U.S. Resumes Use of Johnson & Johnson COVID-19 Vaccine

The CDC and FDA confirmed that the vaccine is safe, and said the recent pause should be lifted for all groups.

April 23, 2021 By Liz Highleyman

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have lifted last week's pause on the Johnson & Johnson COVID-19 vaccine, allowing distribution to resume. The federal agencies stressed that the shot is safe for the vast majority of people, and severe side effects are very rare.

> CDC and @US_FDA lift recommended pause on Johnson & Johnson (Janssen) #COVID19 vaccine use following thorough safety review. See full statement: https://t.co/yTTGfGsgSH pic.twitter.com/1kYETjWUgJ
>
> — CDC (@CDCgov) April 23, 2021

The CDC and FDA jointly halted administration of the single-dose shot on April 13, after six cases of a rare clotting disorder were reported among the 6.8 million people who had received the vaccine. All of the events occurred within two weeks after receiving the vaccine, and all of the affected individuals were white women ages 18 to 48. However, one similar case was seen in a man who participated in a clinical trial of the vaccine. There have now been 15 reported cases among nearly 8 million recipients, including two older women; three cases have been fatal. CDC scientist Sara Oliver, MD, MSPH, estimated that 26 to 45 cases of the clotting disorder could occur among J&J vaccine recipients over the next six months, but withholding the vaccine could lead to 600 to 1,400 additional COVID-19 deaths, The New York Times reports.

The CDC's Advisory Committee on Immunization Practices, meeting on April 23, voted 10 to 4 to resume use of the J&J vaccine (also known as the Janssen vaccine). The panel recommended that

the vaccine should not be restricted based on sex or age, but that it should carry a warning about the rare adverse event.

According to the CDC, people who experience symptoms such as severe headache, blurred vision, seizures, severe abdominal pain, leg pain or swelling, chest pain, shortness of breath, tiny red spots on the skin known as petechiae and easy bruising or bleeding after receiving the vaccine should promptly seek medical care.

“Our vaccine safety systems are working. We identified exceptionally rare events—out of millions of doses of the Janssen COVID-19 [vaccine] administered—and we paused to examine them more carefully,” CDC director Rochelle Walensky, MD, MPH, said in a joint press release. “I continue to be encouraged by the growing body of real-world evidence that the authorized COVID-19 vaccines are safe and effective, and they protect people from disease, hospitalization and death.”

The pause was intended to further investigate possible links between the vaccine and the unusual disorder, dubbed thrombosis with thrombocytopenia syndrome (TTS), and to inform providers about how to recognize and manage it. The disorder causes blood clots throughout the body, including the brain (cerebral venous sinus thrombosis, or CVST), using up available platelets and leading to a low platelet count. TTS differs from the type of blood clots that can occur in women taking birth control pills (two people who developed TTS after vaccination were using oral contraceptives).

The clotting events resemble those seen in a very small proportion of people who have received the AstraZeneca and University of Oxford vaccine, which is not yet authorized in the United States; 222 cases have been reported among some 34 million people who have gotten this vaccine. The European Medicines Agency (the European Union’s counterpart to the FDA) concluded that the vaccine’s benefits outweigh its risks, but several countries have halted distribution or limited it to older individuals. The EMA this week made the same determination about the J&J vaccine. So far, the unusual clotting syndrome has not been reported among people who received the Pfizer-BioNTech or Moderna mRNA vaccines.

The J&J and AstraZeneca vaccines both use modified adenovirus vectors to deliver genetic blueprints for the SARS-CoV-2 coronavirus spike protein. The mRNA vaccines, in contrast, encase the viral genetic material in lipid nanoparticles, or fat bubbles. The J&J vaccine employs adenovirus type 26—a common cold virus—which is also used for the company’s Ebola virus vaccine and for an experimental HIV vaccine. The AstraZeneca vaccine uses a chimpanzee adenovirus. The Russian Sputnik V and Chinese CanSino vaccines also use adenovirus vectors.

Although much remains to be learned, a growing number of experts think the rare clotting disorder, which some are calling vaccine-induced immune thrombotic thrombocytopenia, may be related to the adenovirus vectors. These vaccines appear to trigger production of antibodies against platelet factor 4 (PF4), a protein found inside platelets and on the surface of blood vessels. A similar immune overreaction is rarely seen among people treated with heparin, a commonly used blood thinner. Most people who developed TTS after vaccination tested positive for anti-PF4

antibodies. Hormonal differences may explain the apparent higher risk among women, who are more likely to develop autoimmune conditions. People with the clotting disorder should not be treated with heparin; other anticoagulants can help if given early, but they can't undo the damage that results from clots cutting off blood circulation.

Lifting the J&J vaccine pause will increase the number of doses available for immediate use, though U.S. officials have said the supply will be adequate even without this vaccine. But the "one and done" vaccine improves access particularly for harder-to-reach groups, such as people experiencing homelessness, and in more remote areas. Unlike the mRNA vaccines, it does not require ultra-cold storage, so it easier to transport and deliver.

Some experts and advocates fear that the pause could worsen vaccine hesitancy, but others have suggested that the pause could bolster confidence by showing that the CDC and FDA are taking rare adverse events seriously.

"Safety is our top priority. This pause was an example of our extensive safety monitoring working as they were designed to work—identifying even these small number of cases," said acting FDA commissioner Janet Woodcock, MD. "We have concluded that the known and potential benefits of the Janssen COVID-19 vaccine outweigh its known and potential risks in individuals 18 years of age and older. We are confident that this vaccine continues to meet our standards for safety, effectiveness and quality."

As of today, every American is eligible to receive the COVID-19 vaccine. For yourself, your neighbors, and your family — please, get your vaccine.

pic.twitter.com/o75JYpGe6r

— President Biden (@POTUS) April 19, 2021

As of April 19, everyone age 16 or older in the United States is eligible to be vaccinated, and the proportion of adults who have received at least one dose has crossed the 50% mark. More than 137 million people have gotten at least one shot, and more than 91 million are full vaccinated, according to the CDC's vaccine tracker. But vaccination coverage varies widely. Some Black and Latino communities that have been hard-hit by COVID-19 have lower vaccination rates, and more people in heavily Republican areas say they do not intend to get a vaccine.

This week the U.S. reported a slowdown in vaccine administration—despite increasing supplies—suggesting that the country is nearing the point at which most people who are eager to

get vaccinated have been able to do so. Now the priority will shift to convincing those who remain unwilling or uncertain.

Click here for more news about COVID-19 vaccines.
