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** NOTICE: This health alert provides written guidance for health care professionals and others who may need to take action to prevent or control a notifiable condition. It is not intended to provide guidance for the general public.*

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

Actions Requested:

- 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.
- 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.
- Evaluate patients with a thrombotic event and thrombocytopenia after the J&J COVID-19 vaccine, initially with a screening PF4 enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune HIT. Consultation with a hematologist is strongly recommended.
- Do not treat patients with thrombotic events and thrombocytopenia following receipt of J&J COVID-19 vaccine with heparin, unless HIT testing is negative.
- Consider non-heparin anticoagulants and high-dose intravenous immune globulin 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.
- Report adverse events to VAERS at <https://vaers.hhs.gov/>, 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.

Background:

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 Event Reporting System (VAERS).

VAERS is a national passive surveillance system jointly managed by CDC and FDA that monitors adverse events after vaccinations. The six patients described in these

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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 Cerebral Venous Sinus Thrombosis (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. The data presented 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 (Pfizer or Moderna) 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.



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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.

Resources:

New England Journal of Medicine (NEJM) 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>

Health and Human Services (HHS) frequently asked questions about VAERS reporting for COVID-19 vaccines: <https://vaers.hhs.gov/faq.html>

Health and Human Services (HHS) How to report to VAERS: <https://vaers.hhs.gov/reportevent.html>

Center for Disease Control and Prevention (CDC) materials on stroke: <https://www.cdc.gov/stroke/index.htm>

Center for Disease Control and Prevention (CDC) COVID-19: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

National Institutes of Health (NIH) materials on thrombocytopenia: <https://www.nhlbi.nih.gov/health-topics/thrombocytopenia>

Food and Drug Administration COVID-19 Vaccines: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>

THANK YOU FOR REPORTING

TO REPORT A NOTIFIABLE CONDITION IN THURSTON COUNTY	
Voice mail for reporting non-immediately reportable conditions (24 hours a day)	Phone: 360-786-5470 Fax: 360-867-2601
Day time immediately reportable conditions – Call detailed information to the 24-hour Notifiable Condition Reporting Line at 360-786-5470. Messages are picked up hourly. If a call back can't wait call 360-867-2500 and ask staff to locate a Communicable Disease staff.	Phone: 360-786-5470
After hours immediately and 24-hour reportable conditions or a public health emergency	Call 1-800-986-9050
No one is available with Thurston County Public Health and condition is immediately notifiable	1-877-539-4344

Communicable Disease Updates are posted online at: <http://bit.ly/CDUpdatePHSS>