

## Facts on the Johnson & Johnson COVID-19 Vaccine

### What is the new guidance for the Johnson & Johnson COVID-19 vaccine?

The CDC's immunization advisory committee voted 15-0 on Friday December 17, 2021, to amend guidance for the Johnson & Johnson (J&J) COVID-19 vaccine. The CDC now recommends the use of mRNA (Pfizer or Moderna) COVID-19 vaccines and boosters over the use of the J&J COVID-19 vaccine and booster in all individuals 18 years and older for the prevention of COVID-19.

### Why did the Johnson & Johnson COVID-19 vaccine guidance change?

The FDA and CDC updated guidance regarding the J&J COVID-19 vaccine on December 17, 2021, after reviewing data on the increased risk of Thrombosis with thrombocytopenia syndrome (TTS) following the administration of a J&J COVID-19 vaccine in individuals 18 years and older.

### What is TTS?

TTS is a serious, but rare, adverse event that causes blood clots with low platelets. As of December 8, 2021, more than 16.9 million doses of the J&J COVID-19 vaccine have been given in the United States. The CDC and FDA identified 57 confirmed reports of people who got the J&J COVID-19 vaccine and later developed TTS. VAERS reports have identified nine deaths that have been caused by or were directly attributed to TTS following J&J COVID-19 vaccination.

### I want the Johnson & Johnson COVID-19 vaccine, can I still get it?

Yes. The COVID-19 vaccine that an individual receives is a decision left to be made by each individual and their health care provider. However, mRNA vaccines are strongly recommended over the use of the J&J COVID-19 vaccines for the prevention of COVID-19. The CDC and North Dakota Department of Health (NDDoH) strongly prefer the use of mRNA vaccines unless an individual has 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), if a person would otherwise remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines, or when a person

wants to receive the J&J COVID-19 vaccine despite the safety concerns identified.

### I received a Johnson & Johnson COVID-19 vaccine and I am worried about TTS, what should I do?

TTS is a very rare, but serious, side effect associated with the J&J vaccine. Seek medical help immediately if you have any of these symptoms within 3 weeks of receiving the J&J COVID-19 vaccine:

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

### Does this change in guidance mean that COVID-19 vaccines are unsafe?

No. FDA approved or authorized COVID-19 vaccines available in the United States are safe and effective at preventing COVID-19 illness, hospitalization, and death. However, the updated guidance for the J&J COVID-19 vaccine proves that the safety monitoring systems in place, such as VAERS and V-Safe, are working to alert officials of risks associated with COVID-19 vaccines as they arise. Millions of Americans have and continue to receive COVID-19 vaccines under the most intense safety monitoring efforts in US history.

### When did this vaccine become available in North Dakota?

The FDA issued an emergency use authorization (EUA) for [Johnson & Johnson](#) COVID-19 vaccine for use in people 18 years and older on February 27, 2021. In March 2021, North Dakota received its first allocation of J&J vaccine.

### What type of vaccine is it?

The J&J COVID-19 vaccine is a non-replicating viral vector vaccine. This differs from the Pfizer and Moderna vaccines, which are both mRNA vaccines.

### How does this vaccine work?

This vaccine [works](#) by using a viral vector, a harmless virus called adenovirus 26, which has been modified to include a gene that codes for the SARS-CoV-2 spike protein. Once the viral vector enters the human cell, it produces the SARS-CoV-2 spike protein and that triggers an immune response in our bodies. J&J used this same approach to make an Ebola vaccine that has been authorized for use by the European Medicines Agency.

#### **How many doses does it require?**

The J&J COVID-19 vaccine requires one dose. This differs from the Pfizer and Moderna vaccines that both require two doses to complete the series.

#### **What is the effectiveness of this vaccine?**

Clinical trial data indicated that this vaccine is 66% effective at preventing moderate to severe COVID-19 and 85% effective at preventing severe disease 28 days after vaccination. Real world data has shown that J&J provides [strong protection against variants](#) (like Delta), reducing the risk for COVID-19 associated hospitalization by 71%.

#### **I'm immunocompromised and received a J&J vaccine, can I receive an additional dose?**

At this time there is not enough data to determine whether immunocompromised people who received the J&J COVID-19 vaccine also have an improved antibody response following an additional dose. The FDA and CDC are actively working to provide guidance on this issue.

#### **If I received a J&J vaccine, do I need a booster?**

Yes, all individuals 18 years and older who received a single dose of the J&J COVID-19 vaccine should receive a COVID-19 vaccine booster dose at least 2 months after completing their primary vaccine series.

#### **Which vaccine should I get for my booster dose?**

The CDC recommends that individuals who received an initial dose of J&J COVID-19 vaccine should receive either a Pfizer or Moderna (mRNA) vaccine as their COVID-19 booster dose at least 2 months following their initial J&J dose.

However, the CDC does allow for a "mix and match" approach to booster doses for all three available COVID-19 vaccines in the US. It is up to the health care provider and the patient to determine which COVID-

19 vaccine brand is the best option for a booster dose. More information can be found on the NDDoH's [booster dose FAQ](#). All persons who elect to receive a J&J COVID-19 vaccine booster should be informed about the risk and symptoms of TTS that could occur after vaccination.

#### **What are the side effects from this vaccine?**

Most common side effects reported were pain at the injection site, headache, fatigue, muscle aches and nausea. J&J vaccine has been linked to two potentially serious but extremely rare adverse events: [blood clots with low platelets](#) (also known as TTS) and [Guillain-Barre Syndrome](#).

#### **Were different races and ethnicities included in the J&J clinical trials?**

J&J is reporting that 26% of its participants in the U.S. and 31% of its participants globally are from diverse backgrounds.

#### **Were fetal cells used to create the vaccine?**

The J&J vaccine did require the use of fetal cell cultures to develop and manufacture the vaccine. The [Catholic Church](#) and the [Southern Baptist Ethics and Religious Liberty Commission](#) have both stated that receiving a COVID-19 vaccine that required fetal cell lines is morally acceptable. However, if an individual can choose among the available vaccines, the [Catholic Church](#) has stated that Pfizer's and Moderna's COVID-19 vaccines are preferable to J&J's COVID-19 vaccine.

#### **How can I find COVID-19 vaccine in my area?**

To see where COVID-19 vaccine is available in your area, check out the NDDoH [website](#).

#### **I still have questions, who can I speak to?**

To contact the NDDoH Division of Immunizations, call 701-328-3386 or toll-free 1-800-472-2180.