

What doctors wish patients knew about the Johnson & Johnson vaccine

APR 27, 2021

Sara Berg

Senior News Writer

Editor's note: *The FDA has updated the Fact Sheet for the Janssen-owned Johnson & Johnson (J&J) COVID-19 vaccine and added Guillain Barré Syndrome as a risk of the vaccine. Guillain-Barré Syndrome is a rare disorder that occurs when a person's immune system damages nerve cells and causes muscle weakness or paralysis. About 3,000 to 6,000 people develop the syndrome every year in the U.S. While most people fully recover, there are some reports of long-term nerve damage.*

About 100 preliminary reports of Guillain-Barré have been detected among the 12.8 million doses administered of the J&J vaccine in the United States, according to the CDC. The cases have largely been reported about two weeks after receiving the J&J vaccination and mostly in men 50 years and older. ACIP will meet to further review and discuss the Guillain-Barré cases.

The fact sheet states that "the chance of having this occur is very low and the benefits of the vaccine continue to outweigh the risks." It also notes that patients should immediately seek medical care if they "develop any of the following symptoms after receiving the Janssen COVID-19 vaccine:

- *Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body.*
- *Difficulty walking.*
- *Difficulty with facial movements, including speaking, chewing, or swallowing.*
- *Double vision or inability to move eyes.*
- *Difficulty with bladder control or bowel function."*

After receiving emergency use authorization from the Food and Drug Administration (FDA), Johnson & Johnson-owned Janssen Pharmaceuticals became the third company to make its coronavirus vaccine available in the country. The Johnson & Johnson (J&J) SARS-CoV-2 viral vector vaccine joined mRNA vaccines made by Pfizer-BioNTech and Moderna to help prevent more severe COVID-19 outcomes, including hospitalizations and death.

The J&J one-shot vaccine for adults was another major step toward vaccinating millions of people across the country. While its single-dose, easy-to-store logistical advantages make it an attractive option, it's important to understand why there was a recent pause in J&J vaccine administration due to a rare brain blood clot combined with low platelets—cerebral venous sinus thrombosis with thrombocytopenia (TTS). These adverse events were identified through the Vaccine Adverse Event Reporting System, which is jointly managed by the Centers for Disease Control and Prevention (CDC) and FDA.

Among nearly 8 million doses of the J&J vaccine administered through April, the FDA and CDC reviewed data involving 15 reported cases in the U.S. of cerebral TTS in people receiving the vaccination. Most were in women between 18 and 48, with symptoms developing six to 13 days after vaccination. Since the pause has been lifted, the J&J Janssen vaccine is recommended for those 18 or older under an amended FDA emergency use authorization, which includes additional warnings and precautions, especially for women under 50.

Two physician experts took time to share what patients should know about the J&J vaccine: AMA Chief Health and Science Officer Mira Irons, MD, and Sandra Fryhofer, MD, an Atlanta general internist who serves as the AMA's liaison to the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). Dr. Fryhofer also is a member of ACIP's COVID-19 Vaccine Work Group.

Only one dose is needed

The J&J vaccine "is the first authorized vaccine to require one dose instead of two," said Dr. Irons during an episode of the "AMA COVID-19 Update" about the Janssen COVID-19 vaccine.

"The good thing about the Janssen vaccine is it's one dose and you're done," echoed Dr. Fryhofer, a member of the AMA Board of Trustees. That means "you don't have to go back for a second dose. You don't have to make a second appointment. You can get fully vaccinated at one visit."

Additionally, the J&J Janssen vaccine "can be stored at regular refrigerator temperatures and does not require dilution, which makes storage and administration easier," she said. "Many clinicians had

high hopes of using this vaccine in hard to reach geographical areas.”

Don't compare the three vaccines

“Don't get caught up necessarily on the numbers game, because it's a safe and effective vaccine and what we need is to have as many effective vaccines as possible,” said Dr. Irons. Rather than focusing on efficacy rates, “accept the fact that now you have three highly effective vaccines.”

“These vaccines have not been tested head to head, so it's impossible to do a really accurate comparison,” she said. “What matters most is ... they are all effective at preventing the most severe COVID outcomes, including hospitalization and death.”

“All three vaccines far exceeded FDA's 50% efficacy threshold,” said Dr. Fryhofer.

Read about what to tell your patients when they ask which vaccine to get.

Vaccine pause showed system's strength

The “CDC and FDA acted quickly and issued a joint statement recommending the pause,” Dr. Fryhofer said during a recent “AMA COVID-19 Update” episode about the J&J Janssen COVID-19 vaccine pause. The CDC also “released additional information through its Health Alert Network,” which “could lead to more cases being reported as a result of increased awareness.”

Additionally, the CDC warned “that in these cases, heparin, a standard therapy for blood clots, could cause tremendous harm,” Dr. Fryhofer added, noting that the “CDC advises checking for platelet activating antibodies by doing a platelet factor four (PL4) antibody test.”

The “CDC advises against heparin therapy if platelet factor four antibody test is positive,” she said. “If PL4 test is positive, use of non-heparin anticoagulants and high dose intravenous immune globulin should be considered. Hematology consultation is also advised.”

After a thorough review, ACIP lifted the J&J Janssen vaccine pause April 23.

AMA President Susan R. Bailey, MD, commended ACIP for “reaffirming its recommendation on the use of the Janssen COVID-19 vaccine” for those 18 or older under the FDA's emergency use authorization. “The population-level data presented during ACIP's meeting ... clearly demonstrates that the benefits of this approach outweigh the risks,” she said.

“The pause on the Janssen COVID-19 vaccine has demonstrated the strength of our nation's vaccine

safety monitoring system and the transparent and careful deliberations by the ACIP should raise confidence in FDA-authorized and CDC-recommended COVID-19 vaccines,” Dr. Bailey added. “The AMA continues to encourage everyone who is eligible for COVID-19 vaccines to get vaccinated as soon as possible.”

