DEPARTMENT OF HEALTH

Health Advisory: Cerebral Venous Sinus Thrombosis After Johnson & Johnson Vaccine

Minnesota Department of Health, Tue, Apr 13 15:00 CST 2021

Action Steps

Local and tribal health department: Please forward to hospitals, clinics, urgent care centers, emergency departments, pharmacies, and convenience clinics in your jurisdiction. *Hospitals, clinics and other facilities*: Please forward to occupational health and employee health leadership, infection preventionists, infectious disease physicians, emergency department staff, hospitalists, primary care clinicians, pharmacists, and all other health care providers who may be vaccinating with COVID-19 vaccines. *Health care providers*:

- Continue temporary suspension of Johnson & Johnson (Janssen) COVID-19 vaccination.
- Maintain a high index of suspicion for symptoms representing serious thrombotic events or thrombocytopenia in patients that recently received Johnson & Johnson COVID-19 vaccine.
- Strongly consider consultation with hematology specialist if patient has these symptoms.
- Follow guidance for screening and treatment of immune thrombotic thrombocytopenia, including alternative anticoagulant therapy (not heparin) and intravenous immune globulin.
- Report all events to <u>Vaccine Adverse Event Reporting System</u> at <u>https://vaers.hhs.gov/reportevent.html</u>.

Background

Through the surveillance system, VAERS, CDC and FDA have identified cases of a rare type of blood clot after receiving the Johnson & Johnson COVID-19 vaccine. Initial presenting symptoms were notable for headache in five of six patients, and back pain in the sixth who subsequently developed a headache. One patient also had abdominal pain, nausea, and vomiting. Four developed focal neurological symptoms (focal weakness, aphasia, visual disturbance) prompting presentation for emergency care. One patient died. In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred among women aged 18–48 years. The interval from vaccine receipt to symptom onset ranged from 6–13 days.

Unusual for patients presenting with thrombotic events, all six patients showed evidence of thrombocytopenia (<150,000 platelets per microliter of blood), consistent with a condition known as thrombotic thrombocytopenia, with platelet nadir counts ranging from 10,000 to 127,000 during their hospitalizations. Four patients developed intraparenchymal brain hemorrhage and one subsequently died. All data presented in this HAN are preliminary and investigations of these VAERS reports are ongoing.

As with heparin-induced thrombocytopenia, the administration of the anticoagulant heparin should be avoided in patients with potential vaccine-associated immune thrombotic

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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 Johnson & Johnson COVID-19 vaccination. Consultation with hematology specialists is strongly recommended.

To date, VAERS has received no reports of CVST with thrombocytopenia among persons who received either of the two mRNA-based COVID-19 vaccines.

Current Guidance

- 1. Continue to pause Johnson & Johnson COVID-19 vaccination activities until further evaluation of these cases are conducted.
- 2. Maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the Johnson & Johnson COVID-19 vaccine. These include severe headache, backache, new neurologic symptoms, severe abdominal pain, shortness of breath, leg swelling, petechiae (tiny red spots on the skin), or new or easy bruising. Obtain platelet counts and screen for evidence of immune thrombotic thrombocytopenia.
- 3. In patients with a thrombotic event and thrombocytopenia after the Johnson & Johnson COVID-19 vaccine, evaluate initially with a screening PF4 enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune HIT. Consultation with a hematologist is strongly recommended.
- 4. Do not treat patients with thrombotic events and thrombocytopenia following receipt of Johnson & Johnson COVID-19 vaccine with heparin, unless HIT testing is negative.
- 5. If HIT testing is positive or unable to be performed in patient with thrombotic events and thrombocytopenia following receipt of Johnson & Johnson COVID-19 vaccine, non-heparin anticoagulants and high-dose intravenous immune globulin should be strongly considered.
- 6. Report adverse events to VAERS, including serious and life-threatening adverse events and deaths in patients following receipt of COVID-19 vaccines as required under the Emergency Use Authorizations for COVID-19 vaccines.

For More Information

- <u>Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination</u> (<u>https://www.nejm.org/doi/full/10.1056/NEJMoa2104882</u>)</u> Resources on thrombotic thrombocytopenia after AstraZeneca COVID-19 vaccine
- <u>VAERS (https://vaers.hhs.gov/faq.html)</u> Frequently asked questions about VAERS reporting for COVID-19 vaccines
- Report an Adverse Event to VAERS (https://vaers.hhs.gov/reportevent.html)
- CDC Stroke (https://www.cdc.gov/stroke/index.htm)
- NIH Thrombocytopenia https://www.nhlbi.nih.gov/health-topics/thrombocytopenia
- Call MDH at 651-201-5414 or 877-676-5414

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A copy of this HAN is available at: <u>MDH Health Alert Network</u> (<u>http://www.health.state.mn.us/han</u>)

The content of this message is intended for public health and health care personnel and response partners who have a need to know the information to perform their duties.