

FDA's latest on J&J vaccine safety concerns and more with Andrea Garcia, JD, MPH

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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 a newly released estimate for COVID-19 related deaths using excess mortality, as well as summer spikes of coronavirus cases, hospitalizations and that masking up in airports or high-risk settings continues to reduce chances of COVID infection.

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 so much for joining us for today's update. Big news on the vaccine front with the J&J vaccine, what is the latest there?

Garcia: Thanks for having me, Todd, and that's right. Last week, the FDA said that the J&J vaccine should only be used for adults who can't access the mRNA vaccines, so Pfizer or Moderna vaccine. And the J&J vaccine should only be used for those who've experienced a severe allergic reaction or

another issue with one of the mRNA vaccines and for whom the mRNA vaccines have been deemed not clinically appropriate. So the J&J vaccine can still be given to adults in those situations or to adults who would otherwise not receive a COVID vaccine. And the agency came to this decision after weighing the risks and the benefits of the J&J vaccine.

Unger: I'm curious. What do we know more about those risks, specifically, and why the change now?

Garcia: Well, the agency said there have been 60 cases of a rare but serious blood clotting disorder, known as thrombocytopenia or TTS. And that includes nine deaths out of about 18 million doses administered. In a statement, Johnson & Johnson said that the FDA's action really reflected what we've already known about the risk of the side effect and it's not about new data on the rate at which it occurs. However, federal officials have said that the vaccines produced by Pfizer and Moderna are both safer and more effective. And as a reminder in December, the CDC had already gave a preferential recommendation for adults to either get a Moderna or Pfizer booster instead of J&J and that was even for those who had initially received a J&J vaccine. I would just note that the J&J vaccine does remain an important tool in the pandemic, particularly globally as we think about the storage considerations for those mRNA vaccines. So J&J is still used widely in other countries.

Unger: Well, speaking of global news, one of the additional pieces of information that came out was about a potential undercount in deaths related to COVID. Let's talk a little bit more about that. Where does that come from in terms of excess deaths?

Garcia: Yeah. So last Thursday, the World Health Organization reported that nearly 15 million more people died during the first two years of the pandemic than would've been expected during normal times. That's more than twice the number than originally thought. So if we look at countries reporting COVID death, that previous count was about six million.

Unger: Well, that's quite a big difference. What underlies an under count like that?

Garcia: Yeah. So the new estimates were calculated by a panel of experts from the WHO using, like you mentioned, excess mortality, which many scientists see as the more reliable gauge of the pandemic's impact. We've often talked about how there are huge gaps in the global death data. So we can't really rely on those individual countries reporting to capture that true figure. By calculating based on excess mortality, the panel basically looked at the difference between the number of people who died in 2020 and 2021 and the number of people who would've been expected to die during that time if the pandemic hadn't happened.

Unger: So can you attribute all of those excess deaths to COVID or are there other causes?

Garcia: So we think most of those excess deaths were from COVID itself. However, as we know, some of those deaths happened because of various points in the pandemic. It was more difficult to get

medical care for conditions such as a heart attack. So that obviously impacts deaths as well. We know that many of the deaths occurred in 2021, when we had more contagious variants circulating in countries that previously had survived outbreaks and we continue to see evidence of disparities in those numbers. So nearly eight million more people than expected died in lower to middle-income countries. And as we look at deaths reported in the U.S., according to the figures from Johns Hopkins, were nearing in on that one million death mark and we're expected to hit it sometime this week. According to the Washington Post, we have a far larger number, about nine million Americans who've lost a spouse, or a parent or a grandparent, or siblings and children in COVID.

Unger: It's really difficult to even to comprehend the scope of those losses. When you look at the state of things right now, how we're looking at some, it seemed like from what I'm hearing, that the numbers continue to creep up.

Garcia: Yeah. They definitely are. According to the New York Times, we're now averaging about 73,000 cases per day, that's up 49% over the last two weeks. And this surge appears to be driven by the new BA.2.12.1 variant, which as of this morning represents about 42.6% of COVID cases in the U.S. We know that in more than a dozen states, the daily case average is twice as high than it was two weeks ago. And there are jurisdictions like Hawaii, Maine and Puerto Rico where the case counts are now approaching or surpassing those levels that we saw during the Delta surge.

