

Andrea Garcia, JD, MPH, on EUA requests for boosters & children ages 5-11

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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 COVID-19 vaccine emergency use authorization (EUA) requests from Pfizer for children ages 5-11, as well as movement on boosters for Johnson & Johnson and Moderna vaccine recipients.

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'm Todd Unger, AMA's chief experience officer, in Chicago as well. Andrea, speculation's beginning about what we can expect this winter but first we have a holiday approaching in just a few weeks. And unlike maybe in previous holidays, Dr. Fauci recently weighed in, saying people should get out there and enjoy the holiday, at least those that are vaccinated. Can you tell us more about that?

Garcia: Yeah, that's right. While we're seeing some cancellations of Halloween parades and other events around the country, Dr. Fauci over the weekend really came to the defense of Halloween,

saying that outdoor trick or treating was perfectly safe. He said it's a good time to reflect on why it's important to get vaccinated, though, urging those who are eligible for COVID shots to get them before Halloween, to protect themselves, to protect their children. Because we know the ability for parents to get vaccinated, combined with the low risk of the virus spreading outdoors, really offers reassurance for celebrating Halloween.

Unger: And I'm sure that Dr. Fauci does not like to deliver discouraging news about any holiday and will probably look forward to one where he can have a more upbeat assessment. And I think all of us are kind of looking ahead to these winter months, into the holidays. Is there any consensus on what we can expect this winter?

Garcia: Well, in that same interview, Dr. Fauci did warn that enough people remain unvaccinated, which will allow the virus to rebound during colder months. So this is our second full winter of COVID-19, and people once again will be heading indoors, where we know the risk of transmission is higher. So as we talked about last week, the surge driven by Delta is receding in the U.S. but experts really continue to say that increased transmission during the coming colder months remains a threat and that steady rates of vaccination are key to keeping the virus at bay.

Most agree that the next few months are really going to be critical, with the combination of increased vaccination and some level of natural immunity from the infections that we've been seeing across the country. Those two things in combination could prevent a catastrophic wave, like the one we experienced last winter.

Unger: I am hoping so, so that we can enjoy this winter. Vaccination obviously crucial to making this happen. Where are we with vaccination at this point?

Garcia: So providers are administering an average of 949,000 doses per day. That includes first, second and additional doses. So this we know is far below the April peak but it's higher than the recent September 28 low point of about 625,000 doses. According to the CDC, 216.8 million Americans have received one dose. That's just over 65% of the total population. And of those, 187.2 million are fully vaccinated. So we're at about 56.4% of the population. So the CDC is estimating that 7.79 million people have received a booster dose, which is a pretty significant number.

Unger: Is there any indication that as we look at that increase in doses that because of the Delta variant, because of just constant news about the benefits of being vaccinated, that we're finally seeing some of the vaccine hesitant beginning to change their minds?

Garcia: So yeah, surveys from the Kaiser Family Foundation have shown that many of the recently vaccinated did so out of fear of the Delta variant. We've seen almost 40% of the newly inoculated respondents sought the vaccine because of the rise in cases and more than a third said that they became alarmed with the overcrowding in local hospitals and the rising death rates.

Unger: Now, it's interesting because we're proceeding to a point where we've got people getting booster shots and then we still have people on the other end of that who are unvaccinated. There's been some discussion about boosters complicating efforts, at least around communication. What is it that's behind that?

Garcia: Yeah. So despite the initial bump that came with the surges caused by the Delta variant, the number of eligible people still weighing whether or not to get a COVID vaccine has sharply dwindled. The remaining unvaccinated population we think is more the hardcore vaccine refusers. They're not hesitant. Counseling isn't going to sway this group. So the arrival of boosters is making efforts to convince some of these people even more difficult.

In September, the vaccine monitor survey from Kaiser Family Foundation found that 71% of unvaccinated respondents said the need for boosters indicated that the vaccines were not working. We know that's not the case. We know that the vaccines are preventing severe illness and death but experts in vaccine behavior fear that the country is starting to bump up against that feeling of persuadable people. And unfortunately, that feeling is significantly lower than the threshold needed for broad immunity from Delta and also possible future variants.

Unger: That's really frustrating news. I mean, so on one end, you're going to have a group of people who are hardened in terms of their resistance. And on the other end, what I called the max vaxxed crowd, who have received their boosters. We still have a lot of work ahead of us. On a more positive note, the number of people eligible for vaccinations is about, or could be soon to increase. There was a movement last week on the Pfizer vaccine authorization for children. Can you tell us where that stands now and what it could mean for our overall vaccination efforts?

Garcia: Yeah. So Pfizer asked federal regulators last Thursday to authorize emergency use of its COVID-19 vaccine in children ages five to 11. We know that that could help protect 28 million people in the U.S. The company is submitting data supporting this change to the FDA and the FDA has promised to move quickly. And they've tentatively scheduled a meeting of their advisory committee on October 26 to consider the application.

