12 symptoms of long COVID, FDA Paxlovid approval & mpox vaccines with Andrea Garcia, JD, MPH

AMA Update covers a range of health care topics affecting the lives of physicians, residents, medical students and patients. From private practice and health system leaders to scientists and public health officials, hear from the experts in medicine on COVID-19, medical education, advocacy issues, burnout, vaccines and more.

Featured topic and speakers

A new study outlines the 12 symptoms of long COVID and the FDA fully approves Paxlovid for adults. In today’s AMA Update, AMA's Vice President of Science, Medicine and Public Health, Andrea Garcia, JD, MPH, also discusses who should get a monkeypox vaccine ahead of festival season this summer. AMA Chief Experience Officer Todd Unger hosts.

Watch this episode with Akiko Iwasaki, PhD, who shares what you need to know about long COVID.

Learn more at the AMA COVID-19 resource center.

Speaker

- Andrea Garcia, JD, MPH, vice president, science, medicine & public health, American Medical Association

Transcript

Unger: Hello and welcome to the AMA Update video and podcast series. Today, we have our weekly look at the headlines with the AMA's Vice President of Science, Medicine and Public Health, Andrea Garcia in Chicago. I'm Todd Unger, AMA's chief experience officer also in Chicago. Welcome back, Andrea.

Garcia: Thanks. It’s good to be here.
Unger: Well, we're coming off a big holiday weekend, which to many of us felt, well, we'll call it normal, like it did pre-pandemic. But I think, as you've been reading out there, we know that's not true for everybody, and especially those with long COVID. It's still affecting more than 65 million people worldwide. Now there's a new study that gives us more insight. Andrea, what can you tell us about that?

Garcia: Yeah. Well, the benefit of this new study is it really brings us a little closer to standardizing that definition of "long COVID." That's something that we really haven't been able to do to date. It's been three years. People are still defining long COVID differently.

And I think part of what's made it so difficult to define is that there are more than 200 lingering symptoms that are associated with it. And this study really narrowed down that list and identified 12 key symptoms that best define the condition. Long term, these findings could influence how long COVID is diagnosed, how it's treated, and how it's studied.

The study was published last Thursday in JAMA. It was based on nearly 10,000 participants who self-reported their symptoms through standardized questionnaires. It's part of the RECOVER initiative, which stands for Researching COVID to Enhance Recovery. It's that four-year, $1.15-billion study that is being funded by the NIH.

Unger: I read some quotes over the weekend in articles written about this particular thing and just frustration with the length of time it takes. But three years to kind of get to the symptoms. This is a lot of work going on right now out there. I understand there's also a point-scoring system that's involved as they narrow down these symptoms. What can you tell us about that?

Garcia: Yeah, that's right. And the study used that point-scoring system based on how likely the symptom was a true signal of long COVID versus another condition. And it assigned points to each of the 12 key symptoms. And researchers determined a meaningful threshold for identifying participants with long COVID.

So a participant needed to score a total of 12 points once all of their symptoms were added up. And some symptoms were more common in people who had COVID but less common in people who never had COVID. So if you think of things like loss of taste or smell or post-exertional malaise, which is a worsening of symptoms following even minor or—minor physical or mental exertion, those symptoms received higher points because if a person has them, it's more likely due to long COVID.

Other symptoms we know, like brain fog and chest palpitations, are common both in long COVID patients, but there are other people who have those conditions. So those symptoms received fewer points.
Unger: Just digging in a little bit more on that point system that you’re talking about, can you give us some examples for reference? How many points did loss of taste or smell, which you said were highly correlated with COVID symptoms—how much did that get?

Garcia: Yeah, so loss of smell and taste received the highest, which was 8 points. So you don’t need many other symptoms before you meet that long COVID definition. Likewise, post-exertional malaise was seven points. But then if you look at things like brain fog, that was three points. Chest palpitation was two points.

There are other things, like chronic cough, which was four, or chest pain, which is two. And then a handful of things that were really one point, like fatigue, dizziness, GI symptoms, issues with sexual desire or capacity and abnormal movements, including tremors. So those are things we know that can be common with other conditions as well.

Unger: So is this something that physicians should be implementing when they see patients as a "right now" thing?

Garcia: I think right now this should be viewed as very preliminary. And while the scoring is important for research and it’s an early step toward diagnosing and monitoring patients with long COVID, it does have limitations. And it’s too soon to be using the study or the scoring system to diagnose or determine eligibility benefits or even exclude people from treatment.

This is really one step toward helping us learn more. We know that more research is coming. And this research will really provide a foundation for planned clinical trials that are expecting to be enrolling patients this year.

