FDA advisors recommend COVID vaccine update for fall with Andrea Garcia, JD, MPH [Podcast]
In today’s COVID-19 Update, Omicron summer surges, progress on booster shots for fall, kid’s COVID vaccine rollout, monkeypox vaccines distributed and more discussed by AMA Director of Science, Medicine and Public Health Andrea Garcia, JD, MPH, and AMA Chief Experience Officer Todd Unger.

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, coming off this big Fourth of July weekend, let's start by taking a quick look at the numbers.

**Garcia:** Thanks for having me back, Todd. And yes, heading into the holiday weekend, daily reported COVID cases continued to really largely remain flat. And as we've talked about, they've been that way for quite some time. And if we look back at the month of June, we really saw very little fluctuation in the reported cases. They never really went below 95,000 and they never rose above 115,000.
Even in some of the areas that are seeing the largest per capita outbreaks, like Florida, cases are really only falling or rising by a few percentage points.

**Unger**: Besides Florida, do you see any other kind of geographic trends in the U.S.?

**Garcia**: Yeah. So according to The New York Times, there are significant regional differences. In much of the Northeast, cases have decreased continuously throughout the month of June. In the South, many states have cases that have doubled or tripled in that same time period.

Hospitalizations have increased a little throughout the month, though they remain relatively low. Just over 32,000 people are in the U.S. hospitals with COVID on an average day and about 4,000 of those patients are in intensive care. Deaths have been more difficult to track because of the delays in holiday reporting. Overall, they do remain below 400 a day, which continues to be significantly lower than that 2,600 a day we saw at the height of the Omicron surge.

**Unger**: I saw a reference to the July 4 travel as "airmageddon," but traffic in airports, of course, at pre-pandemic levels. Any insight as to whether this is going to affect the numbers?

**Garcia**: I think we don't know yet. And we probably won't know for some time what, if any, effect increased travel, particularly over the holiday, will have on COVID cases. You said we do know that according to TSA checkpoint metrics, travel is approaching those pre-pandemic levels and it was the case before the holiday. And of course, that turning point came around mid-June when the U.S. dropped its testing requirement for reentry, and that change has also brought with it some of that summer travel chaos.

**Unger**: I guess one of the big questions is around new Omicron subvariants that have become dominant in the U.S. as of late last week. Let's take a deeper look into where we stand with that and what it means.

**Garcia**: According to estimates from the CDC last Tuesday, the Omicron subvariants known as BA.4 and BA.5 combined together became the dominant circulant variant in the U.S. That data was refreshed today, and BA.5 alone now represents 53.6% of cases and BA.4 is up to 16.5%.

So definitely BA.5 is increasing rapidly across the country. These statistics are based on modeling. They're revised as data comes in. But this, really, the surge in BA.4, BA.5 comes less than six months after these subvariants were first detected in South Africa.

**Unger**: What do we know about these particular subvariants other than, of course, very contagious?

**Garcia**: Very contagious. We're still learning but early research shows that they are capable of eluding neutralizing antibodies produced after both vaccination and infection, and that includes infection...
caused by some of the earlier versions of Omicron. So this obviously helps explain why these subvariants have spread even faster than some of the others in the Omicron family.

I think, obviously, it's still early. The good news so far, though, is that there's not much evidence that these subvariants cause more severe disease. We've talked about South Africa. They've been detected throughout much of the world. That wave in the spring in South Africa saw a rise in cases but deaths did not rise as sharply. And we saw South Africa recently repeal their indoor mask requirements and that is because the BA.4-BA.5 wave there is now fading.

**Unger:** I know one of the big questions I'm hearing out there are about boosters in the fall and along those lines. The FDA advisors came out with a decision last week about boosters for that time frame. What is the news there?

**Garcia:** So shortly after we wrapped filming last week, the FDA's vaccine advisory committee, VRBPAC, voted 19 to 2, and their vote was around recommending a SARS-CoV-2 Omicron component for the COVID-19 booster vaccines in the United States. And then following that meeting, the FDA indicated that the next round of COVID booster shots should be modified to target the Omicron subvariants BA.4 and BA.5.

