Vaccine trials ramp up for possible fourth dose in fall 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 Chief Experience Officer Todd Unger reviews rising COVID-19 case numbers and trending topics related to the pandemic over the past week with AMA Director of Science, Medicine and Public Health Andrea Garcia, JD, MPH.

Also covering updates from FDA’s vaccine advisory committee meeting regarding a revised version of the COVID vaccine for fall, the FDA suspending use of a monoclonal antibody drug by GlaxoSmithKline known as sotrovimab to treat high-risk COVID-19 patients in the U.S. because it’s unlikely to be effective against BA.2 and a clinical trial published in NEJM confirms that the anti-parasitic drug, ivermectin, showed no sign of alleviating COVID.

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, also in Chicago.
Andrea, thanks for joining us. Last week, the FDA’s advisory committee met across the ... about the country’s booster strategy going forward. Do we have any clarity coming out of that meeting?

**Garcia:** Thanks for having me back, Todd. Yeah, that advisory committee meeting, of course, followed the FDA’s authorization of that second mRNA booster dose in select populations, so those over 50 and people who are immunocompromised. The meeting last week was more the overall framework for booster doses, so thinking about a process for determining strain composition for future COVID-19 vaccines and then optimal use of those booster doses in the general population.

At this point, experts still will have to make decisions with a lot of uncertainties. I think, listening to that meeting, we came away with that with more questions than answers but the basic questions they talked about were how are we going to modify our existing vaccine so they work better? I think the one thing that is clear is that, if we hope to redesign our COVID vaccines before the fall, it’s going to have to be done so on a very tight timeline. Essentially, the clinical trials would have to be underway next month in order to produce those shots in time for the fall.

**Unger:** Wow, that is a super tight timing as we think about how to get ready for the fall. Are there any clinical trials that are underway now?

**Garcia:** There are clinical studies that are already underway, some being conducted by the NIH and some being conducted by the vaccine manufacturers themselves. We’ve talked before about how Pfizer and Moderna are both doing studies of vaccines that are focused on the Omicron variant. Those trials are pretty small and they're not going to give us the level of data that we had when our existing vaccines were authorized but they could give us enough information on immune response data to allow us to determine whether those new retooled vaccines will work better than the ones we're currently using. FDA did say that they’re going to need a clear basis for deploying a modified vaccine in lieu of the current vaccines, so I think the other thing we just need to keep in mind is the timeline for manufacturers to produce a vaccine and that's certainly going to be a factor.

**Unger:** It sounds a little bit to a layman like me, the flu vaccine where there’s always some kind of predictive work going on. Is there, I don’t want to use the word, guesswork, but involved in designing a new vaccine at this point?

**Garcia:** Yeah. There were a lot of comparisons to that flu vaccine process that we go through every year. I think, with COVID, no one really knows which variant of the virus is going to be dominant in the fall and there are some chance that another variant like Omicron will emerge that changes things entirely. As you know, COVID has just been difficult to predict. One expert at the meeting pointed out that COVID has been mutating at a much faster pace than the flu virus, so we do redesign vaccines for flu annually. We'll have to see how the trials play out. There's a chance that our existing vaccines will still turn out to be the best ones.
Unger: All right. Well, we'll continue to track that story as it develops. We haven't talked about vaccine mandates in a while, but there has been a new development at the federal level. Will you give us some background on that?

Garcia: Yeah, so on Thursday, a federal appeals court reversed a decision that had blocked the White House from requiring federal workers to be vaccinated against COVID. Back in September, President Biden had said the vast majority of federal workers would have to be vaccinated or they would face disciplinary measures, and then that preliminary injunction was instated in January by a federal judge from Texas and that stopped the administration from enforcing the mandate. However, at that time, the White House said that about 95% of federal workers were already in compliance with the mandate but this 2-1 vote from the U.S. Court of Appeals for the Fifth Circuit ruled that the judge in Texas did not have jurisdiction to block that mandate.

Unger: Wow. That is quite a development. Also, on the government front, the $10 billion COVID response package that we talked about last week has now stalled at Congress. What's happening there?

Garcia: Yeah, so that essentially boils down to a dispute over immigration restrictions. Lawmakers from both sides have said that they support this money for vaccines, for testing and for therapeutics but Republicans last week indicated that they wanted the chamber to first hold a vote on maintaining an immigration policy that restricted immigration at U.S. borders since the beginning of the pandemic, and then Democratic leaders declined to hold such a vote and that is why we're seeing that package currently stalled. The White House press secretary did say that this is a step backwards for our ability to respond to the virus and she said, of course, that the administration is going to continue to work with Congress to move that legislation forward.

