

Vaccine-induced Immune Thrombotic Thrombocytopenia syndrome (VITT) following J&J /Janssen COVID-19 vaccine Q&A

Clinicians: For help with evaluation and initial management, see clinical guidance [here](#) or visit the UCSF Hospital Epidemiology and Infection Prevention (HEIP) COVID-19 website [here](#).

What prompted the FDA and CDC to pause the Johnson & Johnson/Janssen vaccinations?

On April 13, 2021, Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA) recommended a pause in the use of J&J/Janssen COVID-19 Vaccine.

Federal health officials called for a pause in vaccination after reports that six patients who received the vaccine developed rare and serious blood clots (“thrombosis”), along with low blood platelet counts (“thrombocytopenia”). This syndrome is being referred to as vaccine-induced immune thrombotic thrombocytopenia (VITT), or in some literature, thrombosis with thrombocytopenia (TTS). During the pause, medical and scientific teams at the FDA and CDC examined available data to determine the risk of blood clots involving the cerebral venous sinuses (large blood vessels in the brain), and other sites in the body including but not limited to the blood vessels of the lungs, abdomen and legs.

After the vaccination pause, several additional cases were reported. However, cases so far remain extremely rare. At this time, there have been nearly 8 million doses of the J&J/Janssen COVID-19 Vaccine administered in the United States to date, meaning that the reported rate of VITT is approximately 2 cases per million doses of administered vaccine. Risk of death and serious outcome of COVID-19, including thrombosis, may outweigh risk of VITT possibly associated with a highly effective vaccine.

Who is being affected by this syndrome?

The cases that have been reported so far are in patients between the ages of 18 and 59, with symptoms starting between 6 and 15 days after vaccination. All of the confirmed cases have been in female patients, but several cases in male patients are currently under review. People who have received their J&J/Janssen vaccine between 4 and 30 days ago should monitor for symptoms. Patients who received the vaccine more than 30 days ago are not thought to be at risk at this time.

What are the symptoms of vaccine-induced immune thrombotic thrombocytopenia (VITT)?

Symptoms may vary, depending on the severity of disease and the presence and location of a blood clot. Patients with cerebral venous sinus thrombosis may have headaches, vision changes, or weakness in part of their body. Symptoms of blood clots in other areas of the body may include pain and swelling, nausea and vomiting, or trouble breathing. Responding quickly to these symptoms makes it more possible to recover.

If patients received the J&J/Janssen vaccine recently, they should be on the lookout for following symptoms:

V2

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- Severe headache
- Visual changes
- Abdominal pain
- Nausea and vomiting
- Backache
- Shortness of breath
- Leg pain or swelling
- Petechiae or easy bruising

Patients should monitor for symptoms for 30 days after receipt of the J&J/Janssen vaccination. If they develop more severe symptoms, they should proceed directly to the nearest emergency department, or call 911. If patients need additional information, they can call the UCSF COVID Hotline at 415-514-7328 or their primary care provider or specialist.

How is VITT diagnosed?

Clinicians will start by taking a medical history. Depending on symptoms, patients may need to be seen for a physical exam and additional studies, such as blood tests or specific diagnostic imaging exams (CT scan, MRI, ultrasound, etc). If certain lab abnormalities (such as low platelets) or blood clots are discovered during testing, patients will often be admitted to the hospital for treatment and observation.

How is information on these cases being collected and evaluated by UCSF and others?

All reports of health problems following COVID-19 vaccination are taken very seriously. On a national level, adverse events can be reported by patients and clinicians via [V-safe](#) and through the [Vaccine Adverse Event Reporting System](#) (VAERS).

COVID vaccine reactions identified by UCSF clinicians, including vaccine-induced immune thrombotic thrombocytopenia (VITT) or other severe reactions, will be submitted in UCSF [Incident Reporting](#) (IR) system, available on the Carelinks homepage.

For VITT events, UCSF clinicians should email MedSafety@ucsf.edu with the IR report number, to ensure prompt review and reporting. Events will then be submitted to the Vaccine Adverse Event Reporting System (VAERS) and reported to San Francisco Department of Public Health by the Medication Safety Team, when appropriate.

Any questions about what should be reported or how to report, contact MedSafety@ucsf.edu.

Will Johnson & Johnson/Janssen COVID-19 vaccination resume after the pause?

On April 23, 2021, following a thorough safety review, the FDA and the CDC determined that the use of the Johnson & Johnson/Janssen COVID-19 vaccine should resume. The FDA and CDC have confidence that this vaccine is safe and effective in preventing COVID-19, and the available data show that the vaccine's known and potential benefits outweigh its known and potential risks. Available data suggest that the chance of VITT occurring is very low, but the FDA and CDC will remain vigilant in continuing to investigate this risk. Points to emphasize from the CDC / FDA include:

V2

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- The reported case rate of VITT is estimated to be 1.9 per million people vaccinated with the J&J / Janssen vaccine.
- For women aged 18 to 49 years, the estimated VITT rate is higher, at 7.0 per million vaccinated. Women in their 30s had the highest rate.
- In comparison, vaccinating 1 million adults with the Johnson & Johnson vaccine in the U.S. could be expected to lead to roughly 2100 fewer COVID-19-related deaths and roughly 6000 fewer COVID-19 hospitalizations, according to data from the manufacturer. Data on rates of long-term complications of COVID-19 were not provided.

Health care providers administering the vaccine and vaccine recipients or caregivers should review the [Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#) and [Fact Sheet for Recipients and Caregivers](#), which have been revised to include information about the risk of the VITT syndrome, which has occurred in a very small number of people who have received the J&J/Janssen COVID-19 Vaccine.