COVID-19 HEALTH

There's a temporary halt on Johnson & Johnson vaccinations in Virginia. Here's why

BY: **KATE MASTERS** - APRIL 14, 2021 12:01 AM

Vials of Johnson & Johnson's COVID-19 vaccine. (NBC12)

Virginia will temporarily stop administering doses of the Johnson & Johnson vaccine as federal health agencies review six reported cases – out of millions of doses administered – of blood clots developed in patients within two weeks of receiving the shot.

In a Tuesday statement, state vaccine coordinator Dr. Danny Avula said the pause would continue until federal agencies completed their investigation. It could extend days to weeks, he added in a later news briefing, based off information state health officials received from the U.S. Centers of Disease Control and Prevention.

"I think we will have a much clearer answer on whether this will be an extended process by the end of tomorrow," Avula said. The CDC is convening a Wednesday meeting of the Advisory Committee on Immunization Practices, better known by ACIP. The 15-member panel is made

up of independent medical and public health experts unaffiliated with federal agencies or the pharmaceutical industry. Those experts will review the cases and issue recommendations on whether federal health agencies should continue to authorize the vaccine for all adults.

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"It could be that they do a deep dive on the data and really don't see an increased incidence and say it's fine to use J&J again," Avula said. "But it could be that they need more information and this could last several days or longer."

The state will continue administering both the Moderna and Pfizer vaccines, which have also received emergency authorization from the U.S. Food and Drug Administration. But it's postponed roughly 30 Johnson & Johnson vaccination events scheduled over the next several days.

Several major hospital systems, including VCU Health and UVA Health, also announced they would suspend use of the vaccine. VCU is shifting to its supply of Moderna and Pfizer doses to

honor existing appointments on Tuesday, according to a statement, though the decision could affect future vaccinations.

UVA will also switch to Moderna and Pfizer for future community vaccination clinics, according to spokesman Eric Swensen. In many cases, the move will affect smaller vaccination efforts in communities that benefit most from a one-dose vaccine. The Richmond-Henrico Health District announced Tuesday that four upcoming small or mobile clinics – scheduled to vaccinate fewer than 750 people – would switch from Johnson & Johnson to Pfizer and Moderna. But in response to the news, the district is suspending vaccinations for homebound patients and a new initiative to reserve walk-up vaccinations for seniors, both of which depended on Johnson & Johnson supplies.

Dr. Danny Avula, Virginia's vaccine coordinator, speaks at a news conference in March. (Ned Oliver/ Virginia Mercury)

'Extremely rare' risk

Side effects from any vaccine, including the Johnson & Johnson shot, are "extremely rare," Avula said. In a joint statement on Tuesday, the FDA and U.S. Centers for Disease Control and Prevention also described the blood clots – an uncommon variety known called cerebral venous sinus thrombosis, which affect the brain – as rare but severe.

All six cases occurred among women between the ages of 18 and 48 and the blood clots were coupled with low levels of blood platelets. According to The New York Times, one woman

died and another woman in Nebraska has been hospitalized in critical condition. Health officials are trying to determine if the deaths are related to the vaccine.

One of the six deaths being examined happened in Virginia, VDH confirmed on Tuesday evening. According to a release from the department, the CDC is investigating the death of a 45-year-old Virginia woman as part of its review of potential adverse side effects. The agency's Vaccine Adverse Event Reporting System reports that the woman was vaccinated on March 6 at a school or student health clinic. A week after receiving the vaccine, she began to experience a "gradually worsening headache," according to the report. On March 17, she went to the emergency room.

Her symptoms included "cerebral venous thrombosis," the report states – the same type of blood clot identified in similar cases. The patient died on March 18. VDH stated that "no additional details" would be provided during the investigation.

Given the extreme rarity of adverse events, though, there's been public criticism of the federal decision to temporarily halt Johnson & Johnson vaccines. More than 6.8 million doses have been administered nationwide and six adverse events are currently being investigated. Avula said 184,000 doses have been administered in Virginia.

With the current rate of reported adverse events, there's a higher risk of blood clots from birth control pills, which millions of American women still take without incident.

"All of this is a big risk-benefit calculation," Avula said. "In relative terms, about 10 percent of the American population has contracted COVID. Out of the the 31 million folks who have actually contracted COVID, one out of every 585 of them have died. So, thinking about those odds – six out of 6.8 million is really, really rare."

Virginia's decision came hours after the FDA and CDC recommended an immediate nationwide pause in Johnson & Johnson vaccine administration as they investigate the cases. That recommendation was made "out of an abundance of caution" until federal regulators can review the reports and assess their potential significance, according to the joint statement from both agencies.

Dr. William Petri, an infectious disease specialist at UVA, said adverse reactions from the Johnson & Johnson vaccine are currently so uncommon that reports may reflect the baseline incidence rate for those specific types of blood clots – or how often they might be expected to occur in the average population. But a few factors likely contributed to the decision to review the vaccine.

"It's an unusual form of a blood clot and it's unusually associated with low platelet counts," he said. All six cases were also recorded among women, and there's been a similar blood clotting disorder reported – in very rare cases – among patients who received the AstraZeneca COVID-19 vaccine.

Dr. William Petri receives a COVID-19 vaccine dose.

