

What doctors want patients to know about the Johnson & Johnson vaccine

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Editor's note: The emergency use authorization of the J&J COVID-19 vaccine has expired as of May 2023, and the vaccine is no longer available in the U.S. People 18 or older who received one dose of the J&J COVID-19 vaccine should get one bivalent mRNA dose from Moderna or Pfizer-BioNTech at least two months after completion of the previous dose. Learn more from the CDC about [updated clinical consideration for use of COVID-19 vaccines](#).

After receiving emergency use authorization from the Food and Drug Administration (FDA) and recommendation from the Centers for Disease Control and Prevention (CDC), 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.

J&J's 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 what to expect with the Johnson & Johnson COVID-19 vaccine and the need for a booster shot.

The AMA's What Doctors Want Patients to Know™ series provides physicians with a platform to share what they want patients to understand about today's health care headlines, especially throughout the COVID-19 pandemic.

In this installment, two physician experts took time to share what patients should know about the J&J vaccine. They are:

- Mira Irons, MD, president and CEO of the College of Physicians of Philadelphia. In a prior role, Dr. Irons served as chief health and science officer at the AMA.
- [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.

One dose is a full vaccine series

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](#).

"A Janssen vaccine series is still a single dose of vaccine that's designated in Janssen's emergency use authorization from FDA," said Dr. Fryhofer, a member of the [AMA Board of Trustees](#). "One dose is still considered a full dose series for public health purposes, but now a booster is recommended at least two months later for everyone 18 and older who has received a single Janssen dose.

"Some experts say Janssen should have been a two-dose vaccine from the beginning," she added. "When and if Janssen receives full FDA approval, the one dose recommendation could change and possibly become two, but that has not happened yet and it may not. It will be interesting to see what happens."

Additionally, the J&J Janssen vaccine "can be stored at regular refrigerator temperatures and does not require dilution, which makes storage and administration easier," Dr. Fryhofer explained. "Many clinicians had high hopes of using this vaccine in hard to reach geographical areas. We need this vaccine as an option."

There are three safe 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.”

“We do have three safe and highly effective COVID vaccines. COVID vaccines continue to maintain high protection against severe disease, hospitalization and death,” said Dr. Fryhofer. “However, we are seeing breakthrough infections. It’s all about waning immunity—with time and with the Delta variant, along with concern about vaccine effectiveness against future variants of concern.

“Studies presented to FDA and others reviewed by ACIP show some waning of immunity with time,” she added. “For example, a recent study published in Sept. 28 MMWR looked at COVID vaccine effectiveness against hospitalization from mid-March through mid-August. VE—vaccine effectiveness—was higher for Moderna vaccine at 93% as compared to Pfizer-BioNTech vaccine at 88%.”

“Pfizer vaccine effectiveness declined significantly from 91% down to 77%—at more than four months after the second vaccine dose. Moderna vaccine effectiveness did not wane as much as Pfizer,” Dr. Fryhofer explained. “VE for both mRNA vaccines was higher than Janssen. Janssen’s single dose vaccine had the lowest vaccine effectiveness at 71%.

“Janssen protection is pretty stable—it doesn’t wane as much, but its vaccine effectiveness has never been up to par with mRNA vaccines,” she added. “Janssen never made it up to mRNA vaccine standards when it came to vaccine effectiveness, so the booster recommendation for everyone who received Janssen should help enhance its protection.”

Read about [what to tell your patients when they ask which vaccine to get](#).

Everyone should get a booster shot

“For adults who receive the Janssen vaccine, the time frame’s different” than booster shots for Pfizer-BioNTech and Moderna mRNA vaccines, explained Dr. Fryhofer during an episode of the “[AMA COVID-19 Update](#)” about [the new mix and match strategy for](#)

[boosters](#). “A booster is recommended at least two months after a single Janssen dose primary series. This applies to everyone 18 and older who received it.

“This broad eligibility is due to Janssen's lower vaccine effectiveness as compared to mRNA vaccines. The boost can help increase Janssen vaccine effectiveness,” she added. “And to get a booster, it's still the honor system. If people say they're eligible, they can get it.”

For side effects from the booster shot, “people should expect more of the same—pain at the injection site, headache, fatigue, muscle aches, fever, chills,” said Dr. Fryhofer, adding that side effects “probably won't be worse with one exception, tender swollen lymph nodes under the vaccinated arm.”

Additionally, “risk of vaccine-specific adverse reactions in certain age groups, as well as sex-based differences could be considered,” she said. “For example, Janssen vaccine has been linked to TTS—thrombosis with thrombocytopenia syndrome—in which rare types of blood clots in unusual places along with really low platelets.

“The TTS risk is higher in females under 50 and this is why some ACIP members were concerned about young women receiving a second Janssen vaccine dose and push for the nonspecific language for the kind of booster allowed,” Dr. Fryhofer added, also noting that “Guillain Barré Syndrome, GBS, risk is highest in males 50-64, in the 42-day window after the first dose.”

Discover [what doctors must know about Moderna and J&J COVID-19 vaccine boosters](#).

Mixing and matching is OK

“The language CDC uses in the recommendation for the kind of booster to give is neutral and vague. ... It doesn't specify what kind of booster to give, and this is not an oversight,” said Dr. Fryhofer. “The bottom line: you can boost with any authorized COVID vaccine.

“The booster doesn't have to match the primary vaccine series type. This is called heterologous boosting,” she added. “On the other hand, boosting with the same type of vaccine as the one you originally received is called homologous boosting. Either strategy is

permitted.”

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.”

There is also risk of a rare brain blood clot combined with low platelets—cerebral venous sinus thrombosis with thrombocytopenia, or TTS. These adverse events were identified through the Vaccine Adverse Event Reporting System, which is jointly managed by the CDC and FDA. The highest reporting rate is in 30–39-year-old females within 21 days of vaccination and occurs at a rate of 10 cases per million doses administered.

“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.

Additionally, the FDA updated the [fact sheet](#) (PDF) for the J&J COVID-19 vaccine and added Guillain Barré Syndrome—a rare disorder that occurs when a person’s immune system damages nerve cells and causes muscle weakness or paralysis—as a risk of the vaccine. The chance of having this occur is very low and the benefits of the vaccine outweigh the risks. Most cases occurred in males 50 and older about two weeks after J&J vaccination with increased risk during the 42-day window after vaccination.

Patients should seek medical care if they develop weakness or tingling sensations in the legs or arms that worsens and spreads to other parts of the body. Other symptoms to be mindful of are difficulty with walking, facial movements and bladder control or bowel function as well as double vision or inability to move their eyes.

You have other vaccine choices

The FDA updated the [J&J Janssen vaccine EUA](#) (PDF) 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](#).

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 and risk of GBS 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 want patients to know about COVID-19 vaccination](https://patients.ama-assn.org/public-health/infectious-diseases/what-doctors-want-patients-know-about-johnson-johnson-vaccine).

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 vaccinated. CDC's mix and match booster strategy enhances the flexibility of keeping people 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](#) (PDF), and another to address [physicians' COVID-19 vaccine questions](#) (PDF).