

April 27: Johnson & Johnson Vaccine Pause Lifted and Vaccine-Induced Immune Thrombotic Thrombocytopenia Update

Today's issue includes an update from the U.S. Food & Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) on the Johnson & Johnson vaccine, as well as information about the diagnosis and treatment of patients who develop vaccine-induced immune thrombotic thrombocytopenia (VITT).

JOHNSON & JOHNSON VACCINE PAUSE LIFTED

On Friday, April 23, the Illinois Department of Public Health (IDPH) **announced** that it will resume use of the Johnson & Johnson vaccine, effective immediately, following an **announcement** from the FDA and CDC lifting the vaccine pause.

As part of the announcement, the FDA issued an Emergency Use Agreement (EUA) amendment for the Johnson & Johnson COVID-19 vaccine that includes warnings and precautions. Healthcare providers administering the vaccine should review the **Fact Sheet for Healthcare Providers Administering Vaccine**. The **Fact Sheet for Recipients and Caregivers** is also available to support communications with patients and their families.

Both fact sheets have been revised to include information about the risk of thrombosis involving the cerebral venous sinuses (CVST) and other sites in the body, including but not limited to the large blood vessels of the abdomen and the veins of the legs, as well as thrombocytopenia or low blood platelet counts. Thrombosis with thrombocytopenia syndrome (TTS) has occurred in a very small number of people who have received the Johnson & Johnson vaccine. As of April 23, the FDA and CDC confirmed that 15 cases of TTS have been reported, including the original six cases that led to the pause on April 13. 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 6 and 15 days after vaccination. The IDPH continues to recommend that physicians talk to patients about the risks and benefits of any COVID-19 vaccine.

Additional information and resources

- **Fact Sheet for Healthcare Providers Administering Vaccine**
- **Fact Sheet for Recipients and Caregivers**
- **CDC Health Alert for Healthcare Providers**
- **Johnson & Johnson EUA Amendment Approval**

Additional information regarding Johnson & Johnson orders, inventory and clinical considerations will be available incrementally by the IDPH, and will be shared as soon as it becomes available.

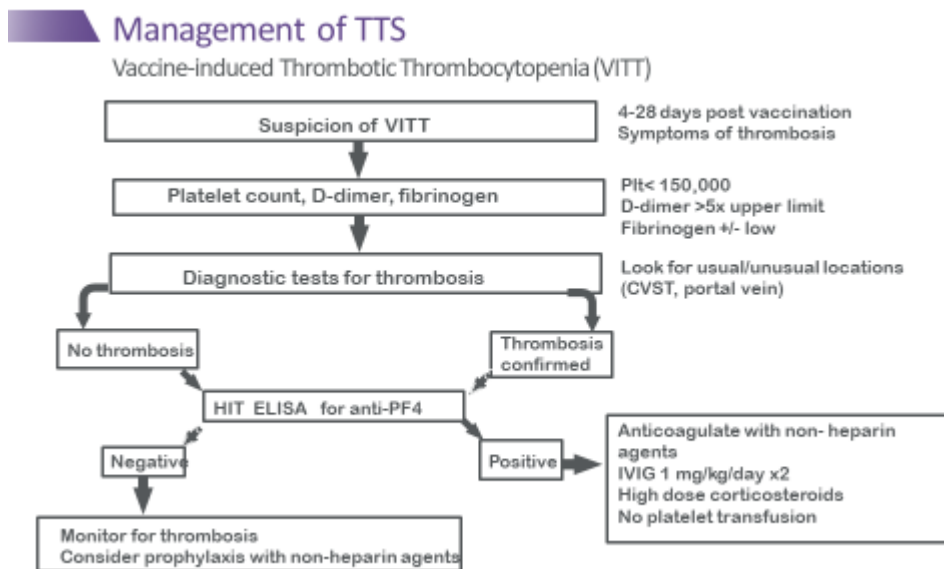
For additional information and tip sheets regarding patient vaccination, please visit the [Patient Vaccine Toolkit](#) on Physician Forum and [NM Interactive](#) (login required).

VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA DIAGNOSIS AND TREATMENT

New research from Europe demonstrates that vaccine-induced immune thrombotic thrombocytopenia (VITT) can occur with both types of COVID-19 adenovirus vector vaccines (Johnson & Johnson and AstraZeneca). The European Medicines Agency reports the following among 99 million vaccinated individuals:

- 169 cerebral venous sinus thrombosis (CVST) and 53 splanchnic vein thrombosis among 34 million people who received AstraZeneca
- Six possible CVST/splanchnic vein thrombosis among 7 million who received Johnson & Johnson

If symptoms of thrombosis develop — typically between four and 28 days after vaccination — patients should be tested for thrombocytopenia, D-dimer and fibrinogen, and HIT ELISA for anti-platelet factor 4 antibodies. If positive, IVIG in dose of 1 mg/kg daily x 2 should be given with high dose of corticosteroids. Anticoagulation with non-heparin agents should be started. Platelets should NOT be administered. See algorithm below.



Almost 9 million doses of the COVID-19 vaccine have been administered in Illinois, and 29.8% of the population is fully vaccinated. Please continue to encourage your patients to get vaccinated as doses are readily available throughout the state.

Gary A. Noskin, MD
Senior Vice President, Quality
Northwestern Memorial HealthCare

Chief Medical Officer
Northwestern Memorial Hospital