COVID-19 Fact Sheet
Johnson & Johnson COVID-19 Vaccinations Resume in Ohio

The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) recommended on April 23, 2021, that use of the Johnson & Johnson (Janssen) COVID-19 vaccine could resume following a 10-day pause. This joint recommendation followed a thorough safety review by scientific advisors that included two meetings of the CDC Advisory Committee on Immunization Practices (ACIP).

The federal health agencies advise that the benefits of the vaccine in preventing COVID-19 outweigh the risks of rare blood clotting that has occurred in a small number of people who have received the Janssen COVID-19 vaccine, but that warnings about the potential for rare clots are essential.

Rare blood clots reported

Approximately 6.8 million Johnson & Johnson COVID-19 vaccine doses were administered in the U.S. before the pause was issued by the FDA and CDC on April 13, 2021. Six cases of a blood clot called cerebral venous sinus thrombosis (CVST) were seen in combination with low levels of blood platelets (thrombocytopenia), according to the FDA and CDC, warranting further study. Nine additional cases were reported after the temporary pause was issued, for a total of 15 cases of thrombosis with thrombocytopenia syndrome (TTS). All 15 cases were reported to the Vaccine Adverse Event Reporting System (VAERS). All of these cases occurred in women between the ages of 18 and 59, with a median age of 37 years. Reports indicated symptom onset between six and 15 days after vaccination.

Recommended treatment of TTS is different from the treatment that might typically be administered for a blood clot, according to the CDC. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this case, administration of heparin could worsen symptoms and should not be used to treat this condition. Alternative anticoagulant treatments need to be given with a TTS diagnosis. The CDC issued a health alert on April 13 to provide recommendations for clinicians, including treatment options for TTS.

The following information has been added to the Johnson & Johnson emergency use authorization Fact Sheet for Recipients and Caregivers: *Thrombosis involving large blood vessels, including the cerebral venous sinuses, portal vein, lower extremity veins, and pulmonary artery, with thrombocytopenia have been reported following the Janssen COVID-19 vaccine.*

Warning signs and symptoms

This adverse event is rare, occurring at a rate of about seven per 1 million vaccinated women between 18 and 49 years old, according to the CDC. For women 50 years and older and men of all ages, this adverse event is even more rare.

For three weeks after receiving the vaccine, people should be on the lookout for possible symptoms of a blood clot with low platelets and **seek medical care immediately if you have one or more of these symptoms:**

- 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 beyond the injection site.

Patients with any of these symptoms should disclose their vaccination history to medical providers to ensure proper care.

People should not be concerned about mild headaches and flu-like symptoms the first few days after vaccination. Those are common, harmless side effects brought on by the immune system's response to the vaccine.

Does this impact other COVID-19 vaccines?

Women younger than 50 years old, in particular, should be aware of the rare but increased risk of this adverse event and that there are other COVID-19 vaccine options available for which this risk has not been seen, according to the CDC.

The Johnson & Johnson vaccine uses a modified version of a virus to deliver instructions to cells to make copies of the surface spike protein on SARS-CoV-2 (the virus that causes COVID-19). An inactive virus, such as one that causes the common cold, is used as a vector (or transportation device) to deliver instructions for making the spike protein. The body sees the protein as an invader and creates an immune response to fight it.

The Moderna and Pfizer vaccines use a different technology than the Johnson & Johnson vaccine. No safety concerns, including TTS, have developed from clinical trials or since emergency use authorization with either of the messenger RNA (mRNA) vaccines. MRNA vaccines use strands of genetic material to deliver a genetic code to cells to make the surface/spike protein on the SARS-CoV-2 virus. The proteins made with the mRNA instructions activate the immune system, teaching it to see the spike protein as an invader, and to develop antibodies to fight it.

Ongoing safety monitoring

COVID-19 vaccine safety is a top priority for the federal government, and reports of health problems following COVID-19 vaccination are taken very seriously. CDC and FDA will continue to monitor the safety of all COVID-19 vaccines. Detecting these rare adverse events demonstrates that the systems in place to monitor the safety of these vaccines are effective. The thrombosis with thrombocytopenia syndrome (TTS) reports were detected early, and the pause reflected the federal government's commitment to transparency and safety as CDC and FDA gathered and reviewed additional data. COVID-19 vaccines have undergone and will continue to undergo the most intensive safety monitoring in U.S. history, according to the CDC.

If someone experiences an adverse event after getting vaccinated, their vaccination provider will send a report to the Vaccine Adverse Event Reporting System (VAERS). VAERS is a national system that collects reports from healthcare professionals, vaccine manufacturers, and the public about adverse events that happen after vaccination. Reports of adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns are followed up with specific studies. If an investigation reveals that a vaccine does pose a potential risk, regulators may issue updated guidance about who should or should not receive it.

Updated April 30, 2021.

For additional information, visit coronavirus.ohio.gov. For answers to your COVID-19 questions, call 1-833-4-ASK-ODH (1-833-427-5634).

Your mental health is just as important as your physical health. If you or a loved one are experiencing anxiety related to the coronavirus pandemic, help is available 24 hours a day, seven days a week. Call the COVID-19 CareLine at 1-800-720-9616.