Discover what physicians should know about the J&J vaccine and brain blood clots.

Which symptoms to look for

“After COVID vaccination, patients should expect flu-like symptoms, a mild to moderate headache, fatigue, fever, muscle aches,” Dr. Fryhofer said, noting that “these symptoms are expected and usually resolve within one to two days.”

“The risk of this concerning combination of blood clots and low platelets is rare but serious,” she said. “Patients who’ve had the Janssen vaccine should seek immediate medical attention if they develop shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms including severe or persistent headache or blurred vision, or petechiae beyond the site of vaccination.

“Patients with these symptoms should contact their physician and seek medical evaluation,” Dr. Fryhofer added.

You have other vaccine choices

The FDA updated the J&J Janssen vaccine EUA with an additional warning, noting that “women under 50 should be made aware of a rare risk of blood clots and low platelets following vaccination,” said Dr. Fryhofer. “They also need to know there are other COVID vaccines out there that don’t pose this small risk.

“That empowers patient choice. It also means vaccination clinics should make clear which vaccine or vaccines are being offered and when,” she added.

With the J&J Janssen vaccine, the benefits of the one-dose regimen far outweigh the risks. But, if people are worried, they can access Pfizer or Moderna COVID-19 vaccines. There have been more than 180 million doses of mRNA vaccines by Pfizer and Moderna administered with no reports of cerebral venous sinus thrombosis with thrombocytopenia.

Discover what to tell your patients when they ask which COVID-19 vaccine they should get.

It prevents hospitalization

While J&J's vaccine has 66.3% effectiveness overall and 74.4% effectiveness in the United States, it has "100% efficacy against hospitalization and death from the virus," said Dr. Irons. "That's really what we have to focus on."

She noted that White House Chief Medical Adviser Anthony Fauci, MD, among other top experts, are "saying is that it's really important to focus on the severe end of the spectrum, preventing hospitalization and death."

"No hospitalizations occurred in the vaccine group 28 days or more after vaccination as compared to 16 in the placebo group," said Dr. Fryhofer. "There were also no COVID-associated deaths among those who were vaccinated. That's pretty powerful."

Variants were spreading during testing

"When it came time for the Janssen vaccine trial, the background COVID incidence was higher," said Dr. Fryhofer. "There were more variants circulating, including the variants of concern that can increase transmissibility and disease severity."

"When the Janssen vaccine was tested, it was at the height of the pandemic," she said. "The variants of concern were out there, so the test for the Janssen vaccine was harder—you can't compare them."

"If you look at the Janssen vaccine, the efficacy did vary across geographic regions," said Dr. Fryhofer. "In the United States, it was 74.4% effective. In South Africa, it was only 52% effective and that's where that variant B.1.351 was dominant."

Discover what doctors wish patients knew about new coronavirus variants.

Adenovirus vector vaccines aren't new

"Janssen's phase three clinical trial included more than 40,000 participants. In addition, Janssen's viral vector platform is supported by an even larger body of evidence, including an Ebola vaccine that's already been tested in pregnant women and children and approved in Europe," said Dr. Fryhofer. "More than 193,000 people—including patients of different ages and conditions—have been vaccinated with various investigational vaccines using this adenovirus platform."

“The adenovirus vector vaccine uses a modified cold virus—an adenovirus called Ad26—as the viral vector and several genes have been removed from this virus,” she explained. “It’s replication deficient, so it cannot multiply in the body.”

This means that “it cannot give someone COVID-19,” said Dr. Fryhofer. “The company says this safety sign imbalance—blood clots and low platelets—did not show up in the phase three trial or with their research on other Ad26 based viral vector vaccines.

“However, in the phase 3 trial, one patient, a 25-year-old male, did suffer CVST, had low platelets and also had PF4 antibodies,” she added.

Expect the same side effects

Aside from the extremely rare blood clots discussed above, “the side effects for the J&J vaccine are very similar to those for the mRNA vaccines, including injection-site pain, headache, fatigue, fever, chills and muscle aches,” said Dr. Fryhofer.

With most of the side effects occurring within one to two days following vaccination, Dr. Fryhofer recommends choosing a day or two when “you don’t have a lot of important stuff going on, because you might not feel well.”

Learn more from the AMA about what doctors wish patients knew about COVID-19 vaccination.

There is easier access

Since the J&J vaccine doesn’t require colder temperatures for storage as the Moderna and Pfizer vaccines do, “it’s more mobile, so it’s perfect for people who are homebound, that can’t—or won’t—go to a second appointment,” said Dr. Fryhofer. “It’s also good for people who move around a lot.”

“As I’ve talked to other physicians about this vaccine, one physician who provides health care for those in jails and prisons said, ‘We have people constantly coming in and out of the system, it’s hard keeping track,’” she said. “So, this is one way we could give them this vaccine and feel good that they’re now fully protected.”

Tested in large, diverse groups

As with the Moderna and Pfizer COVID-19 vaccine trials, the J&J vaccine was tested with in large and diverse populations of patients. Nearly 44,000 people in South Africa, certain countries in South America, Mexico and the U.S. took part in the J&J testing.

“These vaccine manufacturers, when they’ve recruited participants, they’re thinking about diversity,” said Dr. Fryhofer. “They’re including people with different ethnicities and different geographies. They also include both older and younger people as well as those with underlying medical conditions.”

The AMA has developed frequently-asked-questions documents on COVID-19 vaccination covering safety, allocation and distribution, administration and more. There are two FAQs, one designed to answer patients’ questions, and another to address physicians’ COVID-19 vaccine questions.