VERMONT
DEPARTMENT OF HEALTH

Health Advisory
April 13, 2021

TO: Vermont Health Care Providers and Health Care Facilities
FROM: Jennifer S. Read, MD, FIDSA; Medical Epidemiologist

Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson (J&J) Janssen COVID-19 Vaccine

As noted in the previous Health Advisory regarding the Johnson & Johnson (J&J) Janssen COVID-19 vaccine, the U.S. Food and Drug administration (FDA) issued an Emergency Use Authorization (EUA) for the use of this vaccine on February 27, 2021. As of April 12, 2021, approximately 6.85 million doses of the J&J Janssen COVID-19 vaccine have been administered in the U.S.

Today the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) issued a joint statement regarding six cases in the U.S. of a rare type of blood clot (cerebral venous sinus thrombosis (CVST)) in combination with thrombocytopenia among persons who received the J&J Janssen COVID-19 vaccine. The CDC also issued a health alert. CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on April 14, 2021 to review the available data regarding these cases. Subsequently, the FDA will review that analysis. In the interim, the CDC and the FDA recommend a pause in the use of the J&J Janssen COVID-19 vaccine. Administration of the available mRNA vaccines (Pfizer and Moderna) should continue.

The six cases of CVST with thrombocytopenia occurred among women between the ages of 18 and 48 years of age. Symptom onset occurred at a median of nine days (range: 6 to 13 days) after vaccination. The initial presenting symptoms were:

- Headache (5 of 6 patients)
- Back pain and subsequently a headache (1 of 6 patients)
- Abdominal pain, nausea, and vomiting in one patient (in addition to other symptoms)
- Focal neurological symptoms (local weakness, aphasia, visual disturbance) in four patients

Hospitalization occurred at a median of 15 days (range: 10-17 days) after vaccination. All patients were diagnosed with CVST after intracranial imaging. Two patients were also diagnosed with splanchnic and portal vein thrombosis.

Unusual for patients with thrombotic events, all six patients had thrombocytopenia (platelet count < 150,000/microliter), consistent with thrombotic thrombocytopenia. Platelet nadirs ranged from 10,000-127,000 during hospitalization. Four patients had intraparenchymal brain hemorrhage (one of whom died).

Data regarding these six patients were reported to the Vaccine Adverse Event Reporting System (VAERS). To date, there have been no reports to VAERS of CVST with thrombocytopenia among persons who received either of the two mRNA-based COVID-19 vaccines.

These reports of thrombotic events after receipt of the J&J Janssen COVID-19 vaccine are similar to reports from Europe of such events after receipt of the AstraZeneca COVID-19 vaccine. It should be noted that both vaccines contain replication-incompetent adenoviral vectors (human [Ad26.COV2.S] for J&J Janssen and chimpanzee [ChAdOx1] for AstraZeneca) that encode the spike glycoprotein of SARS-CoV-2. The pathogenesis of these rare adverse events may be related to platelet-activating antibodies against platelet factor 4 (PF4). Anti-PF4 (heparin-PF4 antibody) can induce thrombotic thrombocytopenia in a small percentage of persons exposed to heparin.

Clinicians should be prepared to recognize and manage symptoms consistent with serious thrombotic events or thrombocytopenia in persons who recently received the J&J Janssen COVID-19 vaccine. People who have recently received the J&J Janssen vaccine who develop symptoms such as severe headache, back ache, severe abdominal pain, shortness of breath, leg swelling, new neurologic symptoms, petechiae, or new or easy bruising should have a platelet count obtained and should be screened for evidence of immune thrombotic thrombocytopenia. For those patients with a thrombotic event and thrombocytopenia after the J&J Janssen COVID-19 vaccine, the initial evaluation should include a screening PF4 enzyme-linked immunosorbent (ELISA) assay (as would be performed for autoimmune HIT). Consultation with a hematologist is strongly recommended.

When these specific types of blood clots are observed following J&J COVID-19 vaccination, treatment is different from the treatment that might typically be administered for blood clots. Similar to heparin-induced thrombocytopenia, the administration of the anticoagulant heparin should be avoided in patients with potential vaccine-associated immune thrombotic thrombocytopenia (VITT), unless heparin-induced thrombocytopenia (HIT) testing is negative. Non-heparin anticoagulants and high-dose intravenous immune globulin should be considered in treatment of patients who present with immune-mediated thrombotic events with thrombocytopenia after J&J COVID-19 vaccination. Again, consultation with a specialist in hematology is strongly recommended.

Pause the use of the J&J COVID-19 vaccine until the ACIP is able to further review these CVST cases in the context of thrombocytopenia and assess their potential significance.

REQUESTED ACTIONS:

1. Be aware of the adverse events reported among recipients of the J&J Janssen COVID-19 vaccine. In patients with the appropriate clinical presentation, obtain a platelet count as initial screen for immune thrombotic thrombocytopenia.

2. Pause the use of the J&J Janssen COVID-19 vaccine until further notice. Continue administration of the available mRNA vaccines.

3. Be prepared to recognize and manage, in consultation with a specialist in hematology, these potential adverse events among persons who have received the J&J Janssen COVID-19 vaccine.

4. Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).

If you have any questions, please contact the HAN Coordinator at 802-859-5900 or vthan@vermont.gov.

HAN Message Type Definitions
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Health Advisory: Provides important information for a specific incident or situation may not require immediate action.
Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.
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