The AstraZeneca shots are not currently used or authorized in the U.S. But Stat reports that both vaccines use modified adenoviruses, which cause common diseases like colds or pneumonia, to help the human immune system defend itself against SARS-2 viruses. Avula said it's possible that those adenoviruses trigger an unusual autoimmune response in some patients, causing the very uncommon combination of CVST blood clots and low platelet counts.

"All that to say, it's happening on such a small frequency at this point and that's why it didn't show up in clinical trials," he said. Petri similarly said that growing awareness of a rare potential side effect could lead to more active monitoring among vaccine providers. The FDA already recommends that patients who receive the Johnson & Johnson vaccine and go on to develop severe headaches, abdominal pain, leg pain, or shortness of breath within three weeks

after vaccination should contact their health care provider. Health care providers are also required to report all adverse reactions to VAERS.

“It’s a great testament to how much emphasis is being placed on safety, that they’re pausing this vaccine,” Petri said. It’s also a way to ensure that health providers know how to appropriately treat any adverse reactions. Petri pointed out that a specific blood thinner used as heparin is usually used to treat blood clots, but can’t be used in these cases because of the associated low platelet counts.

“But you can use a different class of blood thinners, so to speak,” he said. “So you make everyone aware of the potential diagnosis, then there’s tests you can use to confirm it, then there’s therapy. And all of that goes much more smoothly if there’s time to raise some awareness.”

Looking forward

In another briefing last week, Avula said it was large shipments of Johnson & Johnson vaccine that allowed Virginia to “confidently move” into Phase 2 of its vaccine rollout on April 18. Last week, the state received around 124,000 of doses through its state allocation and another roughly 150,000 doses through a retail pharmacy partnership run by the federal government.

But supplies of Johnson & Johnson vaccine plummeted this week after millions of doses were contaminated and later discarded at a production plant in Baltimore. Avula said the state received 14,800 doses this week — about a tenth of the supply it was initially expecting. Coupled with a days- or weeks-long moratorium on the shots, the delay will likely effect the availability of appointments when the entire state opens appointments to residents 16 and older.

“I talked to a number of health district directors who actually have enough Moderna and Pfizer on hand to replace doses in their clinics for today,” he said on Friday. But in some cases, those replacements will mean that future clinics are canceled or postponed.

While the state still anticipates that every local health district will open to Phase 2 by Sunday, fewer total doses will also mean fewer total available appointments. It’s not the first time that Virginia’s rollout has been hindered by bad news at the federal level. In January, Gov. Ralph Northam expanded 1b eligibility to roughly half the state, only to learn that vaccine shipments would stagnate over the next several weeks.

Residents of Richmond, Henrico, Chesterfield and Chickahominy Health Districts check in to receive the Moderna COVID-19 vaccine at Richmond Raceway in Richmond, Va., February 2, 2021. (Parker Michels-Boyce/ For the Virginia Mercury)

But Avula said there were important differences this time around. In January, a large portion of eligible Virginians were clamoring for a limited supply of vaccines. But as Pfizer and Moderna shipments have increased, there's also been a notable drop in demand. According to Avula, Fairfax County and the Blue Ridge Health District, which covers Charlottesville and surrounding counties, are the only areas where there are more people who want the vaccine than there is supply.

Those areas are likely to feel the biggest squeeze when it comes time to open eligibility. But Avula said Virginia is still on track to offer appointments to every adult who wants one by the end of May.

"It might even be sooner than that," he said. "But that's not really good news through the lens of herd immunity. I really just think it means there's less low-hanging fruit than we otherwise thought, and getting more people vaccinated is going to take much more on-the-ground approach."

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An award-winning reporter, Kate grew up in Northern Virginia before moving to the Midwest, earning her degree in journalism from the University of Missouri. She spent a year covering gun violence and public health for The Trace in Boston before joining The Frederick News-Post in Frederick County, Md. While at the News-Post, she won first place in feature writing and breaking news from the Maryland-Delaware-DC Press Association, and Best in Show for her coverage of the local opioid epidemic. Before joining the Mercury in 2020, she covered state and county politics for the Bethesda Beat in Montgomery County, Md.

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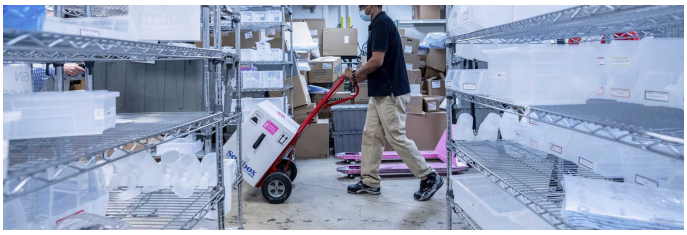

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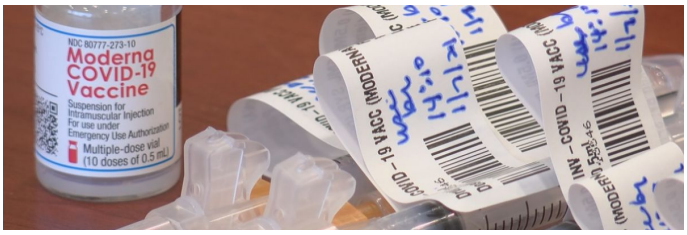

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