



DATE

April 13, 2021

SUBJECT

Johnson & Johnson COVID-19 Vaccine Restriction

INSTRUCTIONS

DISTRIBUTE to your local HAN contacts. This HAN is intended for general sharing of information.

- Time for Forwarding: **As Soon As Possible**
- Please forward to DPHHS at hhshan@mt.gov
- Remove this cover sheet before redistributing and replace it with your own

For LOCAL HEALTH DEPARTMENT reference only
DPHHS Subject Matter Resource for more information regarding this HAN, contact:

Immunization Section
1-406-444-5580

For technical issues related to the HAN message contact the Emergency Preparedness Section at 1-406-444-0919

DPHHS Health Alert Hotline:
1-800-701-5769

DPHHS HAN Website:
www.han.mt.gov

REMOVE THIS COVER SHEET BEFORE REDISTRIBUTING AND REPLACE IT WITH YOUR OWN

Please ensure that DPHHS is included on your HAN distribution list.
hhshan@mt.gov

Categories of Health Alert Messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

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.

Information Service: passes along low level priority messages that do not fit other HAN categories and are for informational purposes only.

Please update your HAN contact information on the Montana Public Health Directory

DPHHS HAN

Information Sheet



DATE

April 13, 2021

SUBJECT

Johnson & Johnson COVID-19 Vaccine Restriction

BACKGROUND

See CDC HAN, *Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine*

INFORMATION

Since the Emergency Use Authorization of the Johnson & Johnson (Janssen) COVID-19 vaccine, Montana providers have administered approximately 19,600 doses of the vaccine. To date, there have been no known reports of blood clots after administration of the vaccine in Montana, however, healthcare providers should be aware of the symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the J&J COVID-19 vaccine and how to treat it.

RECOMMENDATIONS

See the recommendations included in the attached CDC HAN to discontinue use of Janssen vaccine and be aware of potential complications.

- COVID-19 vaccine providers should ensure that Janssen vaccine inventories are stored within the recommended temperature range. Existing Janssen inventory should be held between 2°C and 8°C (36°F and 46°F).
- Vaccine providers should label existing stocks of Janssen COVID-19 vaccine with ***"DO NOT USE. AWAITING GUIDANCE"***.
- Providers should continue with COVID-19 vaccination events using Pfizer and Moderna vaccines.

Contact the Montana Immunization Program if vaccine supply becomes an issue.

This is an official
CDC HEALTH ALERT

Distributed via the CDC Health Alert Network
April 13, 2021, 1:00 PM ET
CDCHAN-00442

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

Summary

As of April 12, 2021, approximately 6.85 million doses of the Johnson & Johnson (J&J) COVID-19 vaccine (Janssen) have been administered in the United States. The Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) are reviewing data involving six U.S. cases of a rare type of blood clot in individuals after receiving the J&J COVID-19 vaccine that were reported to the Vaccine Adverse Events Reporting System (VAERS). 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. One patient died. Providers should maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the J&J COVID-19 vaccine. 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. Based on studies conducted among the patients diagnosed with immune thrombotic thrombocytopenia after the AstraZeneca COVID-19 vaccine in Europe, the pathogenesis of these rare and unusual adverse events after vaccination may be associated with platelet-activating antibodies against platelet factor-4 (PF4), a type of protein. Usually, the anticoagulant drug called heparin is used to treat blood clots. In this setting, the use of heparin may be harmful, and alternative treatments need to be given.

CDC will convene an emergency meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday, April 14, 2021, to further review these cases and assess potential implications on vaccine policy. FDA will review that analysis as it also investigates these cases. Until that process is complete, CDC and FDA are recommending a pause in the use of the J&J COVID-19 vaccine out of an abundance of caution. The purpose of this Health Alert is, in part, to ensure that the healthcare provider community is aware of the potential for these adverse events and can provide proper management due to the unique treatment required with this type of blood clot.

Background

VAERS is a national passive surveillance system jointly managed by CDC and FDA that monitors adverse events after vaccinations. The six patients (after 6.85 million vaccine doses administered) described in these VAERS reports came to attention in the latter half of March and early April of 2021 and developed symptoms a median of 9 days (range = 6–13 days) after receiving the J&J 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. The median days from vaccination to hospital admission was 15 days (range = 10–17 days). All were eventually diagnosed with CVST by intracranial imaging; two patients were also diagnosed with splanchnic* and portal vein thrombosis. 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. The Clinical Immunization Safety

Assessment (CISA) project which includes experts in infectious disease and hematology are also reviewing these cases. To date, VAERS has received no reports of CVST with thrombocytopenia among persons who received either of the two mRNA-based COVID-19 vaccines.

These reports following the J&J COVID-19 vaccine are similar to reports of thrombotic events with thrombocytopenia after receipt of the AstraZeneca COVID-19 vaccine in Europe. Both vaccines contain replication-incompetent adenoviral vectors (human [Ad26.COV2.S] for J&J and chimpanzee [ChAdOx1] for AstraZeneca) that encode the spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. Based on studies conducted among the patients diagnosed with immune thrombotic thrombocytopenia after the AstraZeneca COVID-19 vaccine in Europe, the pathogenesis of these rare and unusual adverse events may be associated with platelet-activating antibodies against platelet factor 4 (PF4). Anti-PF4, also known as heparin-PF4 antibody, can induce thrombotic thrombocytopenia in a small percentage of persons exposed to heparin. However, none of the cases reported from Europe had recent heparin exposure. As with 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. Consultation with hematology specialists is strongly recommended.

* The term 'splanchnic circulation' describes the blood flow to the abdominal gastrointestinal organs including the stomach, liver, spleen, pancreas, small intestine, and large intestine.

Recommendations

For Clinicians

1. 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.
2. Maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the J&J COVID-19 vaccine, including 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 J&J 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 J&J 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 J&J 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 Public Health

1. Pause the use of the J&J COVID-19 vaccine in public health clinics until the ACIP is able to further review these CVST cases in the context of thrombocytopenia and assess their potential significance.
2. Encourage healthcare providers and the public to report all serious and life-threatening adverse events and deaths following receipt of COVID-19 vaccines to VAERS as required under the EUAs for COVID-19 vaccines.
3. Disseminate this alert to healthcare providers in your jurisdictions.

For the Public

1. If you have received the J&J COVID-19 vaccine and develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination, contact your healthcare provider, or seek medical care.
2. Report adverse events following receipt of any COVID-19 vaccine to VAERS.
3. If you are scheduled to receive the J&J vaccine, please contact your healthcare provider, vaccination location, or clinic to learn about additional vaccine availability.

For More Information

- Resources on thrombotic thrombocytopenia after AstraZeneca COVID-19 vaccine
<https://www.nejm.org/doi/full/10.1056/NEJMoa2104840>,
<https://www.nejm.org/doi/full/10.1056/NEJMoa2104882>
- Frequently asked questions about VAERS reporting for COVID-19 vaccines [VAERS - FAQs \(hhs.gov\)](#)
- How to report to [VAERS](#)
- CDC materials on [stroke](#) and NIH materials on [thrombocytopenia](#)

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

Categories of Health Alert Network messages:

Health Alert Requires immediate action or attention, highest level of importance

Health Advisory May not require immediate action; provides important information for a specific incident or situation

Health Update Unlikely to require immediate action; provides updated information regarding an incident or situation

HAN Info Service Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##