Andrea Garcia, JD, MPH, on Omicron, mandate challenges and the COVID pill

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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 the Omicron variant, vaccine mandate challenges and pending FDA authorization for Merck's COVID pill.

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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, AMAs chief experience officer, also in Chicago.

Andrea, a lot has changed since we spoke last before Thanksgiving, including the emergence of a new variant of concern, Omicron. We talked with Dr. Peter Hotez in depth about it this morning and
that episode is going to air on Monday. In the meantime, what are the main issues that we need to be thinking about as we wait for new information to become available?

Garcia: Well, thanks for having me and that's right. When a new variant emerges, scientists are really looking for three things: that's whether the variant spreads faster or is more transmissible, whether it's evading immune response and whether it causes more serious illness than other variants. We should know more about this by the middle to end of December. But as you likely talked about with Hotez, while we don't know definitively how protective our current vaccines are against this variant, we do know that it's unlikely for this variant to completely escape the vaccinated immune response all together.

Unger: So a lot to learn and information will be coming from all over the globe on that and different kinds of research, we will eagerly await. Dr. Hotez's advice, just to give a little preview of it, was like the roadmap remains the same, get vaccinated, get your booster. What other messages are out there? Is that basically it?

Garcia: The message continues to be get vaccinated and the sooner, the better. CDC Director Dr. Rochelle Walensky said, "I strongly encourage the 47 million adults who are not yet vaccinated to get vaccinated as soon as possible and to vaccinate their children and teens as well." New variants emerge when we have a large proportion of a population unvaccinated. That can be at the community level, at the country level or at the global level, so getting vaccinated not only helps protect the individual and those around them, it also gives the virus fewer opportunities to mutate in a way that can be harmful to all of us.

Unger: And that's a global issue. And we have obviously a large unvaccinated population here, but in Africa we're talking under 10% vaccination rates. And so according to Dr. Hotez the emergence of these kinds of variants, it's predictable that it will happen, so just getting vaccinated. But what advice do we have for people who are already vaccinated?

Garcia: Well, it's important even for vaccinated people to get tested for the virus if they develop symptoms. I think the good news is that our tests do detect the new variant. But if you listen to what CDC said, they're saying increased testing is going to help us identify this new variant quickly. Everyone should also continue practicing prevention strategies that we know work like masking, distancing, avoiding crowds and poorly ventilated spaces. These things are going to be especially important this winter and important even in individuals who are vaccinated.

We also know that getting a booster shot should be a top priority for vaccinated adults. Boosters have been shown to raise antibody levels significantly and those antibodies may not be able to neutralize the new variant entirely, but experts have said that having more antibodies is generally beneficial.
Unger: And I watched yesterday's news conference with Dr. Walensky. CDC does agree. The agency has strengthened its booster recommendation. What in that has changed?

Garcia: So on Monday the agency updated the recommendation language to say that all adults in the U.S. should get booster doses of the available COVID-19 vaccines if you're six months past your primary series with Pfizer or Moderna vaccines or two months after the single shot of the J&J vaccine. So that previous recommendation said that people over age 50, as well as those 18 and older living in long-term care facilities should get a booster shot. The previous recommendations said that all other adults may decide to get a booster based on individual risk, so that shift from “may” to “all should” for all adults is the big change and that really reflects a growing concern about the new variant.

Unger: Now, we may also assume or see booster eligibility expanding to younger people too. Any news there?

Garcia: News is circulating both in the New York Times and the Washington Post that Pfizer may apply for regulatory authorization for a booster shot of its COVID-19 vaccine in 16- and 17-year-olds as early as this week. If authorized, this would be the first booster shot available to those under age 18. Of course, at the time of this filming, that hasn't yet happened, but certainly we'll be watching for that.

Unger: Now, the Omicron variant has now been identified in 20 different countries and most experts feel it's only a matter of time before we see it in the U.S. It may already be here, that we don't know. We're now ramping efforts to find out. You mentioned this kind of a little bit before. Through testing, is that how that happens? How do we see if it's here already or when it does appear?

Garcia: Federal health officials said on Tuesday that they're expanding surveillance programs at four international airports: New York, Atlanta, Newark and San Francisco. And in a news conference on Tuesday, Dr. Walensky said the agency is actively looking for the variant. She also said that CDC was examining ways to make international travel safer. I think the other thing to keep in mind is genomic surveillance has really increased since the beginning of the pandemic. We saw increased funding put towards that, and we are now sequencing more samples than we were early on, so we have a better chance of identifying it earlier.

Unger: So, a lot of confusion out there in terms of travel. What does it mean for people that are trying to come into the U.S. at this point?

