AMA Update

Jynneos, Tpoxx & federal services for long COVID with Andrea Garcia, JD, MPH

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In today’s COVID-19 Update, AMA Director of Science, Medicine and Public Health, Andrea Garcia JD, MPH, covers monkeypox cases, vaccines, Tecovirimat used for treatment, as well as two Biden administration reports and support services for Americans with long haul COVID. AMA Chief Experience Officer Todd Unger hosts.

Learn more about federal services and supports for people experiencing longer-term impacts of COVID-19.

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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 Affairs, Andrea Garcia in Chicago. I'm Todd Unger, AMA's chief experience officer, also, in Chicago. Well, welcome back, Andrea.
Garcia: Thanks. It's good to be here.

Unger: Last week, we started to possibly see some good news in terms of potential overall decreases in COVID cases. Does that continue this week?

Garcia: According to the New York Times data, the daily case counts have continued to tick downward and that's accompanied by similar declines in test positivity. Cases have decreased since mid-July in more than half of states, and in the states where cases are increasing, those increases overall are relatively small. We're only seeing a few states that have seen cases increase by more than 20% in the past two weeks.

Reported COVID cases are around 120,000 per day. That's down slightly from last week's number of 124,000 but still higher than numbers reported for much of the spring and summer. And the recent declines, I think, are good news and do suggest that conditions are improving.

Unger: Are we seeing those, I guess, slightly decreased numbers translate to hospitalizations and deaths as well?

Garcia: Well, for hospitalisations after increasing steadily from April through July, they have decreased slightly over the past week. And I think, if that trend continues, it's a good sign that the situation is improving. We know deaths lag behind hospitalisations. Deaths, unfortunately, are still increasing. They increased by about 11% in the last two weeks but they remain much lower than at most points during the pandemic.

And just to give you some idea, last week, we saw about 440 daily deaths, and this week, we're closer to 500. So not the right direction, higher numbers than we want to see but as we've repeatedly discussed here, those numbers are down from more than 2,600 deaths per day at the height of the Omicron surge. So hopefully, we'll start to see these numbers come down soon.

Unger: And one thing we're seeing a lot more about, obviously, in the news, as we continue to learn about the aftermath of COVID, is about long COVID and there were some efforts at the federal level about treating long COVID. Can you talk about the news there?

Garcia: Yeah, so last Wednesday, the Biden administration released two new reports on long COVID to support patients, and also, further research. In April, the Biden administration issued a memorandum on addressing the long term effects of COVID-19 and that memorandum called for the creation of these reports. The reports were developed by the Department of Health and Human Services and the two reports paved an actionable path forward to address long COVID and associated conditions.

Unger: What does that path look like?
**Garcia:** So the services and supports for longer term impacts of COVID-19 report outlines the federal services available to the American public to address those long term effects of COVID-19, including long COVID and other related conditions, as well as other impacts on individuals and families. The second report is the National Research Action Plan on long COVID. That was created with coordination of 14 government departments and agencies, and it introduces the first U.S. government wide national research agenda.

And that's focused on advancing prevention, diagnosis and treatment, as well as the provision of services and supports for those impacted. Both of these represent the federal government's response to ensure the acceleration of scientific progress and to provide individuals with long COVID with, really, the support and services they need. And more information about those plans can be found at covid.gov/longcovid.

**Unger:** That's good news. A lot of questions unanswered and a lot of people suffering out there. The federal government also took further action to help address the monkeypox outbreak, declaring it a national health emergency late last week. We had a conversation with Dr. Sandra Fryhofer, the AMA's board chair, with more details for physicians. Since that's happened, anything else new that we need to know?

**Garcia:** Last week, we talked about how CDC had designated monkeypox as a nationally notifiable condition and that was meant to help them collect data. They were going to be able to get data from states within 24 hours and that was to help CDC get a better understanding of spread of the virus. On August 4, as you mentioned, we saw that National Public Health Emergency, that declaration. That really signals the seriousness and the urgency with which the administration is responding. It helps free up emergency funds with some regulatory hurdles in responding to the virus. I think the big question now is if the outbreak is still at a point where it can be contained.

**Unger:** Can you tell us how specifically the National Health Emergency Designation changes or influences our response?

**Garcia:** Yeah, so a National Public Health Emergency Designation gives federal agencies the power to direct funding toward developing, evaluating vaccines and treatments, allows access to emergency funding, which otherwise wouldn't be available, and gives them flexibilities to hire additional workers to help manage the outbreak. It also has implications for data sharing with the federal government, which we know has been a challenge in this outbreak, and it provides authorities to CMS to collect testing and hospitalization data. And I think public health emergencies feel common now, because we've been living under one with COVID for years.

