Second booster for over 50 & monkeypox antivirals with Andrea Garcia, JD, MPH

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, AMA Director of Science, Medicine and Public Health Andrea Garcia, JD, MPH, on the latest from the FDA and CDC, covering Novavax vaccine updates, getting a second booster shot and the continued spread of monkeypox across the United States. AMA Chief Experience Officer Todd Unger hosts.

The CDC Emergency Operations Center contact phone number (monkeypox): (770) 488-7100.

Find more information for health care providers on obtaining and using TPOXX (Tecovirimat) for treatment of Monkeypox.

Learn more at the Monkeypox resource center.

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. Well, Andrea, the BA.5 subvariant continues to make
headlines this week. How is this affecting cases.

**Garcia:** Well, it's good to be here, Todd. And as we discussed last week, BA.5 has emerged as the country's dominant variant and CDC modeling data released just this week shows that BA.5 now accounts for about 77.9% of new infections. And BA.4 is declining. It's at about 12.8% of infections. And while reports of cases had been relatively stable, the number of cases are, again, rising in the U.S.

The New York Times is reporting that daily cases grew to more than 129,000 cases last week and they are now rising in more than 40 states. And I feel like a broken record but we know as more people rely on those rapid tests, those reported numbers are an undercount. And that true number of cases is far higher. It has been widely reported that BA.5 is the most transmissible variant yet and it is driving that uptick in new cases.

**Unger:** Yeah, well, it's definitely a survey of one. I don't think I've ever seen this many people have COVID. So, definitely, that issue around the kind of testing certainly probably having an impact on that. Are you seeing those increased numbers in cases translating into any increases in hospitalizations or deaths?

**Garcia:** So, unfortunately, we are seeing hospitalizations also start to rise. About 40,000 people are hospitalized in the U.S. with COVID on average per day. That's up about 20% since the beginning of the month. The good news, I think, for now is that deaths are remaining fairly stable. That likely indicates that we're not yet seeing more severe disease with this variant.

That number is hitting around 400 deaths being reported each day nationwide. And, again, that is lower than that 2,600 a day at the height of the Omicron surge. So while BA.5 is better at evading immunity from prior infection and vaccination than previous variants, I think the good news is if you're vaccinated and boosted, your risk of serious disease and death still appears to remain low.

**Unger:** Well, that is good news and we're going to talk more about vaccination. First up on the vaccination front, it looks like people may soon have another option to get vaccinated. Last week, the FDA authorized another vaccine for emergency use. Tell us more about this new Novavax vaccine.

**Garcia:** So Novavax has been in development for quite a while but it was plagued by manufacturing challenges. It's a two-dose series administered three weeks apart and there's some excitement because this vaccine uses more traditional protein-based vaccine technology than our currently available mRNA vaccines, which may make it more appealing to some of those who had concerns about the mRNA vaccines. Which we know is a newer vaccine platform.

Also, it's a good option for those who have an allergy to a component of the mRNA vaccines. The Novavax vaccine contains a synthetic Coronavirus spike protein and an adjuvant to encourage
immune response. So FDA authorized it for people 18 and older. It's primary series only, so it'll be used for those roughly 10% of adults who have not yet received a COVID vaccine in the U.S.

And I would just note that ACIP is actually reviewing that data right now as we speak, and they'll be making a recommendation on use of that vaccine in the U.S. population. And, of course, we know if ACIP recommends the vaccine, and then, the CDC director signs off, that vaccine will then be made available in the U.S.

**Unger:** We'll keep everyone up-to-date. When you look at the application for emergency use authorization, what data was the FDA'S authorization based on?

**Garcia:** So it was a trial of more than 26,000 adults. Two doses of the vaccine were more than 90% effective at preventing symptomatic disease, and in those adults 65 and older, effectiveness was more than 78% at preventing symptomatic disease. I think the thing to keep in mind is these trials were completed during a time when alpha and beta variants were circulating in the U.S. So before Delta, before Omicron.

So we don't yet know how that vaccine is going to stand up against the current subvariants. The most commonly reported side effects to the Novavax vaccine were pain, tenderness, redness and swelling at the injection site, fatigue, muscle pain, headache, nausea, vomiting and fever. There were a few cases of myocarditis in the trial, which seemed more common in younger men. And those numbers were small, similar to what we've seen in the mRNA vaccine.

**Unger:** Well, it's good to know that we may soon have another vaccine for at least some of those people who remain hesitant, as you said, about the mRNA vaccines or might have allergies to that. Booster shots also continue to be really important as you talked about up front, especially as waning immunity becomes a bigger challenge. A new CDC report confirms the specifically for Omicron subvariants. What did that report say?

