

U.S. health officials raise flags about AstraZeneca's COVID vaccine trial data

March 23 2021, by Ernie Mundell and Robin Foster Healthday Reporters



U.S. health officials called the results of AstraZeneca's coronavirus

vaccine trial into question early Tuesday, saying the company may have used outdated data that could have changed its conclusion about the efficacy of the vaccine.

On Monday morning, AstraZeneca had announced that its vaccine was 79 percent effective in protecting against COVID-19 infection in the large U.S. clinical trial.

But in a statement released shortly after midnight on Monday, the National Institute of Allergy and Infectious Diseases (NIAID) said the Data and Safety Monitoring Board, a panel of medical experts under the National Institutes of Health that has been overseeing AstraZeneca's U.S. trial, had notified government agencies and AstraZeneca late Monday that it was "concerned" by information the company had released.

The monitoring board said the company may have relied on "outdated information" that "may have provided an incomplete view of the efficacy data," the NIAID statement said.

NIAID urged AstraZeneca to work with the monitoring board "to review the efficacy data and ensure the most accurate, up-to-date efficacy data be made public as quickly as possible."

AstraZeneca did not return a request for comment early Tuesday, *The New York Times* reported.

Dr. Eric Topol, a [clinical trials](#) expert at Scripps Research in San Diego, said it was "highly irregular" to see such a public display of friction between a monitoring board and a study sponsor.

"I've never seen anything like this," he told the *Times* after the institute's statement was released. "It's so, so troubling."

The results announced Monday seemed to boost global confidence in the vaccine, which was shaken earlier this month when more than a dozen countries, mostly in Europe, temporarily suspended the shot's use over worrying reports of rare cases of blood clots. Most of those countries returned to using the AstraZeneca vaccine late last week, after the European Medicines Agency, which regulates drugs in the European Union, analyzed the data and pronounced the vaccine safe and effective.

AstraZeneca's relationship with U.S. authorities has been tense since last year, when senior health officials believed the company was not being forthright about the design of its clinical trials, its results and safety issues, the *Times* reported.

That U.S. trial, which involved more than 32,000 participants, was the largest test of its kind for the shot. The company has said it will provide the U.S. Food and Drug Administration with a more comprehensive, recent set of data than what it disclosed on Monday, the *Times* reported.

The company's efforts might not make much difference in the United States, where the vaccine is not yet authorized and is unlikely to become available before May, the *Times* said. By then, there will be enough vaccine doses for all of the nation's adults from the three vaccines that have already been authorized: Pfizer, Moderna and Johnson & Johnson.

Already approved in more than 70 countries, the AstraZeneca vaccine has been given to millions of people worldwide, including more than 17 million in Britain and the European Union, the *Times* reported.

"It's clear more questions have been raised about the AstraZeneca vaccine than about any of the other vaccines which are now authorized in the U.S.," Dr. Arnold Monto, acting chair of the FDA's Vaccines and Related Biological Products Advisory Committee, which authorizes all vaccines in the United States, told *CNN* on Monday.

"It does feel different, and it felt different even before the whole blood clot kerfuffle," Dr. William Schaffner, a liaison member of the CDC's Advisory Committee on Immunization Practices, told *CNN*.

As for reports on rare clotting issues, "It's hard to unring that bell," Dr. Paul Offit, a member of the FDA advisory committee told *CNN*. "Once people are scared, it's hard to unscare them."

Biden Met 100 million vaccinations goal early

President Joe Biden's promise of 100 million vaccinations in the first 100 days of his administration was met Friday, more than 40 days ahead of schedule.

"I'm proud to announce that tomorrow, 58 days into our administration, we will have met our goal," Biden said last Thursday during a speech on the state of the country's vaccination campaign. He added that he would unveil a new vaccination target this week, with the United States expecting to have enough of the three currently authorized vaccines to cover the entire adult population by May 1, the *Associated Press* reported.

Ahead of Biden's remarks, the White House announced it was finalizing plans to send a combined 4 million doses of the AstraZeneca COVID-19 vaccine to Mexico and Canada in its first export of surplus shots, the *AP* reported.

White House Press Secretary Jen Psaki said the details of the "loan" were still being worked out, but 2.5 million doses would go to Mexico and 1.5 million would be sent to Canada.

"Our first priority remains vaccinating the U.S. population," Psaki told reporters. But she added that "ensuring our neighbors can contain the

virus is a mission critical step, [and] is mission critical to ending the pandemic."

The 100 million-dose goal was first announced on Dec. 8, days before the United States had even one authorized vaccine for COVID-19, let alone three. By the time Biden was inaugurated on Jan. 20, 20 million shots had been given at a rate of about 1 million per day, the *AP* reported.

Now, an average of about 2.2 million doses each day are going into the arms of Americans. That pace will likely jump later this month with an expected surge in vaccine supply, the *AP* said.

Biden has moved to speed deliveries of vaccines from Pfizer, Moderna and Johnson & Johnson, as well as to expand the number of places to get shots and people who can administer them, the *AP* reported.

As of Tuesday, nearly 82.8 million Americans had received their first dose of a COVID-19 [vaccine](#), while nearly 45 million had gotten their second shot.

A global scourge

By Tuesday, the U.S. coronavirus case count passed 29.8 million while the death toll passed 542,500, according to a *Times* tally. On Tuesday, the top five states for coronavirus infections were: California with over 3.6 million cases; Texas with more than 2.7 million cases; Florida with over 2 million cases; New York with nearly 1.8 million cases; and Illinois with over 1.2 million cases.

Curbing the spread of the coronavirus in the rest of the world remains challenging.

In Brazil, the [coronavirus](#) case count was over 12 million by Tuesday, with more than 295,000 deaths, a Johns Hopkins University tally showed. India had nearly 11.7 million cases and Over 160,000 deaths as of Monday, the Hopkins tally showed.

Worldwide, the number of reported infections passed 123.7 million on Tuesday, with over 2.7 million deaths recorded, according to the Hopkins tally.

More information: The U.S. Centers for Disease Control and Prevention has more on the [new coronavirus](#).

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