



MISSISSIPPI STATE DEPARTMENT OF HEALTH

**This is an official
MS Health Alert Network (HAN) Alert**

MESSAGE ID: MSHAN-20210413-00514-ALT (Health Alert)

RECIPIENTS: All Physicians, Hospitals, ERs, ICPs, NPs, and
Healthcare Providers – Statewide

Tuesday, April 13, 2021

SUBJECT: Cases of Cerebral Venous Sinus Thrombosis with
Thrombocytopenia after Johnson and Johnson
COVID-19 Vaccine

Key Messages

- **MSDH is recommending providers pause the administration of Johnson and Johnson COVID-19 vaccine due to a report from the CDC and FDA of six cases of cerebral venous sinus thrombosis (CVST) in combination with thrombocytopenia after receipt of the J&J COVID-19 vaccine.**
- MSDH has communicated with enrolled COVID-19 vaccine providers regarding the need for a temporary pause in J&J COVID-19 vaccine administration until further guidance is available.
- There are no of CVST with thrombocytopenia among persons who received either of the two mRNA-based COVID-19 vaccines (Moderna and Pfizer).
- The Advisory Committee on Immunization Practices (ACIP) will meet on Wednesday April 14 to review the case data and provide additional guidance.
- The six patients (after 6.85 million vaccine doses administered in the US) were identified through the Vaccine Adverse Events Reporting System (VAERS) between March and early April 2021.
- All six cases in this report occurred among women aged 18–48 years; onset ranged from 6 to 13 days (median 9 days). One patient died.
- The pathogenesis may be associated with platelet-activating antibodies against platelet factor 4 (PF4). In these cases, the use of heparin may be harmful and should be avoided unless heparin-induced thrombocytopenia (HIT) testing is negative.
- Approximately 42,000 doses of J&J have been administered in Mississippi, compared to more than 1.4 million total COVID-19 vaccine doses.
- Individuals should seek medical care if they develop severe headache, abdominal pain, lower extremity pain or shortness of breath within three weeks after vaccination with J&J COVID-19 vaccine. People who received J&J more than a month ago are at very low risk of developing this syndrome.
- MSDH is asking clinicians:
 - Maintain a high index of suspicion in individuals who present with symptoms consistent with thrombotic events in combination with thrombocytopenia in persons with recent J&J COVID-19 vaccine.
 - **Do not treat patients with thrombotic events and thrombocytopenia following receipt of J&J COVID-19 vaccine with heparin unless heparin-induced thrombocytopenia testing is negative. Non-heparin anticoagulants and high-dose intravenous immune globulin should be considered in treatment; consultation with hematology specialists is strongly recommended prior to initiating treatment.**
 - Report these and other adverse events to [VAERS](#)



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Please see the CDC Health Alert Message below for full details.

Regards,

Paul Byers, MD
State Epidemiologist

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 type 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

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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.



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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 \(hhs.gov\)](https://www.hhs.gov/qa/qa-2021-04-29-vaers)
- How to report to [VAERS](https://www.vaers.hhs.gov/)
- CDC materials on [stroke](https://www.cdc.gov/stroke/) and NIH materials on [thrombocytopenia](https://www.nih.gov/health-topics/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##

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Alerting Message Specification Settings

Originating Agency: Mississippi State Department of Health
Alerting Program: MS Health Alert Network (MS HAN)
Message Identifier: MSHAN-20210413-00514-ALT
Program (HAN) Type: Health Alert
Status (Type): Actual ()
Message Type: Alert
Reference: MSHAN-00514
Severity: Unknown
Acknowledgement: No
Sensitive: Not Sensitive
Message Expiration: Undetermined
Urgency: Undetermined
Delivery Time: 600 minutes

Definition of Alerting Vocabulary and Message Specification Settings

Originating Agency: A unique identifier for the agency originating the alert.

Alerting Program: The program sending the alert or engaging in alerts and communications using PHIN Communication and Alerting (PCA) as a vehicle for their delivery.

Message Identifier: A unique alert identifier that is generated upon alert activation (MSHAN-yyymmdd-hhmm-TTT (**ALT=Health Alert**, **ADV=Health Advisory**, **UPD=Health Update**, **MSG/INFO=Message/Info Service**)).

Program (HAN) Type: 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.

Health Info Service: Provides Message / Notification of general public health information; unlikely to require immediate action.

Status (Type):

Actual: Communication or alert refers to a live event

Exercise: Designated recipients must respond to the communication or alert

Test: Communication or alert is related to a technical, system test and should be disregarded



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Message Type:

Alert: Indicates an original Alert
Update: Indicates prior alert has been Updated and/or superseded
Cancel: Indicates prior alert has been cancelled
Error: Indicates prior alert has been retracted

Reference: For a communication or alert with a Message Type of “Update” or “Cancel”, this attribute contains the unique Message Identifier of the original communication or alert being updated or cancelled. “n/a” = Not Applicable.

Severity:

Extreme: Extraordinary threat to life or property
Severe: Significant threat to life or property
Moderate: Possible threat to life or property
Minor: Minimal threat to life or property
Unknown: Unknown threat to life or property

Acknowledgement: Indicates whether an acknowledgement on the part of the recipient is required to confirm that the alert was received, and the timeframe in which a response is required (Yes or No).

Sensitive:

Sensitive: Indicates the alert contains sensitive content
Not Sensitive: Indicates non-sensitive content

Message Expiration: Undetermined.

Urgency: Undetermined. Responsive action should be taken immediately.

Delivery Time: Indicates the timeframe for delivery of the alert (15, 60, 1440, 4320 minutes (.25, 1, 24, 72 hours)).