

Mira Irons, MD, on concerns of outdated AstraZeneca vaccine data

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Featured topic and speakers

In today's COVID-19 Update, AMA's Chief Health and Science Officer, Mira Irons, MD, reviews the latest information on AstraZeneca, COVID-19 numbers and trending topics over the past week, the importance of risk mitigation for spring and summer, as well as state-by-state vaccine availability and roll outs.

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Speakers

- Mira Irons, MD, chief health and science officer, AMA

Transcript

Unger: Hello, this is the American Medical Association's COVID-19 Update. Today, we have our weekly look at the numbers, trends and latest news about COVID-19 with AMA's chief health and science officer, Dr. Mira Irons in Chicago. I'm Todd Unger, AMA's chief experience officer in Chicago. Dr. Irons, big news this week from AstraZeneca, a potential fourth vaccine option, and also some confusion about the data it released. Can you tell us more about that?

Dr. Irons: Oh, absolutely. It's been a little bit of up and down with this information. So AstraZeneca's COVID-19 vaccine was found to be 79% effective against symptomatic COVID-19 and 100% effective against severe disease in a long-awaited U.S. study, according to the results announced by Monday by AstraZeneca. And the plan then was that they were going to complete the paperwork for an application for an Emergency Use Authorization for the FDA. However, on the heels of that

announcement came a highly unusual statement released after midnight from the National Institute of Allergy and Infectious Diseases that said it was concerned AstraZeneca used outdated information from the large-scale trial when it reported the results on Monday, and this is a quote, "which may have provided an incomplete view of the efficacy data."

Unger: Can I just ask you, what does that mean, outdated information? Do you have any insight into that?

Dr. Irons: No, I'm sorry. I really don't. This is really the role of the U.S. Data and Safety Monitoring Board, to work with the company at this point to review the data and release the updated information as quickly as possible. As of Monday, as I said, the company was preparing to apply for an emergency authorization from the FDA, but the shots may not actually be needed in the U.S. as it would likely not become available before May. And now this new concern about the data could add to that timeline.

Unger: And this is on top of a rocky last week with concerns about safety in Europe. Can you talk a little bit more about how that situation has resolved?

Dr. Irons: Yes. So in Europe what we heard was that European regulators, after some safety concerns about the increased incidence of thromboembolic phenomenon, eventually cleared the disease... cleared the vaccine, I'm sorry, although some countries are using it and others are still paused, I believe. And with regards to the U.S. trial, although no clinical trial is large enough to rule out extremely rare side effects, AstraZeneca reported that its study turned up no serious safety issues. Government officials and public health experts expressed hope that the results would improve global confidence in this vaccine. And even if the vaccine is not used in the United States, because we have enough supply of the other vaccines, receiving emergency authorization from the FDA, whose rigorous review process is considered the global gold standard, would be an important milestone for AstraZeneca.

The trial itself had more than 32,000 participants. It was the largest test of its kind for the shot. And another unique aspect of the trial is it showed that the vaccine offered strong protection for older people who had not been as well represented in earlier studies. Now, again, this is all qualified because of the current concerns. However, I have to say that the FDA and especially the external advisory committee, the VRBPAC, look at all of the data very closely. It will, once again, once they convene the VRBPAC, be a public meeting. I'm sure there will be a lot of questions in a close look at the data. And one thing I do feel confident is that the rigorous process that has occurred with the prior vaccines will occur with this one also once that application is submitted.

Unger: Well, it does seem like states are accelerating their vaccines, expanding eligibility to try to increase the pace of vaccinations. Are we seeing this in the numbers? And are we on track to meet that goal that President Biden suggested for May?

Dr. Irons: Yeah, I think we are. We do continue to stay on track. Nationally, about 25% of the U.S. population has received at least one shot. The CDC on Monday said about 82.8 million people have received at least one dose and about 44.9 million had been fully vaccinated. The other thing that's important to note is that the Johnson & Johnson/Janssen vaccine is now integrated into the distribution systems, and those are single dose vaccines. So once people are vaccinated with that one, they immediately go into that fully vaccinated side of the ledger. So I think those numbers are going to start coming up.

The providers are administering about 2.49 million doses per day on average as of Sunday. But I'm sure you've heard the media reports. There been some 3 million dose days. So if the country maintains its current pace of vaccinating people, about half of the total population would at least partially be vaccinated around mid-May, and hopefully nearly all around late July, assuming the supply pledges are met and vaccines are eventually available to...

Unger: That's excellent news. And we are seeing states continue to increase eligibility. What are the trends that you're seeing there?

Dr. Irons: So West Virginia joined Alaska and Mississippi on Monday in making everyone older than 16 eligible. New York said residents older than 50 could sign up for a shot starting this week. And Tennessee announced all adults will be eligible starting April 5th. The White House also announced on Monday another federally-run vaccination site, which will open in Washington state and be able to administer up to 1,200 shots per day. The issue now is that we have to make sure that sites are available in places where everyone can go and get their vaccines, so that access is available for everyone.

