

Missteps could mar long-term credibility of AstraZeneca shot

March 23 2021, by Maria Cheng



In this Sunday, March 21, 2021 file photo a medical worker wearing protective gear sets up boards with the names of the vaccines at a vaccination center in Belgrade, Serbia. Results from a U.S. trial of AstraZeneca's COVID-19 vaccine may have used "outdated information," U.S. federal health officials said early Tuesday March 23, 2021. (AP Photo/Darko Vojinovic, File)

AstraZeneca's repeated missteps in reporting vaccine data coupled with a blood clot scare could do lasting damage to the credibility of a shot that is the linchpin in the global strategy to stop the coronavirus pandemic, potentially even undermining vaccine confidence more broadly, experts say.

The latest stumble for the vaccine came Tuesday, when American officials issued an unusual statement expressing concern that AstraZeneca had included "outdated information" when it reported encouraging results from a U.S. trial a day earlier. That may have provided "an incomplete view of the efficacy data," according to the statement.

AstraZeneca responded that the results, which showed its shot was about 79% effective, included information through Feb. 17 but appeared to be consistent with more up-to-date data. It promised an update within 48 hours.

An independent panel that oversees the study scolded the company in a letter Monday for cherry-picking data, according to a senior administration official. The panel wrote to AstraZeneca and U.S. health leaders that it was concerned the company chose to use data that was outdated and potentially misleading instead of the most recent findings, according to the official, who discussed the contents on the condition of anonymity given the sensitivity of the matter.

"This will likely cause more vaccine hesitancy," said Dr. Paul Hunter, a professor of medicine at the University of East Anglia.

Even if the damage is limited to AstraZeneca itself, it would have far-reaching effects since the shot is cheaper and easier to store than many of its rivals' and thus is expected to be widely used in the developing world. International health agencies have repeatedly said the vaccine is

safe and effective, but it's not the first time the company has run into problems with public trust.



In this Monday, March 22, 2021 file photo, AstraZeneca and Biontech coronavirus vaccine in a fridge at the vaccine center in Ebersberg near Munich, Germany. AstraZeneca's release of encouraging data about its coronavirus vaccine from its U.S. trial raised hopes that the drug company could bury doubts about the shot and put a troubled rollout behind it. But just hours later, U.S. officials released an unusual statement expressing concerns AstraZeneca had included "outdated information" from its study and that it may have provided "an incomplete view of the efficacy data." (AP Photo/Matthias Schrader, File)

Partial results from its first major trial—which Britain used to authorize

the vaccine—were clouded by a manufacturing mistake that researchers didn't immediately acknowledge. Insufficient data about how well the vaccine protected older people led some countries to initially restrict its use to younger populations before reversing course. U.S. officials suspended an AstraZeneca study for an unusual six weeks while they sought details about problems reported in Britain before deciding the vaccine wasn't to blame. Meanwhile, the European Union has complained about delays in vaccine deliveries from the company.

Then last week, more than a dozen countries temporarily halted their use of the AstraZeneca shot after reports of rare blood clots in some people who received it. The European Medicines Agency [concluded the shot did not increase the overall incidence of clots](#), but the unwanted attention appears to have left a mark.

In Norway, a top official warned Monday it might not be able to resume its use of the vaccine because so many people were rejecting it.

"People clearly say that they do not want the AstraZeneca vaccine," Marte Kvittum Tangen, who heads a Norwegian doctors' association, told broadcaster NRK.

Last week in Bucharest, Romania, vaccination coordinator Valeriu Gheorghita said 33,000 AstraZeneca immunization appointments had been canceled in 24 hours and that about a third of the 10,000 people scheduled to receive the vaccine did not show up. In Belgrade, Serbia, a sprawling exhibition center set up for people to get the AstraZeneca vaccine was mostly deserted on Monday.

"This is unfortunately more about perception than it is the science," said Dr. Bharat Pankhania, an infectious diseases specialist at Britain's University of Exeter.



In this Thursday, Feb. 25, 2021 file photo, a health worker holds a vial of the AstraZeneca vaccine to be administered to emergency services personnel during a mass COVID-19 vaccination campaign at Wanda Metropolitan stadium in Madrid, Spain. AstraZeneca's release of encouraging data about its coronavirus vaccine from its U.S. trial raised hopes that the drug company could bury doubts about the shot and put a troubled rollout behind it. But just hours later, U.S. officials released an unusual statement expressing concerns AstraZeneca had included "outdated information" from its study and that it may have provided "an incomplete view of the efficacy data." (AP Photo/Manu Fernandez, File)

"We have now seen, on several parameters, that the AstraZeneca vaccine provides protection and is safe," he said. "But the narrative for the public has not been as clear."

France is a prime example of the confusion.

French President Emmanuel Macron initially suggested the vaccine wasn't effective for older people, before backtracking. Still, France only authorized AstraZeneca's vaccine for use in adults 65 and under, citing a lack of data. Then the government changed its mind, based on new data, and said it's fine for all adults. But when there were reports of rare blood clots in some vaccine recipients, the government suspended use of the shot all together. When France restarted AstraZeneca, it banned the shot for anyone under 55.

The whiplash-inducing messages come at a time when France—like much of continental Europe—is struggling to speed up its vaccination drive while also facing a spike in cases that is close to overwhelming its hospitals and prompting threats of new lockdowns.

At a European Parliament committee Tuesday in Brussels, Sandra Gallina, head of the European Commission's health directorate, described the situation with AstraZeneca as "a shame." She said the struggling vaccination campaigns across Europe were "made much more difficult by the bad performance of AstraZeneca."