Unger: Well, it seems like a tough time for funding to be stalled in my very unscientific feeling. I know a lot of people are getting COVID right now. You read headlines in the paper about that stuff that's happened in Washington at a big event there. Are we seeing good news or bad news with cases and hospitalizations?

Garcia: According to the numbers from the New York Times, after two months of sustained decline, new cases in the U.S. have generally been flat and that outlook at the state level continues to be really mixed. We're seeing COVID cases increasing in about half the states and territories, particularly the Northeast where we know BA.2 has been particularly widespread. Some of those states seeing an increase are Alaska, Vermont, Colorado, Rhode Island and New York but we're also seeing those cases decrease in the other half of the states. As of this morning, CDC has said that BA.2 is now accounting for about 85% of COVID cases. That percentage in the Northeast still remains high, the highest. It's around 92%.
Unger: So, basically, it's pretty much overtaken a prior variant, and it looks like places like New York and Washington, which I just mentioned, have been in the press a lot, seem to be experiencing the biggest spikes. What's happening there?

Garcia: Yeah, certainly, New York City and D.C. are in the news a lot. We've heard a lot of reports about high-ranking government officials in D.C. testing positive over the past week, and in New York, Broadway shows are once again shutting down due to stars who are testing positive as well. Looking at the numbers in those jurisdictions, cases have doubled in D.C. and they've increased to about 60% in New York City since the last week in March.

Unger: All right, so that's a lot, a huge spike. What does it mean?

Garcia: We still don't know exactly what it means overall and how this is going to play out. I mean, certainly, we know that Broadway actors and politicians in Washington are probably tested more frequently than the rest of us are, so we could be finding cases in those populations that would, otherwise, go unnoticed in the general population but I think it's likely that cases are being significantly under-counted and incomplete data is probably masking an upward trend.

We know that those at-home tests, we've talked about this before, they've become more widely used, and they're not typically reported or included in government data. I think, either way, we just need to keep in mind that, with public health mitigation measures being rolled back, BA.2 is highly contagious. It's still spreading. Even if we're not experiencing that widespread surge in cases that we saw in Europe, the virus is still here. I think the other thing to know is Philadelphia yesterday announced the return of their indoor mask mandate due to rising cases and it's something we could certainly see in other jurisdictions.

Unger: The hypothesis there on home testing kits seems to jibe with my anecdotal experience here in Chicago. Is it showing up in the numbers for hospitalizations? Is there anything that would help confirm what the scenario really is?

Garcia: That decline for hospitalization has continued. Hospitalizations are averaging roughly 15,000 per day over the past two weeks. That is still really low. It's the lowest that number has been since the first week of the pandemic. Deaths are also declining, so we're around 600 deaths from COVID being reported each day and that's down 75% from the peak in February during the Omicron surge.

Unger: That is good news. In other news, Ivermectin, which we have not talked about in a while, is making headlines again, this time with some definitive news about its effectiveness. What is the word there?

Garcia: Yeah, so we've seen a large clinical trial now confirm something that we already pretty much knew, and that was that the antiparasitic drug showed no signs of alleviating COVID. The study
compared more than 1,300 people infected with SARS-CoV-2. It took place in Brazil. Participants received either Ivermectin or a placebo and the researchers found that Ivermectin did not cause any significant differences in COVID-related hospitalizations or the duration of time spent in emergency department observations. Those findings were published in the New England Journal. We did see some early conversations around those results in August but this was the first time that dataset was published and, of course, this reaffirms that physicians should not be prescribing Ivermectin as a treatment for COVID.

**Unger:** That is, again, more news to reaffirm that. Additionally, we just saw the FDA suspend the use of another antibody treatment. What do physicians need to know about this latest move?

**Garcia:** Yeah, so the FDA has said they're suspending use of the monoclonal antibody Sotrovimab, which is used to treat high-risk COVID patients and that's similar to actions we've seen from them in recent months, and it's because it's unlikely to be effective against the BA.2 sub-variants. The manufacturer is preparing to submit data to regulators to seek authorization for a higher dose, which they think will work against BA.2. We know that shipments of the drug have already been halted in eight states and two territories in March, and that was because BA.2 was prevalent in those areas and we knew that the drug wasn't working. I think physician need to know that, if they're treating high-risk patients, there are other monoclonal antibodies like the one from Eli Lilly that they can use and there are also the three oral antiviral treatments that have been found in laboratory to be effective against BA.2.

**Unger:** Thanks so much for that update, Andrea. That's it for today's COVID-19 Update video and podcast. We'll be back soon with another update. In the meantime, resources, find them at ama-assn.org/COVID-19. Thanks for joining us today. Please take care.

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