# Andrea Garcia, JD, MPH, shares vaccine updates on boosters & young children

Watch the AMA's COVID-19 Update, with insights from AMA leaders and experts about the pandemic.

## 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, to review COVID-19 vaccine numbers and trending topics related to the pandemic over the past week. Also covering Pfizer's announcement regarding vaccine effectiveness in 5- to 11-year-olds, the FDA's decision on booster shots and a state-by-state look at swings in COVID case count.

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 AMA's Director of Science, Medicine and Public Health, Andrea Garcia in Chicago. I am Todd Unger, AMA's chief experience officer also in Chicago. Andrea, big news this week about vaccines. Let's start first with the most recent announcement from Pfizer earlier in this week about the effectiveness of this vaccine for younger children and what it means for the five to 11 age group to get vaccinated. What's the timeline we're looking at? What are the details?

**Garcia:** Thanks for having me back and it's definitely really good news for parents who've been anxiously waiting to get their children vaccinated against COVID-19. Pfizer reported that its vaccine induced a strong immune response in kids aged five to 11. But I think the caveat here is that these

results were announced in a statement by the company. It did not include the detailed data from the trial and the findings haven't been peer-reviewed or published in a scientific journal. However, the results are consistent with what we've seen in older children and adults and I think the need for younger children to be vaccinated is urgent. Children account for more than one in five new cases and the Delta variant has sent more children into hospitals and ICUs in the past few weeks than at any other time in the pandemic. So there's some hope that kids may be able to get their first shots by late October but we know that a lot has to happen first.

**Unger:** Why don't we go through those steps? Is it a concern for instance that, you talked about that not being peer reviewed. It obviously has to go through other approval processes. What's that look like coming up this month?

**Garcia:** So the data has to be submitted to and reviewed by the FDA. So Pfizer said it plans to apply to the FDA by the end of the month for authorization to use the vaccine in the younger age group. It's the same process they did for adolescents, so Pfizer will be seeking an Emergency Use Authorization. If the FDA grants the EUA for this population, then the CDC Advisory Committee on Immunization Practices would also review that data and make a recommendation on use of the vaccine for these younger kids. And then the CDC director has review and sign off on the ACIP's recommendation. So if that process goes smoothly as it did for older children and adults, it would really pave the way for millions of elementary school students to be potentially inoculated by late October.

**Unger:** I know a lot of parents, including colleagues of mine here at the AMA, are eagerly awaiting that and so hopefully that will go smoothly. I mean, right now we haven't seen the detailed data. Can you share anything about how the trials were conducted?

**Garcia:** Yeah. So the big takeaway was that children who got the vaccine produced a strong immune response. It was comparable to the level of antibodies seen in earlier trials with 16- to 25-year-olds. However, they achieved this with a 10 microgram dose of the vaccine and that's a third of the dose given to older children and adults. At higher doses, the researchers observed more side effects in the younger children and those included fever, headache, fatigue, although none of them were severe. The idea here really is to hit that sweet spot where you're giving the lowest dose that might elicit side effects but it's also high enough to get a good sustained antibody response. We do know that, that trial was not big enough to meaningful conclusions about the vaccine's ability to prevent COVID-19 or hospitalizations. In younger children, those five and under, just three micrograms or a tenth of the adult dose is being tested in trials. But we're not likely going to have those results until the fourth quarter at the earliest.

**Unger:** All right, well, we'll stay on top of this story as it develops. The other big news is around booster shots and this is just another case where you have different parties announcing different things and some confusion that results from that. But did receive definitive news from the FDA

advisory panel last Friday about not recommending boosters for all adults but recommending boosters for those over 65. Can you tell us more details about that particular announcement and its implications?

**Garcia:** Yeah, so the Vaccine and Related Biologics Advisory Committee, which is an advisory committee of the FDA, voted against the recommendation to offer boost doses of Pfizer specifically to everyone age 16 and older. They indicated that there just was insufficient evidence to support a recommendation around that at this time. The committee then endorsed boosters of the Pfizer vaccine for people who are 65 or older, those at high risk of severe COVID-19 and for people whose jobs may put them at higher risk for COVID-19. So I think the key here really is going to be specifically identifying who is in that at high risk population. It could be tens of millions of Americans who could conceivably wind up eligible for booster doses. We have to wait and see what that final definition of high risk looks like. I would say the committee members did indicate support for health care workers, for teachers and for other emergency responders whose jobs put them at increased risk of COVID-19 being eligible for booster shots. So like I said, we'll have to see what that final language looks like.

**Unger:** So tell us about that process. Where do we go from here? How do we get definition around what those groups are as you point out? That could be a lot of people.