The company has blamed delays in its deliveries on production issues.



In this Monday, March 8, 2021 file photo, a health worker shows the media how she prepares a dose of the AstraZeneca vaccine to be administered to a patient at a vaccination center set up in front of Rome's Termini central station. AstraZeneca's release of encouraging data about its coronavirus vaccine from its U.S. trial raised hopes that the drug company could bury doubts about the shot and put a troubled rollout behind it. But just hours later, U.S. officials released an unusual statement expressing concerns AstraZeneca had included "outdated information" from its study and that it may have provided "an incomplete view of the efficacy data." (AP Photo/Alessandra Tarantino, File)

Even if the drugmaker clears up the latest misunderstanding, it could have a lasting impact.

Julian Tang, a virologist at the University of Leicester, pointed to the

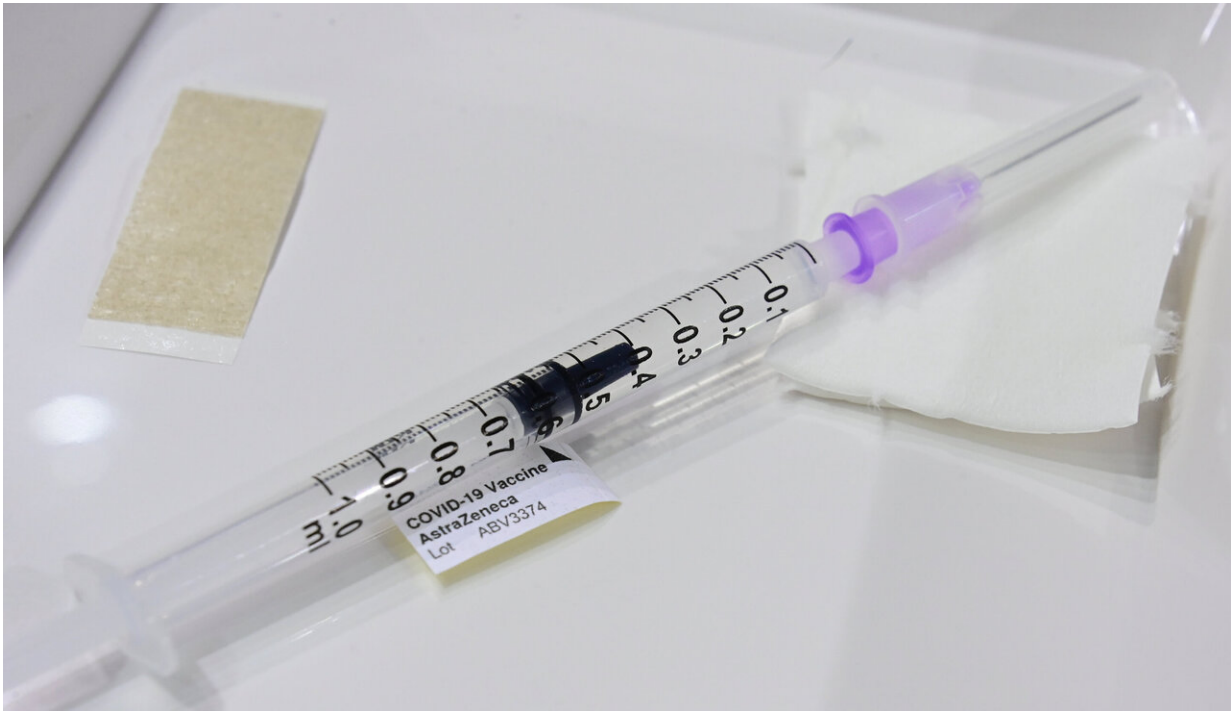
decades-old controversy over the measles vaccine as a cautionary tale.

"There was absolutely no evidence to prove the (measles, mumps and rubella) vaccine caused autism," he said. But despite the retraction of the paper that made that claim, Tang said some people still worry about the vaccine.

The tepid support for the AstraZeneca vaccine in Europe stands in contrast to governments in the developing world that are desperate for supplies.

Dr. Bruce Aylward, a senior adviser at the World Health Organization, said the U.N. agency has a long list of countries "very keen" to get the shot as soon as possible. "We simply cannot get enough of it," he said.

But some experts have worried that [the skepticism in Europe could eventually cast a pall](#) over the vaccine worldwide. They suggested one measure that could reassure a jittery public: a green light from the U.S. Food and Drug Administration.



In this March 8, 2021 file photo, a syringe with the AstraZeneca vaccine is pictured at a new vaccination centre at the former Tempelhof airport in Berlin, Germany. AstraZeneca's release of encouraging data about its coronavirus vaccine from its U.S. trial raised hopes that the drug company could bury doubts about the shot and put a troubled rollout behind it. But just hours later, U.S. officials released an unusual statement expressing concerns AstraZeneca had included "outdated information" from its study and that it may have provided "an incomplete view of the efficacy data." (Tobias Schwarz/Pool Photo via AP, File)

"If the U.S. regulator looks at this data and authorizes AstraZeneca, that will carry a lot of weight," said Jimmy Whitworth, a professor of international public health at the London School of Hygiene and Tropical Medicine.

AstraZeneca said it would be submitting its data to the FDA within weeks.

It's still possible the vaccine can bury the doubts. At a vaccination center in Lisbon, 68-year-old Rui Manuel Martins dismissed the concerns, saying millions had been immunized with very few ill effects.

"There's always some cases of people rejecting any medications," he said before receiving his first dose. "It's better to be vaccinated rather than not."

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