Unger: One of the things we've talked about over the past couple weeks is that hospitalizations didn't seem to be moving up as the numbers in terms of cases were going up. Does that remain the same or has there been a change there?

Garcia: There's been a bit of a change. And we are seeing hospitalizations also increase. We're at about 19,000 people in hospitals with COVID each day in the U.S. That's up about 20% from two weeks ago. So again, we're starting to hear those concerns about strain on our health care system. Those figures of course include patients who are in the hospital because they're very ill with COVID as well as those who've been admitted for other reasons who've tested positive upon arrival. And of course the CDC is keeping a close eye on the nature of hospitalizations. CDC director, Rochelle Walensky, said last week that we're seeing less oxygen use and less ICU stays. And we haven't, fortunately, seen an increase in death associated with these days so far, which is relatively good news.

Unger: So Andrea, how should people be thinking about numbers like this and their risk right now? We, of course, just had families getting together for Mother's Day. I'm going to be going to my daughter's graduation with my whole family next week. We've got proms, other parties, all sorts of things.

Garcia: Yeah. Well, everything that we've talked about previously really still applies. And most experts are still recommending that people test frequently if they're mixing in a large group and that people,

particularly those who are at increased risk, should consider continuing to wear a mask in indoor public settings even if they're not currently required. And just as a reminder, if you are masking, choose a high quality respirator, like an N95, a KN95 or a KF94 and make sure it's well fitting. Ventilation is also key. We know that outdoors remains much safer than indoors and not all indoor settings are equal. There's a big difference between a large room with open windows and lots of space versus a small cramped and closed area where people are packed together.

Unger: What about the situation with masks? Of course, big change a few weeks ago in terms of mask requirements and travel. The CDC also issued a statement about masks and travel. What is the news there?

Garcia: Yeah. On May 3, the CDC released a media statement regarding wearing masks during travel and in public transportation settings. And the CDC does continue to recommend that everyone aged two years of ... two years of age and older, including passengers and workers, properly wear a well-fitting mask or respirator over their nose and mouth. That's in indoor areas of public transportation. So we think about planes, trains, buses and fairies, and transportation hubs. So airports, bus and train stations, and seaports. And that statement, like you said, was issued despite the fact that a judge struck down the federal mask mandate for public transportation last month but we know that masking up in higher risk settings like airport reduces your chance of getting infected and then, of course, having to miss out on those events like graduation or other events that matter to you. The one positive byproduct of the federal mandate being lifted is that the Federal Aviation Administration released data showing that the number of unruly air passenger incidents has reached its lowest level since 2020.

Unger: Well, I guess a silver lining in that news. Last question for you. A lot of headlines out this week about concerns about the fall. Do we have any idea what's going to happen in the months ahead?

Garcia: We know that senior administration officials have said the White House is stepping up their warnings about a COVID surge this fall and winter. They're making contingency plans to provide vaccines to the U.S. population in case Congress does not allocate additional funding for pandemic response. So that contingency plan would focus on ensuring booster doses are available for older populations and for those with compromised immune systems. And again, that's if there's not enough funding to provide them for the general population. And then, I think, officials are predicting to see those waves like we've seen over the previous two years. So in the summer, we would see a wave in the South as people move indoors to escape the heat. And then in the fall, the thinking is it would begin to spread across the rest of the country. Though the hope is that spike in cases would not be as steep.

We know that therapeutics are going to continue to be important. And FDA released an updated fact sheet for health care providers and they've also developed a new Paxlovid Patient Eligibility Screening Checklist. And that really is a good tool for providers to determine which of their patients are eligible for the drug and to help manage those potential drug interactions. And so that resource is going to be

included in the resources in the episode description. And I think, just keep in mind that these are, of course, predictions. And the only thing that is certain about the pandemic is that we continue to be surprised.

Unger: You said it. We'll be here with the latest news as it develops. Andrea, thanks so much for being here. That wrap up today's episode. We'll be back with another COVID-19 Update video and podcast, next week. For updated resources on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us and please take care.

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