, in New Jersey and in New York.

When we look at variants, we're still seeing BA.2.12.1 as the dominant variant but we're starting to see those increases in BA.4 and BA.5. Hospitalizations have begun to decline in the Northeast but they remain on the rise nationally and more than 29,000 people are currently hospitalized with COVID. That's an increase of 16% over the last two weeks and about 3,000 are in the ICU. We are seeing deaths start to decline. We're just seeing just under 300 reported deaths each day.

**Unger:** I know a lot of people expected last summer to be the big summer following the rollout of the vaccine. We know how that year turned out. What are we thinking about this summer?

**Garcia:** I think that experts are mostly saying that we could see outbreaks in certain areas. Of course, it's being predicted that in the South, we'll see that summer surge, which we've seen in previous years but beyond that, outbreaks could be dictated by vaccination rates, demographics and the availability of health care. Overall, the situation is expected to improve over the summer but another wave is expected after that and we're likely to be looking at a worse situation come fall and winter as we've seen over the past two years.

**Unger:** You mentioned the trouble with case counts. Obviously, a great deal of home testing going on right now. There has been some attempt now to capture those results. Why is this an issue? Is it working?

**Garcia:** Well, home tests, obviously, have an advantage in that it makes it easier for us to screen ourselves and our families for COVID and get treatment when needed. However, most of us don't report results from these tests which have made those official case counts increasingly unreliable. If you test positive at a clinic or a community testing sites, those results are required to be reported to public health departments under The CARES Act, so some home tests that are taken under supervision of trained telehealth providers are reported to government officials but the rest of us who take those tests on our own do not report them generally.

**Unger:** How do we get better at capturing this data? Is that realistic do you think?

**Garcia:** Well, one possible way is to report your results to your primary care provider and the CDC actually strongly encourages everyone who self-tests to report their positive results to their health care provider, who then may order a PCR test or report the data to state authorities. When calling or emailing your doctor, people should have key details ready, so the kind of test you took, the time you took it, the date you started experiencing symptoms and also your vaccination status. Physicians can help track new or concerning symptoms, can give you advice about antiviral treatments and also clear people to return to work or school once they fully recovered.
Unger: Letting your physician know your results, that sounds like a smart and a good way for a lot of reasons. Are there other ways that people can report their results?

Garcia: There are some new ways that are emerging which are relatively easy to capture the data and some of the popular rapid test kits like BinaxNow and iHealth include a way to report your results through a mobile app. Many local health departments are also giving people ways to report their results online and if you want to know if your local health department is accepting results in this way, you can check out the National Association of County and City Health Officials Directory to find the contact information for your local health department.

There’s also been some effort to crowdsource results, though. Epidemiologists and software developers at Boston Children’s Hospital in Harvard along with volunteers from across the tech industry have created a new platform called outbreaksnearme.org and this site was originally designed to track flu outbreaks. It's fairly—

Unger: I would say that sounds like a lot of fun, outbreaksnearme.com or .org, but boy, very interesting.

Garcia: Yeah, it shares anonymous aggregate data and makes it available to the public but local health departments and CDC also look at the data for potential outbreaks and to help predict where COVID and flu might have an impact next.

Unger: Well, speaking of outbreaks near me. I'm, of course, still seeing headlines about monkeypox and I know there was a case reported here in Chicago. What do physicians need to know right now?

Garcia: Well, the CDC has raised its monkeypox alert level to Alert 2, which is to practice enhanced precautions, so they're warning travelers to be mindful of approaching sick people. Although they continue to say that the risk to the general public remains low, there are now more than a thousand monkeypox cases reported in 29 countries. There are 31 confirmed cases here in the U.S. in 13 states and D.C. and those states are, of course, expected to rise.

CDC has warned that this may be spreading person to person in the U.S. and because of the potential for community-level transition, they are looking to increase their surveillance. They're urging health care providers to be alert and to keep an eye out for patients who have a rash or an illness consistent with monkeypox. They're also working with state and local health officials to identify those people who may have been in contact with people who've tested positive so they can monitor their health, too.

Unger: Well, we'll continue to monitor the situation as it develops. That's it for today's episode. Thank you, Andrea, again for being here. We'll talk to you next week with another COVID-19 Update video and podcast. In the meantime, for resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us today and please take care.