# **Fast Facts**

# about the Johnson & Johnson COVID-19 Vaccine and the CDC's Preferential Recommendation for mRNA COVID-19 Vaccines

CDC has recently made changes to its recommendation of the Johnson and Johnson (J&J) Janssen COVID-19 vaccine. As of December 16, 2021, CDC now expresses a clinical preference for individuals to receive an mRNA COVID-19 vaccine (Moderna and Pfizer-BioNTech) over the J&J vaccine. mRNA vaccines are now preferred over the Janssen COVID-19 vaccine for the prevention of COVID-19 for those 18 years of age and over.

This change from a full recommendation to a 'preferential recommendation' can be confusing for providers and patients. Below we offer some answers to common questions about the change.

## What is a preferential recommendation?

The Advisory Committee on Immunization Practices (ACIP) can recommend some vaccines over others due to their effectiveness, safety, and availability—this is called a preferential recommendation.

#### Why are mRNA vaccines preferred over the J&J vaccine?

The CDC's preference to use mRNA vaccines comes after a review of new evidence, which suggests that rates of a rare blood clotting disorder (thrombosis with thrombocytopenia syndrome or TTS) linked to the J&J vaccine are higher than previously estimated.

# Is the J&J vaccine still authorized by the FDA?

Yes, the J&J COVID-19 vaccine still maintains its Emergency Use Authorization (EUA) to prevent COVID-19 in individuals 18 years of age and older. The EUA has been updated with the risk data mentioned below, but the preferential recommendation is not mentioned in the EUA because such a recommendation is the domain of the CDC and not the FDA.

#### Does CDC still recommend the J&J vaccine?

To some extent, yes. While the use of mRNA COVID-19 vaccines is preferred over the J&J COVID-19 vaccine for all vaccine-eligible persons, ACIP and CDC agree that receiving any vaccine is better than being unvaccinated. CDC continues to recommend the J&J COVID-19 vaccines in some situations.

# Under what circumstances may a J&J vaccine be administered?

CDC identifies three situations under which the J&J COVID-19 vaccine may be administered:

- When there is a **contraindication** to mRNA COVID-19 vaccines (e.g., severe allergic reaction after a previous dose or to a component of an mRNA COVID-19 vaccine)
- When a person would otherwise remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines
- When a person wants to receive the Janssen COVID-19 vaccine despite the safety concerns

# How long after receiving the J&J COVID-19 vaccine might TTS occur?

Reports of TTS following the use of the J&J COVID-19 Vaccine indicate onset of symptoms began approximately 1 to 2 weeks after vaccination. It is recommended that for **3 weeks** after receiving this vaccine, patients should be aware of possible symptoms of a blood clot with low platelets and seek medical care immediately if these symptoms occur.

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#### Preferential Recommendation, Cont.

# What are the symptoms of TTS?

The primary symptoms of TTS following vaccination include:

- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Severe or persistent headaches or blurred vision
- Easy bruising or tiny blood spots under the skin beyond the injection site

# How common are cases of TTS following administration of the J&J vaccine?

The overall reporting rate of TTS following J&J vaccinations is

~3.8 cases per million doses

For women between 30-49 years of age, this rate increases to

~10 cases per million doses

15% of all these TTS cases have been fatal.

Given this safety profile and the abundance of mRNA COVID-19 vaccines available in the U.S., the CDC prefers mRNA vaccines over the J&J COVID-19 vaccine. This updated CDC recommendation follows similar recommendations from other countries, including Canada and the United Kingdom.

## Should patients receive the J&J vaccine as a booster dose?

CDC's preferential recommendation applies to the use of the J&J vaccine as a primary dose and a booster shot. When possible, mRNA COVID-19 vaccines are preferred.

It is contraindicated to administer the J&J vaccine to persons with a history of TTS following receipt of this vaccine or any other adenovirus vector-based COVID-19 vaccines. These people should receive a dose of an mRNA COVID-19 vaccine as a booster at least 2 months (8 weeks) following their dose of the J&J vaccine and after their clinical condition has stabilized.

Prior to booster vaccination, a conversation between the patient and their clinical team, including a hematologist or other specialists, may assist with decisions about using an mRNA COVID-19 vaccine as a booster and the timing of the booster vaccination.

# What do I do if a patient asks for the J&J vaccine?

Providers and vaccinators should encourage their patients to take a COVID-19 mRNA vaccine if they are readily available, but if a patient shows interest in the J&J vaccine and is opposed to the mRNA vaccines (for whatever reason, be it a preference for viral vector vaccines, contraindications, or concerns about the safety profile of mRNA vaccines regarding myocarditis), then they can still receive the J&J COVID-19 vaccine.

Before administering the J&J vaccine, providers should ensure that the patient knows the risks associated with the J&J vaccine. They should check that the patient has read the fact sheet fully and understands all the risks involved. They need to discuss the possibility TTS after receipt of the J&J COVID-19 vaccine and explain that there are other COVID-19 vaccine options available for which this specific risk has not been seen.

#### If the patient gives full informed consent, then they can still receive the J&J vaccine.

After administering the J&J vaccine, providers should encourage their patients to be attentive to symptoms of TTS for the next 3 weeks.

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