4 Things to Know About the J&J COVID Vaccine Pause

Health officials have paused distribution to investigate a rare blood clotting disorder.

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Four months into the largest U.S. vaccine rollout in decades, it's become clear that the messaging surrounding COVID-19 vaccination efforts is as important as the science behind them.

That was true when the first COVID vaccines were introduced in December at hospitals and nursing homes and even more so after the federal government on Tuesday [April 13] paused the Johnson & Johnson vaccine after reports of extremely rare but very serious — in one case, fatal — side effects emerged.

Most health experts largely applauded the government for its decision, saying it showed regulators making vaccine safety their top priority. They said regulators need to strike a balance between addressing small but serious risks while encouraging millions to get inoculated to quickly end the pandemic.

"The pause is a good decision and shows the public health system is working," said Noel Brewer, a professor in the health behavior department at the University of North Carolina-Chapel Hill.

1. What exactly happened with the J&J single shot anyway?

The Centers for Disease Control and Prevention and the Food and Drug Administration recommended Tuesday that health providers and states temporarily stop the use of J&J's COVID vaccine after reports emerged that six women in the U.S. who got the single-shot preventive developed a rare but serious blood clot. One of the women died and another is in critical condition.

All six cases occurred among women between the ages of 18 and 48, and symptoms occurred six to 13 days after vaccination, FDA and CDC officials said.

It's the latest in a series of messaging challenges.

This pause comes less than a week after three vaccine clinics in Georgia, North Carolina and Colorado temporarily stopped using the vaccine when several people fainted or became dizzy immediately following their shots. Fainting is a known risk from all vaccines, affecting about 1 in

1,000 people, health experts say. In response to these cases, some health experts questioned whether even the short-term halt was necessary.

In addition, federal regulators are concerned that the blood clotting seen with the J&J vaccine is the same type as seen globally with AstraZeneca's vaccine. The AstraZeneca vaccine isn't in use in the United States but has been authorized in more than 70 countries. The European Medicines Agency recently concluded that unusual blood clots with low blood platelets should be listed as "very rare side effects" on the AstraZeneca vaccine label. While advising the public to look out for signs of clots, the European regulators said the benefits of the shot were still worth the risk.

It also comes on the heels of questions faced by J&J regarding its rollout after a Baltimore subcontractor who was making its vaccine accidentally spoiled 15 million doses earlier in April. The problems at the facility were contributing to a drop in J&J doses this month.

2. But what does all this mean in terms of my risk?

More than 560,000 Americans have died of COVID in the past year — or 1 in 586 people. Ani ndividual's risk of dying of or being hospitalized with COVID is far higher than the risk of getting a rare blood clot from the J&J vaccine.

Meanwhile, the risk of getting a blood clot is also far higher if you have COVID.

To put the less-than-1-in-a-million risk of getting a severe blood clot from the J&J vaccine in perspective, people face a 1-in-500,000 chance each year of being struck by lightning.

"It's important to keep these numbers in context," Jonathan Watanabe, a pharmacist and an associate dean in the College of Health and Sciences at the University of California-Irvine, said of the rare blood clots. "While frightening, it's a rare event." The risk of blood clots associated with COVID infection is actually greater, he added.

The pause, which FDA officials said they expect will be a few days, will give regulators time to alert doctors to the added risk and show them how to recognize and treat the clots and make reports to the government.

The CDC will convene a meeting of the Advisory Committee on Immunization Practices today [April 14] to further review these cases and assess their potential significance. The committee could recommend adding the blood clot risk to the list of warnings about the vaccine or could recommend that certain populations avoid the vaccine.

3. Why is messaging important?

How the concerns about risk are communicated could have a lasting impact on whether some people go ahead and get vaccinated.

“The messaging is very important because science alone does not get us to the outcomes we need,” said Zoë McLaren, associate professor in the School of Public Policy at the University of Maryland-Baltimore County.

McLaren said the FDA is known for being risk averse and that’s how it developed its reputation for protecting Americans’ food and drug supply. “Part of messaging is communicating to the public what the FDA is doing,” said McLaren, who was inoculated with the J&J vaccine.

J&J’s is one of three COVID vaccines that have been cleared for use under an emergency authorization in the U.S. Unlike the Pfizer and Moderna vaccines, which require two doses, the J&J version requires only one shot.

According to the CDC’s vaccine tracker, nearly half of U.S. adults have been at least partially vaccinated, and the numbers have been soaring in recent weeks to an average topping 3 million doses a day.

Of the more than 190 million doses of COVID vaccine administered in the U.S., about 7 million were J&J.

Nonetheless, the number of new COVID infections is still rising in many states and there are concerns from CDC Director Rochelle Walensky and others about another surge as a result — in part — of people hesitating to get vaccinated.

On the bright side, though, the blood clot issue comes months after the vaccination rollout began and as Moderna and Pfizer have committed to having enough doses to vaccinate most Americans.

4. How does this play into vaccine hesitancy? Does transparency help or hurt?

The latest surveys show 13% of adults say they won’t get a COVID vaccine and 15% will get one only if required by their employer or to travel.

Experts are torn on whether the J&J pause will increase hesitancy among some people or give them more confidence in how federal regulators are overseeing the vaccination effort.

Dr. Amesh Adalja, a senior scholar at the Johns Hopkins Center for Health Security, said he worries the pause will have a lasting effect. “We have a lot of vaccine hesitancy that exists, and that is only going to be magnified.”

But to Dr. Kartik Cherabuddi, an infectious-disease specialist at the University of Florida health system, this is one hurdle in the long vaccination game. He predicts the overall effect from the pause will be minimal within a few weeks as regulators and health providers put the vaccine risks in perspective for the public. He said Americans are used to being told about the health risks of drugs, as they are bombarded with television drug advertising.

Meanwhile, UC-Irvine's Watanabe said he hopes the pause will lead to more discussions with hesitant Americans about how they have several vaccine options. Watanabe said it was wise of the FDA to show "an abundance of caution" by pausing use of the J&J vaccine now, particularly because there are two other vaccine options for Americans that can more than fill the gap.

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