

## Andrea Garcia, JD, on recent EUA for Pfizer vaccine for 5–11-year-olds

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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, on COVID-19 vaccine numbers and trending topics related to the pandemic over the past week. Also covering the FDA's authorization of Pfizer-BioNTech's coronavirus vaccine for emergency use in children 5 to 11, vaccine mandates in schools and the AMA's support of the Biden administration's plan to address the nation's overdose epidemic.

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, the big news this week is about vaccines for this five to 11 age group. I want to kind of walk our viewers out there through where this stands. First, starting with where we are with the FDA but kind of giving a big picture of what process needs to take place for this to come to fruition. Why don't we start there?

**Garcia:** Well, thanks for having me back. The FDA on Friday authorized the Pfizer–BioNTech COVID vaccine for emergency use in children five to 11. We know that's a move that millions of families have been waiting for. About 28 million children are in this age group and they will be eligible to receive the

vaccine but that is pending the CDC Advisory Committee on Immunization Practices meeting. That meeting is happening today. They're going to vote on whether or not to recommend the use of the vaccine in this population.

After they vote, their recommendation will go to the CDC director, who needs to sign off on their recommendation for use of the vaccine in this population. And then, after that final step, children could start getting the vaccine probably as early as tomorrow if the CDC director signs off within 24 hours, as she has been doing with previous recommendations. This is, obviously, big news for parents who've been anxious about their children getting sick, though some experts worry that those most at risk may still slip through the cracks. I think we also recognize that some parents, even those who are vaccinated themselves, may have concerns about vaccinating their kids.

**Unger:** We're going to talk about that more in depth but just make sure I understand this and it is a little confusing. We do have authorization from the FDA. Then, the other input will be coming from ACIP with their recommendation, then it will be up to the CDC to approve. Is that the right process here?

**Garcia:** That's right. Yep. FDA takes that regulatory action, authorizing the vaccine and then CDC would make that recommendation on use of the vaccine in the population, and come out with some clinical recommendations.

**Unger:** We'll be talking to Dr. Sandra Fryhofer, AMA trustee and our liaison to the ACIP, on Friday for more details about that, so do tune in there. We talked about how the administration is trying to reach all eligible children to make it easy for parents to get them the shot. You talked a little bit about this before about some people slipping through the cracks, not reaching everyone. Is the distribution plan in place to make this happen?

**Garcia:** I think so. The Biden administration has promised that children's shots will be easily accessible at pediatrician offices, community health centers, children's hospitals and pharmacies with 15 million doses ready to ship immediately. The administration indicated that the rollout will be at full strength beginning next week. We know that states started ordering doses late last week, under a formula based on how many children they have in that age group and the vaccines were expected to be able to be shipped right after the FDA authorized it.

We know that school nurses, churches and local health officials will be key to reaching some children and families who might not have insurance or access to pediatricians. The vaccines are free to everyone. I think that's an important thing to keep in mind. This, we think, is going to look very different than the adult distribution of the vaccine because we may not have those mass vaccination sites. It's a good thing.

**Unger:** You have to take a step back and just think about how far we've come in this process. I think

one of the major things you learn about is you can get a vaccine but getting it into people's arms requires a distribution plan and a marketing plan, and there's a lot in what you just said to make that happen, including having pediatricians more involved in this process. Kudos to all of those folks out there working on what must be just an enormous task. Andrea, how will the authorization affect our overall efforts to curb the pandemic, bringing in this kind of new age group into the mix?

**Garcia:** We know the school year is already well underway and the pediatric dose is arriving in time for the holidays, which is good news. It's giving families more comfort to gather older and younger people together for the first time since the early months of 2020. This is going to be, I think, an incredibly important tool in the return to normalcy. As a parent, to be able to know your child is protected and not going to get severely ill by going to school is an incredible stress relief. But, as we discussed previously and as you just mentioned, the real key here is getting the vaccine into arms. We know these vaccines show significant protection in children against the virus but the key here is going to be how many kids get fully vaccinated.

**Unger:** Let's go back to something you mentioned upfront that I said we'd dig into more, which is about overcoming obstacles to getting these kids vaccinated. How much of a factor do we think it's going to be, this reluctance on the part of parents, to getting kids vaccinated?

**Garcia:** It could be a big factor but I think the biggest determinant really lies with those 60 million adolescents and adults who have been eligible for the vaccine for a while. They need to get vaccinated. In terms of reluctant parents, we know that a survey from the Kaiser Family Foundation, released last week, found 27% of parents in that five to 11- year-old age group were really eager to vaccinate their children right away. A third say they want to wait and see how the rollout goes. We know the uptake around at adolescence has been slower than public health experts had hoped. The Pfizer vaccine became available for children 12 to 15 in May but fewer than half in that age group are now fully vaccinated, compared to 69% of adults.

**Unger:** I've read a lot about a lot of the concern being that the narrative has been that young people are less likely to get sick. How do you counteract that narrative? It's so important to get these adolescents and young people vaccinated.

**Garcia:** Yeah. But I think we are seeing an increase in cases and hospitalizations in this younger age group with kids going to school in person. The risk isn't zero in this population and the side effects of the vaccine in this group were really minimal. When the FDA was making its determination, that's a risk benefit analysis. The vote was unanimous that the benefits of the vaccine in this population outweigh the risks.

**Unger:** Do you see, given all the discussions we've had about vaccine mandates in so many areas, I mean, top of mind across the country right now, do you expect to see vaccine mandates cropping up in schools?