**Unger:** It feels like we've had a lot of them lately.
Garcia: It does but it's actually pretty rare. And this latest one is really only the fifth National Public Health Emergency since 2001, so this designation is under Section 319 of the Public Health Service Act. It's the secretary of HHS who has the authority to make the declaration. It usually lasts 90 days but as we with COVID, it can be extended.

I think the important thing that we need to keep in mind is this does not give FDA authority to authorize emergency use of vaccines, tests and treatments. That is going to require a separate declaration by HHS under the Federal Food, Drug and Cosmetic Act. But I think, overall, Public Health Emergency Declaration, many feel it's going to help raise awareness, especially in places outside of big cities, where there really has been less of a focus on it.

Unger: So a good step but the question about vaccines, still a big one out there, a lot of people looking for vaccine. In terms of the vaccine supply, where do we stand?

Garcia: So the Jynneos vaccine remains in short supply and that is likely going to be the case for several months. But this shortage is leading to conversations about how we stretch the doses we do have. It does feel a lot like when we had limited access to the COVID vaccine and when those—

Unger: I way going to say, this sounds familiar.

Garcia: It does. Yeah, there are a lot of similarities. The Jynneos vaccine is currently a two-dose vaccine spaced 28 days apart and some jurisdictions have talked about giving one dose to people, instead of two. And that's the strategy that FDA and CDC have disagreed with.

What we've seen, Dr. Robert Califf, the FDA commissioner, indicate that they are exploring a strategy that would expand available doses by giving a partial dose as an intradermal injection, so into layers of the skin rather than a full dose into that underlying fat. And if that works, then one-fifth of the current dose could be used to protect against the virus, like we talked about earlier. If FDA is going to authorize this, we're going to need to see HHS issue that new emergency declaration allowing regulators to invoke the FDA's emergency use powers. And while we've heard that may be coming soon, it hasn't happened yet but Dr. Califf did say that the FDA is optimistic about this idea. And they're expected to make a final decision soon.

Unger: Is there any data to support a strategy like that?

Garcia: There's some data to suggest that injecting the vaccine in this way could be just as effective because the skin is rich in immune cells that mediate the response to the vaccine. So this is sometimes used when vaccines are in short supply. It does require more skill in administering the vaccine.
Reportedly, the NIH had been planning to test the strategy in a clinical trial. That was set to begin in a few weeks with those results expected later in the fall. Now, that remains uncertain. The FDA would need to grant Jynneos an EUA for it to be administered in this way. It's still unclear whether a scaled back regimen is enough to prevent infection, and if so, how long that immunity is going to last.

**Unger:** Well, in addition to shortages on the vaccine side, there's still tough finding treatments. What's the story with that?

**Garcia:** Yeah, so we're definitely hearing from physicians that they are still navigating a cumbersome process with regard to prescribing the antiviral, Tecovirimat or TPOXX. This is FDA approved for the treatment of smallpox and it's being used for monkeypox under an expanded access investigational new drug protocol. The National Public Health Emergency Declaration did not change that, and FDA officials have said they believe that the regulations are necessary to ensure the drug is safe and effective in patients. And we do know that FDA and CDC have eased some of these administrative requirements for prescribing TPOXX but physicians are still suggesting that barriers do remain.

**Unger:** You mentioned earlier, the key question is if we are going to be able to get the situation under control. I mean, the numbers have continued to grow. When you're looking at shortages on the vaccine side, difficulty in finding treatments, what's that going to translate to for patients?

**Garcia:** I mean, I think this comes at a time when the U.S. actually has the largest number of monkeypox cases. It's spreading quickly. Less than a month ago, we were at about 700 cases, and now, we're over 10 times that. We're approaching 9,000 cases, highest per capita in Washington D.C., New York State and Georgia. And Wyoming, at this point, is the only state that doesn't currently have a reported case of monkeypox.

If you look at the currently available data, we know 99% of these cases are occurring in men. 94% have had male to male sexual or close intimate contact, and we know that racial and ethnic minority groups appear to be disproportionately affected. But anyone can get monkeypox. We've seen, at least, five children with confirmed cases now. Those are believed to be the result of household transmission. So really, the sooner that we can increase awareness and make vaccines and treatments readily available, the better.

**Unger:** Absolutely, and you can find out more information on monkeypox, everything that physicians need to know. It's on the AMA site, so visit ama-assn.org for more information. Andrea, we'll see you next week for an update on COVID-19, monkeypox and anything else that mother nature is throwing at us.

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