Garcia: So the travel changes will likely be stricter testing requirements. A spokesperson for the CDC has said that international flyers to the U.S. may be required to provide a negative test within 24 hours of departure. Currently, fully vaccinated people are allowed to take a PCR test up to three days before departing a flight to the U.S. It's still unclear whether the new rule would require a rapid PCR or an antigen test and we don't yet know the timeline for those changes. The president is scheduled to
speak later this week and we should know more about these potential changes then.

**Unger:** Well, speaking of the president, we did hear from him earlier this week. The key message ... There's a lot of panic out there and I think the key message that came across was that this is a cause for concern and not a cause for panic. What else did we hear from the administration on that?

**Garcia:** That's right. That was the message and the president said the administration is working with vaccine manufacturers to modify vaccines and booster shots, only should they prove necessary though. I think at this point we don't know that that change is needed, but we're preparing as much as possible. His direct quote was, "I'm sparing no effort removing all roadblocks to keep the American people safe. Part of those efforts include working with the NIH to outline a strategy for how we're going to fight COVID this winter." He has said that this strategy would not focus on lockdowns, but rather more widespread vaccination, booster doses and testing.

**Unger:** Vaccinations obviously continue to be number one strategy here. We have crossed a little bit of a threshold on terms of vaccination rates getting over 70% in terms of one dose. How are those numbers looking?

**Garcia:** According to the CDC, this week the total is 233.2 million Americans who've received one dose and that is 70.2% of the total population. Of those 197 million are fully vaccinated. That's 59.4% of the population. And so far the CDC is estimating that 41.1 million people have received a booster dose.

**Unger:** In terms of cases and hospitalizations, do we have any knowledge of how the Thanksgiving holiday might have affected this? I mean, we are seeing kind of an interesting pattern that's across the country with different states. What are you seeing there?

**Garcia:** So I mean, I think you hinted at it and we've seen this after almost every holiday, is that we don't have an accurate figure for either cases or hospitalizations due to the holiday weekend. Many health departments do not report data on Thanksgiving and some did not return to normal reporting until after the holiday weekend altogether, so this makes tracking cases immediately post holiday really difficult. And because of this, we tend to see that artificial drop in cases due to a lack of reporting rather than a true decline.

Ahead of Thanksgiving, we were averaging about 95,000 new cases a day. That was up 25% over the previous two weeks. The CDC data from the Monday after Thanksgiving indicated that we had seen more than 504,000 new cases and more than 5,000 deaths over the past week. Again, those numbers are likely distorted due to discrepancies in reporting.

**Unger:** Well, in terms of vaccine mandates, we see continued challenges. Most recently, we've had the vaccine mandate for health care workers that's hit a roadblock. Where does that stand?
Garcia: On Tuesday a federal judge issued a preliminary injunction to halt the start of the administration’s national vaccine mandate for health care workers. That was set to begin next week, with the first dose of the vaccine to be required on December 6. The judge wrote that mandating a vaccine to 10.3 million health care workers is something that should be done by Congress, not a government agency. I think we know that cities, and states and health systems have already been mandating vaccines for health care workers. This was already happening before the president called for nationwide compliance.

Unger: So it's interesting because those have been reviewed, other mandates have been reviewed and supported through the Supreme Court, so we'll see what this comes out. Separately, the one with the mandate for private employers with more than a hundred or more workers also ran into a roadblock. Where do we stand with that?

Garcia: Yeah. An appeals court temporarily halted the OSHA emergency temporary standard mandate as well. The argument is similar, that OSHA has overstepped its authority with that mandate. We did see CMS issue a statement regarding the health care worker mandate. They said while they can't comment on the litigation, CMS has remained committed to protecting the health and safety of beneficiaries and health care workers, and the vaccine requirement for health care workers addresses the risk of unvaccinated health care staff, the patient’s safety, and it provides stability and uniformity across the nation's health care system. The injunction issued Tuesday is a first step in the lawsuit against vaccine mandates and these cases still have to be argued before a judge. And any lower court ruling is likely to be appealed, so there's, I think, a long way to go in settling these cases.

Unger: Well, last question. This week also brought news about Merck's COVID pill treatment for someone that has COVID. What is the update there?

Garcia: So, the FDA's advisory committee met yesterday. In a narrow 13 to 10 vote they voted to endorse the antiviral pill from Merck for adults at high risk of becoming seriously ill with COVID. The drug has been show to modestly reduce the risk of hospitalization and death. The drug could be authorized within days and available in the U.S. soon after. We're waiting to see the news about the Pfizer oral antiviral. That one is expected to be significantly more effective than the Merck pill. And we don't yet know when the FDA advisory committee will be reviewing that data, but it's probably a few weeks behind the Merck decision based on when the press releases came out.


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