**Garcia:** It could. So we're waiting for the FDA, they have the final word on authorization and they're not obligated to follow their advisory committee's recommendation, though they often do. So at the time of this conversation, we're still waiting on that FDA determination, though we'll probably see it later today because the Advisory Committee on Immunization Practices is going to be meeting on Wednesday and Thursday and they don't have this discussion about a clinical recommendation until the FDA has taken their regulatory action. So when ACIP meets Wednesday and Thursday, they'll also be further defining who those populations are and who should be eligible for booster doses. That ACIP recommendation then goes to the CDC director for review and approval.

We also know that the agencies are expecting to soon have data on whether boosters are needed for those who got the Moderna and J&J vaccines. We don't have a specific timeline for that yet and the agencies have indicated they'll continue to examine the need for boosters as the data comes in. I think, in the meantime, everyone's in agreement that in order to have the biggest impact on the pandemic and to avoid a fall and winter surge, we really need to focus on the unvaccinated. We need them to roll up their sleeves and get the vaccine.

**Unger:** Absolutely. And we will have more information from the ACIP meeting as we talk to Dr. Sandra Fryhofer, the AMA's liaison to ACIP. We'll get a full recap from her next week. Turning to the numbers, Andrea, you mentioned, again, continued focus on the unvaccinated because of so many cases out there. What do the numbers of look like this week?

**Garcia:** Well, the data's a bit tricky to read right now because Labor Day reporting delays distorted

that seven-day average for much of this month. So we saw cases plunge artificially during the long weekend and then they surged also artificially in the days after. That said, some in analysts believe that we could be on the verge of a decline in cases. Although scientists don't understand why, COVID has often followed a two month cycle where cases begin rising in a country, they often do so for about two months and then they start to decline. So, in the U.S., Delta began in early July, so that's a bit more than two months ago.

The New York Times recently adjusted for the Labor Day messiness in the data and the picture was encouraging. The number of new cases has fallen more than 10% since September 1. However, several factors have complicated this forecast. Schools across the country are reopening and other activities, I think we're all seeing the large football games that are happening, Broadway plays have restarted so some epidemiologists are predicting that we could, because of these social activities, see cases surge this month.

**Unger:** And I know, state-by-state continues to be a different story. We talked with Dr. Steven Stack last week about Kentucky and the problems they're having there. What are we seeing state-by-state?

**Garcia:** State-by-state, the data's consistent with that trend. In some states where the Delta waves struck early, like California, Florida and Missouri, cases have falling for even longer. In states where the Delta variant arrived later, like Colorado and Massachusetts, that wave has begun to show signs of cresting. The seven-day average of the number of hospitalized Americans is also decreasing having peaked on September 3 and it's fallen about 7%. So it looks like the Delta wave may have in the U.S. after slightly more than two months of rising cases in hospitalizations.

**Unger:** So do I detect optimism in your comments there? What do we see as the prognosis or is I just still too early to tell?

**Garcia:** I think it's really good news but in an analysis in the New York Times, it was pointed out that there's still are two important caveats. One is, even with declining hospitalizations, the current COVID situation really remains dire in much of the U.S. Most hospitals in the mountain west, the Southeast and Appalachia are still filled with COVID and physicians, we know, and nurses are overwhelmed and exhausted. The number of nationwide COVID deaths, which typically lags trends in new cases by a few weeks, has continued rising. So about 2,000 people in the U.S. are still dying of COVID every single day. The situation here, it's worse than almost any other country. The U.S. death rate over the past two weeks adjusted for population is more than twice as high as Britain's, seven times as high as Canada's and 10 times as high as Germany's. So if Mississippi were its own country, it would have one of the world's worst total death tolls per capita. The U.S. also recently passed another grim milestone with one in 500 residents having now died of COVID-19.

**Unger:** So, in terms of those caveats, I mean, anything else that can be thrown into the mix that we may or may not be expecting?

**Garcia:** I think that the other caveat really is these trends are not expected to continue. The two-months cycle is not a scientific law. There have been exceptions to it. So maybe those packed football games will cause new outbreaks and are not yet visible in the data or maybe the onset of colder weather will drive people indoors and we'll see an increase in cases. So I would say, the virus has spent almost two years surprising us and not for the better. So, for now, the best summary may be that COVID is both unnecessarily a bad crisis here in the U.S. and one that appears to be slowly becoming just a little bit less bad.

**Unger:** Wouldn't it be great if we could turn the corner on that through continued vaccination and then vaccinations with younger children five to 11. Well, maybe we can look forward to that. That's it today for our COVID-19 Update Video and Podcast. For updated resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us today. Please take care.

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