And the hope is that manufacturers will have reformulated boosters available in October in time to vaccinate people ahead of an expected winter surge. Dr. Peter Marks, obviously a top FDA official who the AMA has hosted numerous times through our vaccine webinar series, has pointed out that none of us have a crystal ball. He said, if you do come over to my house right now, I would really like it.

I think this really captures the guesswork that inevitably factors into decision-making about this unpredictable virus. However, I think the panel was very clear in voting in favor of recommending these redesigned booster shots to target Omicron or its subvariants rather than simply using the original version of the virus. And obviously, they talked about eroding immunity as a concern there.

**Unger:** So in terms of meeting this recommendation, are we now looking largely to Pfizer and Moderna to do that?

**Garcia:** Yeah. So both Pfizer and Moderna had been working on a booster candidate that combines the existing vaccine with Omicron itself, not its subvariants. However, I think the prevailing view in the meeting is that that vaccine may already be somewhat outdated. So, the companies had been including Omicron BA.1 vaccines in prep for the fall. They indicated that switching to a BA.4-BA.5 design could delay their introduction.

**Unger:** Wow. So is there a vaccine already in the works?
Garcia: So Pfizer said that they would have a substantial amount of a BA.4-BA.5 vaccine ready for distribution by that first week in October, which is good news. Moderna said it would be late October, early November before its modified vaccine will be ready. I just want to be clear here that the advisors are not recommending any change to that primary vaccine series, so if you need that primary vaccine, that will not be changing. You should go get that vaccine now.

Unger: One of the things we’ve talked about over the last two weeks, of course, is the vaccine rollout for kids, with the latest wave being for five and under. What is the update there? How is that going?

Garcia: So the CDC is continuing efforts to engage physicians, who they deem the most trusted sources of information for parents and caregivers, saying that physicians’ strong recommendation is, of course, critical to increasing confidence in COVID vaccines and helping to ensure that children get vaccinated.

The CDC’s efforts include a letter sent to clinicians from CDC Director Dr. Rochelle Walensky, which includes important considerations and tips for increasing uptake of the vaccine as well as a new pediatric vaccination toolkit. And that was launched as part of the Department of Health and Human Services’ public education campaign, which is called “We Can Do This.”

That toolkit is really designed to help physicians increase confidence in and uptake of COVID vaccines among patients and in the communities they serve. And more information can be found at wecandothis.hhs.gov.

Unger: So along with getting kids vaccinated and fall planning for COVID—big jobs—the government is also working on a separate strategy to contain another virus, monkeypox. What do we need to know about those particular efforts?

Garcia: Yes. Late last week, the White House announced that it would be sending out tens of thousands of monkeypox vaccine doses. Those will be going through state health departments and obviously designed to help control what is now a record U.S. monkeypox outbreak with an official case count of about 460. And we know that’s likely an undercount.

According to The Washington Post, this strategy is a part of a broader push for more testing and more public awareness of monkeypox. Vaccine distribution is going to focus on those states with the highest number of confirmed cases. And public health experts have indicated that really anyone can get monkeypox but gay and bisexual men have disproportionately contracted the virus at this point.

We know that according to the WHO, in most cases, monkeypox symptoms will disappear on their own within a few weeks. But for patients who are pregnant, children, people with weakened immune system, the disease can lead to medical complications, including death.
Unger: So just specifically, who should be looking to get this vaccine?

Garcia: So the CDC is now recommending vaccines be provided to both people with a known monkeypox exposure that are contacted by public health and those who have recently been exposed to monkeypox but may not be identified through case investigation and contact tracing. Ideally, people should be vaccinated within two weeks of possible exposure and the sooner you can get the vaccine after the exposure, the better.

Dr. Walensky has also said that she strongly encourages all health care providers to have a high clinical suspicion for monkeypox among their patients. Particularly patients presenting with a suspicious rash should be tested.

Unger: Good to know. And of course, we'll keep an eye on that if things continue to develop. That wraps up today's COVID-19 Update. Andrea, thanks so much for joining us today. We'll be back soon with another segment. For updated resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us today and please take care.

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