

April 15, 2021

HEALTH ALERT: 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, with 22,306 doses administered in San Mateo County. 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). 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 convened 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. Out of an abundance of caution, **CDC and FDA are recommending a continued pause in the use of the J&J COVID-19 vaccine until the next ACIP meeting in 7-10 days..** The purposes of this Health Alert are 1) 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 and 2) to highlight the need for provider surveillance for this adverse event and reporting of any identified events to VAERS.

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 Health Alert 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.COVS.2.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.

Recommendations for Clinicians:

1. **Pause the use of the J&J COVID-19 vaccine** until the ACIP further reviews these CVST cases in the context of thrombocytopenia and assesses 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 a 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.

Recommendations for Non-Clinical Service Providers Who Care for Populations Vaccinated with J&J COVID-19 Vaccine:

1. **Inform frontline staff to maintain a high index of suspicion for symptoms that might represent serious blood clot (thrombotic) events or low platelets (thrombocytopenia)** in clients 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, tiny red spots on the skin (petechiae), or new or easy bruising. Clients with concerning symptoms should be directed to contact their healthcare provider and seek medical treatment urgently.
2. **Report adverse events to VAERS**

For More Information:

- Resources on thrombotic thrombocytopenia after AstraZeneca COVID-19 vaccine



SAN MATEO COUNTY HEALTH

**PUBLIC HEALTH,
POLICY & PLANNING**

Dr. Scott Morrow, Health Officer
Cassius Lockett, PhD, Director

Public Health, Policy & Planning
225 37th Avenue
San Mateo, CA 94403
smchealth.org

- [Thrombotic Thrombocytopenia after ChAdOx1 nCov-19 Vaccination](#)
- [Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination](#)
- 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](#)