**Garcia:** So that CDC report looked at first and second mRNA booster doses and showed that it helped bolster people's defenses. The shots raised people's level of protection against Omicron subvariants, restored some of that protection that was lost as time passed since their last shot. We know that vaccine effectiveness was lower during the BA.2, BA.2.121 period than during the BA.1 period.

And that third vaccine dose provided additional protection against moderate and severe COVID illness in all age groups. With that fourth dose providing additional protection in adults age 50 and older. So, really, the suggestion here is that if you are eligible for a booster shot, you should get one immediately.
Unger: And I've done that. Not to date myself here but very, very important for everyone to get that additional booster if you can. This also supports the administration's recent efforts to push for the expansion of a second booster dose to all adults. Let's talk a little bit more about that.

Garcia: So the Washington Post reported last week that administration officials are developing a plan for all adults to receive that second booster dose. That is, of course, contingent on FDA and CDC signoff. So right now, that second booster dose is only available to those 50 and older, as well as those 12 and older who are immunocompromised.

We heard the CDC director note that many Americans are under-vaccinated with only 28% of those 50 and older having received that second booster dose. So the administration here is really hoping that their plan will help increase that number, especially as we see cases and hospitalizations rising.

Unger: And with that, I think it's big news, too, that the administration also recently announced that it was extending the COVID-19 public health emergency. What exactly does that mean?

Garcia: So the emergency declaration has been in place since January of 2020. That extension for three more months goes through October 13. The administration indicated that this public health emergency provides essential capabilities and flexibilities to hospitals to care for patients, particularly if we're to see a significant increase in hospitalizations in the coming weeks.

It allows patients to obtain free testing, therapeutics, treatments and vaccines. And when that public health emergency ends, we know that people could face out-of-pocket costs depending on whether they're covered by Medicare, Medicaid or private insurance.

Unger: So that extension really, really important. In other vaccine news, it's been now about a month since vaccines rolled out for children under five. What is our update there? How's it going?

Garcia: So we're seeing about 400,000 children under the age of five out of the nearly 19 million who've received at least one dose of the vaccine since that FDA authorization and CDC recommendation last month. CDC is encouraging physicians to help with this effort and correct some of those widely-held misconceptions that are out there.

That includes that, of course, the vaccines aren't safe, or that COVID doesn't affect young children. And just as a reminder that since 2020, there have been over two million COVID cases in kids age six months to four years, over 20,000 hospitalizations and more than 200 deaths. And long COVID is a threat to children as well. But we know that some of the pediatric long COVID clinics around the country have month-long waiting lists for children suffering from long COVID symptoms.

Unger: Wow. That's terrible and really significant. Even more important to get those young folks vaccinated. Well, moving on from COVID-19 to the other infectious disease that's making a lot of
headlines lately, monkeypox. I had a chance to talk to two representatives from the CDC last week to get an outline of a lot of the details around this. What are the updates there, Andrea?

**Garcia:** So the CDC held a media briefing last Friday. We know the monkeypox outbreak continues to grow in the United States and that supply of vaccine is ... the demand is outstripping the supply. The federal government is making another 131,000 doses of that vaccine available to states and other jurisdictions.

But the scope of the outbreak really remains unclear and that's in large part because testing has been challenging. The CDC has teamed up with five commercial labs to expand testing capacity. We're now at about 70,000 samples per week and that capacity is up from 6,000 at the beginning of the outbreak.

Dr. Walensky said on Friday that nearly 1,500 cases have been identified so far in the U.S. We know that number is likely to rise in the coming weeks, and globally, we're at more than 11,000 cases in 65 countries.

**Unger:** When we spoke with the CDC last week, we did talk also about antivirals. Are those easily accessible at this point?

**Garcia:** So we're definitely getting a lot of questions from physicians on that, and we know CDC is trying to make it easier for health care providers to request TPOXX or tecovirimat, which is an antiviral that can be used under special circumstances to treat monkeypox. And the agency recently posted updated information clarifying that ordering process on their website and we'll put that link in the description of this episode.

But they're really clarifying that documentation that is required for obtaining TPOXX can be submitted after clinicians receive the drug and begin patient treatment. And some of the prior requirements to photograph and document lesions and collect and ship specimens from CDC are now being made optional, so health care providers can begin administering TPOXX as soon as they obtain informed consent from the patient.

And we know that additional modifications these protocols are being worked out with the FDA, and they'll be announced soon. Clinicians and health care facility pharmacists can request TPOXX through their state or territorial health department or by reaching out to the CDC Emergency operation center directly.

**Unger:** Well, that should certainly speed up the ability to get those important antivirals out to folks. And we'll include that CDC number, as you said, in the description below, so check that out. That's it for today's COVID-19 Update. Andrea, thanks again for being with us here today. We'll get you back here next week for an update. For resources on COVID-19, you can always go to ama-assn.org/COVID-19. Thanks for joining us today and please take care.
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