An FDA ruling is usually within 24 to 48 hours of its advisory committee's recommendations, so that would be the end of this month. And then the CDC's advisory committee on immunization practices would consider whether or not to recommend vaccines in this younger population. And that meeting is scheduled for November 2 and 3. We know that this could be a huge game changer because children represent such a large portion of the population.

Unger: That would be a pretty amazing development just after Halloween. And we'll look forward to continued coverage on the developments there. Speaking of additional changes, we've also heard that boosters are most likely on the way for recipients of the Moderna and J&J vaccines. Do you have any news for us on that front?

Garcia: Yeah, so FDA's advisory committee will be meeting this week, Thursday and Friday, to discuss booster doses for the recipients of the J&J and Moderna COVID-19 vaccines. So on Thursday, they'll focus on safety and efficacy data regarding boosters for the Moderna recipients and on Friday that discussion will focus on the J&J boosters. The agency typically issues a decision within a few days of their advisory committee meetings and the FDA's expert committee is also going to hear a presentation on Friday that's really been long awaited, that is focused on the effectiveness of mixing different brands of vaccine. And that will be presented by the NIH.

We know that this is a two-step process, so FDA will have their discussion this week. And then next week ACIP will consider booster doses of Moderna and J&J. So that's scheduled for October 20 and 21. And then we usually see a decision by the CDC director within about 24 hours.

Unger: Wow. We will eagerly await that news, especially on that kind of mix and match. That's been a big question mark. On a different front, we've also seen Merck apply for emergency authorization use for what would be, as we talked about last week, the first pill to treat COVID. What's the expected timeline for authorization there?

Garcia: So Merck said on Monday that they had submitted an application to the FDA to authorize its antiviral pill for emergency use. We talked last week about how this would be a convenient, relatively inexpensive treatment that could reach many more high risk people than the current monoclonal antibody treatments. We've heard that when the Biden administration is ... They're preparing for an authorization. That could come within weeks. Senior administration officials have said that the pill would likely be allocated to states, similar to the way vaccines are allocated. And then states would distribute the medications how they wish, so through pharmacies or through doctors' offices.

Unger: A lot of authorizations up for discussion. We'll continue to follow those and keep you informed. In the meantime, how are we looking in terms of cases and hospitalizations? Are those rates still going down, like we started to see a trend last week?

Garcia: Yeah, so nationally the country is averaging below 100,000 new cases daily for the first time since August 4. The average of 97,933 cases is down about 20% from two weeks ago and the new daily deaths are down 14%, to an average of 1,770. However, COVID caseloads do remain high in some parts of the country. So when we look at North Dakota and some of the Western states, like Wyoming, Montana and Idaho, where vaccination rates are relatively low, some of those states and some of those areas are really having to ration health care and send patients to distant hospitals for treatment.

Unger: I saw a post from Dr. Tom Frieden, former CDC director and frequent guest on our COVID-19 update, that said it has fallen below that 100,000 mark but let's be clear, that's a lot of people still. So the number is still relatively high, as you said. And in particular, some of those states that you mentioned are still in pretty dire territory. North Dakota being one of them that's really struggling right now. Anything specific you want to share regionally there?

Garcia: Yeah, I think the thing to point out in North Dakota is that the state's governor and health professionals are really asking residents to avoid any risky activities that could burden hospitals and health care systems. They've asked the public to do things like drive defensively and skip dangerous activities that could lead to head injuries. And of course, visit your primary care physician to make sure you're up-to-date on all your vaccinations. When we look at North Dakota, just 45% of the population is fully vaccinated against COVID. And when we look at that compared to the nation at 56%, we know that those low vaccination rates have an impact.

Unger: We'll keep an eye on that there. Get vaccinated, folks. Finally, any additional messages from the AMA this week that are of note?

Garcia: Just one, it's not COVID related but I think it's still worth mentioning, as it's a huge win for health care. So last week, the AMA came out with a statement in favor of the Biden administration's final Title X rule, which reversed the drastic changes to the Title X family planning program. We know this is a major victory for physicians, for health care professionals and of course, for millions of patients across the country who depend on Title X for access to essential reproductive care.

Since 2019, the AMA has challenged the former Title X gag rule, advocating against its inappropriate interference in the physician-patient relationship. And we're really extremely pleased that the new Title X regulations will restore and improve access to equitable, affordable care for patients.

Unger: That's good news for the ability of physicians to have those conversations with their patients. That wraps up today's COVID-19 Update. Thank you, Andrea, for being here and we'll check in with you again next week. We'll be back soon with another segment. In the meantime, for resources on COVID-19, visit [ama-assn.org/COVID-19](https://www.ama-assn.org/COVID-19). Thanks for joining us. Please take care.



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