Unger: We’ll continue to follow this as it develops. I did want to mention we had just an excellent interview with Dr. Akiko Iwasaki earlier last week just to go over some of the latest developments on the long COVID side. And I do encourage you to take a look at that on our YouTube channel.

Andrea, another development this past week has to do with Paxlovid, which has been around for a while, but there’s some news there. What’s that?

Garcia: Yeah, it didn't receive a lot of media attention. But the FDA did announce last week, that it has fully approved Paxlovid for the treatment of mild-to-moderate COVID in adults who are at high risk for progression to severe COVID-19, so including hospitalization or death.

Paxlovid is the fourth drug and first oral antiviral pill approved by the FDA to treat COVID-19 in adults. According to the FDA press release, Paxlovid is still being manufactured and packaged under an EUA and distributed by the Department of Health and Human Services.
And that's to ensure continued access for adults, as well as treatment of eligible children, so those who are 12 to 18 years old. And those children are not covered under this recent approval. And just as a reminder, Paxlovid is not approved or authorized for use as pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

**Unger:** What does that mean exactly?

**Garcia:** Well, an approval really demonstrates that Paxlovid has met the agency's rigorous standards for safety and effectiveness and that it remains an important treatment option for people at high risk for severe COVID, including those with prior immunity.

For those who may not be familiar, approval of a new drug requires, among other things, substantial evidence of effectiveness, a demonstration of safety for the drug's intended use, and in considering approval of the drug, the FDA is really looking at a benefit-risk assessment based on rigorous scientific standards to ensure that the product's benefits outweigh the risks for that intended population.

**Unger:** Andrea, as I recall, there was a lot of discussion or concerns about potential rebound infections and/or drug interactions with Paxlovid. What's the outcome there?

**Garcia:** Well, based on the currently available data to the FDA, that agency has said that there is not a clear association between Paxlovid treatment and COVID-19 rebound. There is, however, concern about potential drug interactions.

Along with the approval, FDA is providing all prescribers with important information for prescribing Paxlovid properly and safely. That includes dosing instructions. It includes potential side effects and information regarding drugs that may cause those drug-to-drug interactions with Paxlovid. So physicians should definitely review all medications taken by their patients to assess for potential drug interactions and determine if other medicines the patient is taking may require a dosing adjustment, an interruption, or additional monitoring.

**Unger:** All right. That's good to know, Andrea. Let's turn our attention to something we talked a little bit more about last week, which is mpox. Last week, we talked about new data on the mpox vaccine. This week, there's a lot of urging people to get it. Why now? And why is it so important?

**Garcia:** Yeah, well, last week, when we talked, we mentioned that we're at a time when people are beginning to gather for festivals and other events. That results in more opportunities for transmission, particularly as we kick off Pride Month tomorrow.

While cases dropped over the summer, as *The New York Times* article highlighted over the weekend, mpox never really completely disappeared. Public health authorities are warning of a risk of new
outbreaks. We've already seen and talked about that outbreak we saw in Chicago, which had a cluster that reached 30 cases by May 20. Based on those cases, we know we may be seeing some evidence of waning immunity from those vaccines.

Mpox is also a particular risk for people in marginalized communities. Of the 42 people who died in the U.S. during the last outbreak, almost all had poorly-managed HIV and about 40% were homeless. And that's according to data from the Kaiser Family Foundation.

Unger: Now, as I think I remember during the last outbreak, there was a vaccine shortage. Are there still supply issues?

Garcia: So as of right now, there isn't a supply issue. However, much of that emergency infrastructure that cities and other jurisdictions had set up to distribute those doses has been dismantled. Also, because of that initial shortage, we know that many people may have only received one dose of this two-dose vaccine, which means they may still be vulnerable to infection.

Public health authorities and nonprofit groups have begun to publicly remind sexually-active men who have sex with men to get that second dose of the vaccine if they haven't already done so. And we know health departments, like the New York State Department of Health, are launching outreach campaigns this month.

One includes a poster with the slogan, "It takes two," meaning two doses of the vaccine. And the CDC also put out a recent analysis that estimates that just 23% of the U.S. population at greatest risk has been fully vaccinated nationwide. And that ranges from about 5% in West Virginia to about 67% in DC. And the CDC is also estimating that the likelihood of a renewed outbreak this summer is about 35% in most places.

Unger: All right. So still a ways to go there. Andrea, thanks so much for that update. We'll continue to watch what happens there throughout the summer and be back to you with another episode soon.

So in the meantime, you can check out all our videos and podcasts at ama-assn.org/podcasts. Thanks so much for joining us. Have a good week.

Disclaimer: The viewpoints expressed in this video are those of the participants and/or do not necessarily reflect the views and policies of the AMA.