Unger: And it does appear that we're in a race against the time because we're reading reports from the CDC about concerns about a "preventable surge." What are you seeing right now in terms of the trends of cases and deaths?

Dr. Irons: So the numbers today are that 29,870,135 people have been diagnosed with a COVID infection and 542,993 people have died of COVID. On Sunday, at least 444 new COVID deaths and 34,236 new cases were reported. We do not know their reporting is usually down on weekends, so that if you look at the seven day average over the past week, that has continued to kind of stick at that 54,407 cases per day. It's a decrease of about 7% from the average two weeks earlier, but that number has basically been flat for two weeks, and that number is too high because that means that they're still active disease in the community.

Persistent outbreaks in the Northeast and Michigan have offset progress in other parts of the country. Michigan, especially, is adding about twice as many cases a day as it was two weeks ago. New Jersey leads the country by a wide margin. Daily death reports, which have stayed stubbornly high long after the post-holiday surge, finally started to come down sharply. The country's averaging about

a thousand newly reported deaths a day, the fewest since November. And in the last seven days, in the last week, the seven day average has dropped 30%. So we're hopeful that things are continuing to go in the right direction, although the numbers are still high enough so they can move.

Unger: There's concern, obviously, about loosening and restrictions as kind of contributing to this flattening out, and even in some places like Michigan you say, leading to an increase. What other key trends are you noting? Why don't we start first with a lot of action down in the state of Florida?

Dr. Irons: Oh, absolutely. The spring break is a big driver of concern. We've all seen the pictures. We all know the story well enough to know that we should be worried. In South Beach, police struggled to control overwhelming crowds over the weekend. Officials in Miami Beach decided on Sunday to extend an emergency curfew for up to three weeks. Miami-Dade County, which includes Miami Beach, has recently endured one of the nation's worst outbreaks. And the state is thought to have the highest concentration of the B.1.1.7 variant, which is the more contagious and possibly more lethal variant first identified in Britain. The concern is obviously what happens when all these spring breakers return home and whether that could fuel another surge.

Unger: Yes. On top of the trends that we're seeing in travel, just reading that we're, over the weekend, seeing actually a peak since last March. So a lot of risk there, I can see with people traveling and congregating and breaking the rules. So we'll keep our eye close on that data. Any more news about the variants? You mentioned some of them becoming predominant and more contagious and potentially more lethal. What are we seeing there?

Dr. Irons: So Dr. Walensky, the head of the CDC, addressed this at the same White House briefing on Monday. She did say that the virus variants are making up a bigger share of cases and the CDC is scaling up its effort substantially to track down the variants. And that will continue to grow, in large part due to the \$1.75 billion in funds for genomic sequencing in the American Rescue Plan. On the CDC site today, the U.K. variant, the B.1.1.7 variant, is in 51 jurisdictions in the United States. So it's pretty much...it's across the United States. The South African variant's in 26, and the Brazilian variant is in 15 jurisdictions. So the variants are in our communities. Dr. Walensky told lawmakers last week that between 10 and 14,000 test samples were being sequenced each week to locate variants, and that they're aiming for about 25,000.

But I'd like to quote something that she said, which I think really just is an important message. "We are at a critical point in this pandemic. We must act now. I'm worried that if we don't take the right actions now we will have another avoidable surge just as we're seeing in Europe right now, and just as we are so aggressively scaling up vaccination." Europe tends to be about three to four weeks ahead of us. And if history repeats itself, several countries in Europe are on lockdowns currently. So we're just hoping that people hang in there.

Unger: Absolutely, don't want to see a repeat of that. Last question, any big news or statements from the AMA that we want folks to be aware of?

Dr. Irons: Yep. Two of note. So on March 16th, the AMA applauded the Biden administration on acting promptly to update Medicare payment rates for COVID-19 vaccine administration. And on March 17th, the AMA urged Congress to support legislation that would prevent arbitrary across the board Medicare cuts that threaten the viability of physician practices during the pandemic. The letter to Speaker Pelosi and Minority Leader McCarthy points out that "Physician practices still face overwhelming financial challenges and pressures associated with higher overhead costs like the cost of personal protective equipment and lost revenue due to fewer patient visits and delayed elective procedures during the pandemic. Injecting additional uncertainty into the health care system is an unnecessary distraction during a time when physicians and others are focused on fighting the pandemic," the letter said.

Unger: Absolutely. Well, thank you so much for being here today, Dr. Irons, and sharing your perspectives. We'll have you back next week for another look at the trends and data. Thanks for joining us today. Please take care. For more information on COVID-19 visit ama-assn.org/COVID-19.

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