**Garcia:** I think we could start to see vaccine mandates in schools and we know mandates certainly help with uptake but I think there will be concerns and pushback with mandates in schools. We know when the FDA's expert advisory panel met last week, several members came out against school vaccine mandates. We know the governor of California has already announced plans to require the COVID vaccine in order for students to attend school in person. That is the first statewide mandate for school children. But the vaccine, I think this is a key point, won't be required until it receives full federal approval by the FDA. Not under an EUA, it's under a ELA. That California mandate won't be implemented right away and it would be implemented in a phased approach by grade, starting with the middle and high school grades first.

**Unger:** Well, let's talk more broadly about vaccinations and then cases, where do we stand at this point with vaccination rates?

**Garcia:** According to the CDC this week, a total of 221.7 million Americans have received one dose. That's about 66.8% of the total population. Of those, 192.6 million are fully vaccinated or 58% of the population. And so far, the CDCs estimating that 19.2 million people have received a booster dose. That's a pretty significant jump from the 13 million or so we talked about last week.

**Unger:** Yeah, that is up dramatically. On the other end of this, where are we seeing cases and hospitalizations right now? Are we still on a downward trajectory or not?

**Garcia:** Over the past week, cases have stopped falling. The reasons aren't clear, as is often the case with this pandemic. The recent increase is really minuscule but it's a reminder that the pandemic will probably keep having ups and downs. With that being said, overall, the national outlook has certainly improved since early September. Fewer than half as many cases are being identified each day. And tens of thousands fewer patients are being hospitalized.

Reports of deaths have also continued to decline to around 1,400 a day, from more than 2,000 a day during parts of September. Alaska is still leading the country in cases per capita, while Colorado has the fastest rate of case growth. As we talked about last week, Florida, which experienced one of the worst summer surges, now has the lowest case count. Caseloads there continue to rapidly fall and the same is true across much of the south.

**Unger:** Still a lot to understand about the dynamics of this pandemic. Though it's looking more positive for numbers like that in the U.S. right now, globally, we reached another pretty sad and just unbelievable milestone. Can you tell us more about that?

**Garcia:** Yeah. As of Monday, the official global virus death toll has now passed five million, that's according to data from Johns Hopkins University. We know the true number is undoubtedly higher. Some have estimated that the true global death toll could be twice as high as the reported figure. To put that five million in perspective, that loss would be equivalent to almost the entire population of Melbourne, Australia or most of the nation of Singapore. The pace of confirmed deaths does seem to have slowed slightly since the world reached four million in early July, despite the rapid spread of the Delta variant, and that could certainly be a sign that vaccinations could be having an impact, at least in some parts of the world.

**Unger:** Five million deaths is a milestone I don't know that anybody thought about at the beginning of this pandemic but that's such a loss of life. On another topic, we did see a new study from the CDC last week. This one confirming something that physicians and scientists have been saying, which is that vaccine immunity does appear to be stronger than immunity from past infection. What do physicians need to know about this latest data?

**Garcia:** Yeah. As you said, a new CDC study which was shared on Friday, suggests that vaccinations provide stronger and more reliable protections against COVID-19 than past infection. The studies showed that unvaccinated people who had previously recovered from coronavirus infections were five times as likely to get COVID as people who have received both shots of an mRNA vaccines of Pfizer or Moderna. However, the study authors did caution that certain gaps in patient data and bias in their study participants could have influenced the results, and we've seen mixed results from other studies on this topic.

**Unger:** Well, that's important data, not the least of which is because we've seen this question about natural immunity versus vaccine immunity really gained traction across the country because of vaccine mandates. Some people think that past infection should be enough to satisfy a vaccine mandate. Why isn't that enough?

**Garcia:** Now, the truth is even with this study's caveat, scientists have always urged COVID survivors not to skip the vaccine, noting that the strength and durability of immunity depends really heavily on people's age, their health and the severity of their initial infection. The bottom line is that many physicians have stressed that acquiring so-called natural immunity is uncertain. Not everyone survives COVID in the first place and those who do may not be able to count on a vigorous immuneresponse. It remains very clear that you should get vaccinated, even if you've previously have hadCOVID. If you haven't had COVID, all the more reason to get vaccinated because waiting to acquireimmunity through infection is far more risky and unreliable than the vaccine.

**Unger:** Besides you should get vaccinated, are there any other messages coming out of the AMA this week?

**Garcia:** While not directly related to COVID, the nation's overdose epidemic is something that we've certainly seen worsen during the pandemic. Last week, the Biden administration came out with a plan to address the epidemic, recognizing the need for a comprehensive evidence based approach. The AMA came out in support of this plan. Part of that statement read, "The AMA commends the Biden Administration for responding to the spike in drug overdoses with an evidence-based, humane approach to increasing access to care for patients with a substance use disorder and harm reduction services. The AMA has urged a public health response that's focused on how best to treat substance use disorders as well as prevent overdoses and encourage recovery. This comprehensive approach recognizes that we need an inclusive federal approach free of stigma and based on the best available data."

**Unger:** I'd encourage those interested in finding out more about the overdose epidemic and efforts in that arena to check out our video with Dr. Bobby Mukkamala on that topic from several weeks ago. Andrea, thanks for being with us here today. That wraps up today's COVID-19 Update. We'll be back soon with another COVID Update video and podcast shortly. For resources on COVID-19, check out [ama-assn.org/COVID-19](https://ama-assn.org/COVID-19). Thanks for joining us. Please take care.

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