

Update on the Johnson & Johnson/Janssen COVID-19 Vaccine

The Johnson & Johnson/Janssen COVID-19 vaccine is available in NYC for people age 18 and older following a short pause in use to investigate a potential health issue related to the vaccine. The NYC Department of Health and Mental Hygiene (NYC Health Department) continues to have confidence in the safety and effectiveness of the Johnson & Johnson vaccine and other authorized COVID-19 vaccines. Vaccination remains the most important step you can take to protect yourself, your loved ones and our communities from COVID-19.

Why was there a pause in the use of the Johnson & Johnson vaccine?

On April 13, 2021, the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) recommended use of the Johnson & Johnson vaccine be temporarily stopped following reports of a rare blood clot in six people who received the vaccine. The cases were identified through the CDC and FDA's vaccine safety monitoring system. Use of the vaccine was paused so additional information could be collected and reviewed.

What did the investigation show?

As of April 21, 2021, there were 15 cases of a rare type of blood clot with low blood platelets out of the approximately 8 million people who received the Johnson & Johnson vaccine since it was authorized. This condition is called thrombosis (blood clot) with thrombocytopenia (low blood platelet count) syndrome (TTS). All reported cases of TTS were in women between ages 18 and 59, with symptoms beginning six to 15 days after vaccination. This is a rate of about seven cases of TTS per one million women between ages 18 and 49 who were vaccinated and less than one case per one million women age 50 and older who were vaccinated. There was also one case of TTS in a male participant in the vaccine clinical trials.

What does the CDC and FDA recommend about use of the vaccine?

The CDC and FDA recommend the Johnson & Johnson vaccine continue to be given to people age 18 and older. This decision is based on a recommendation by the Advisory Committee on Immunization Practices, an independent group of medical and public health experts who reviewed the available data and information, and weighed the potential health risks of getting the vaccine against the benefits. People who receive the vaccine, especially women less than 50 years old, should be aware of the rare but increased risk of TTS and that there are other COVID-19 vaccine options available for which this risk has not been seen.

Why is NYC still using the vaccine given this safety issue?

The risk of TTS is very low, and the vaccine is very effective at preventing severe illness, hospitalization and death due to COVID-19. Now that we know about the risk, we can give people who get the Johnson & Johnson vaccine the information they need to identify possible symptoms of TTS and get care right away. Health care providers are now also aware of this risk, which means they can diagnose and treat patients who develop TTS after getting the Johnson & Johnson vaccine. No medication, therapy or vaccine is 100% risk-free.

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If I choose to get the Johnson & Johnson vaccine, are there extra precautions I should take?

While your risk of TSS from the Johnson & Johnson vaccine is very low, you should monitor yourself for potential symptoms for three weeks after getting the vaccine, such as:

- Shortness of breath
- Chest pain
- Leg swelling
- Lasting abdominal pain
- Severe or lasting headache

- Blurred vision
- Bruising easily
- Tiny red spots under the skin beyond the area of the injection site

If you have any of these symptoms within three weeks of vaccination, seek medical care immediately — go to a nearby hospital or call **911**. Tell the treating provider you received the Johnson & Johnson vaccine.

In contrast, side effects that are common after vaccination include soreness and swelling on the arm where you got the shot, tiredness, mild achiness, chills, mild headache or low-grade fever. These are expected side effects and usually begin within the first three days after vaccination (the day after vaccination is the most common) and usually last one to two days after they begin.

Is there a risk of TTS from the other COVID-19 vaccines?

TTS has not been linked to the Pfizer-BioNTech and Moderna COVID-19 vaccines after more than 200 million doses of vaccine administered in the U.S. We strongly encourage people who do not want to get the Johnson & Johnson vaccine to consider getting one of these vaccines.

Hundreds of vaccination sites are available around NYC. Visit <u>vaccinefinder.nyc.gov</u> to find a vaccination site (the vaccines offered at each site are listed) or call 877-VAX-4NYC (877-829-4692) for help with an appointment at a City-run site. Many sites are also accepting walk-ins. See <u>here</u> for a list of City-run walk-in sites.

How do we know there are no other vaccine safety issues?

COVID-19 vaccines continue to go through intensive safety monitoring by the CDC, FDA and other groups. The identification of a small number of cases of TTS from the millions of doses of vaccine given around the U.S. and pause in use of the Johnson & Johnson vaccine show that the safety systems work and that safety and transparency are top priorities. We are committed to sharing information about the vaccines, including any potential safety issues.

Where can I get more information?

If you have any questions, please call your provider or **311**. For COVID-19 vaccine information and resources, visit nyc.gov/covidvaccine. The FDA's revised Johnson & Johnson vaccine patient fact sheet can be found here. Additional information is available on the CDC website here.

The NYC Health Department may change recommendations as the situation evolves.