

ALERT: Call for Pause of Use of Johnson & Johnson COVID-19 Vaccine

DATE:	4/13/2021
TO:	Health Alert Network
FROM:	Alison V. Beam, JD, Acting Secretary of Health
SUBJECT:	Call for Pause of Use of Johnson & Johnson COVID-19 Vaccine
DISTRIBUTION:	Statewide
LOCATION:	n/a
STREET ADDRESS:	n/a
COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a

This transmission is a “Health Alert,” conveys the highest level of importance; warrants immediate action or attention.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL; **EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS:** PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; **LONG-TERM CARE FACILITIES:** PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

- On April 13, CDC and FDA recommended a pause of administering any doses of Johnson & Johnson/Janssen (J&J) vaccine in order to review data involving six reported cases of cerebral venous sinus thrombosis (CVST), in combination with thrombocytopenia, seen after receiving the J&J vaccine.
- Effective immediately, DOH is asking that providers pause the administration of any doses of Johnson & Johnson vaccine until April 20, 2021.
- DOH will not be enforcing the order to administer 80% of doses over 7 days.
- 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 vaccine.
- **Providers who were planning to administer Johnson & Johnson vaccine to individuals are asked to cancel those appointments immediately, or, if possible reschedule those appointments using Pfizer or Moderna vaccine**
- Health care providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at <https://vaers.hhs.gov/reportevent.html>.

Pennsylvania Department of Health (DOH) provides this guidance based on available information about COVID-19 and is subject to change.

On April 13, the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) issued a joint statement on the Johnson & Johnson/Janssen (J&J) COVID-19 Vaccine. CDC, FDA, and DOH, effective immediately, are **requesting** a pause of administering any doses of J&J vaccine until at least **April 20**, pending further guidance from the CDC and the FDA. DOH will **not** be enforcing the order to administer 80% of doses over 7 days.

The CDC and 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). 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.

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.

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.

CDC and DOH have the following 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.

It is very important that providers continue to proceed with administration of Pfizer and Moderna vaccine to patients as planned, and explain to patients who may have fears that all of the vaccines are being constantly monitored for safety and effectiveness, and this latest announcement shows this process is working.

Providers who were planning to administer Johnson & Johnson vaccine to individuals are asked to cancel those appointments immediately, or, if possible reschedule those appointments using Pfizer or Moderna vaccine. Patients should be clearly informed which vaccine they will be receiving to alleviate any concerns.

If you have any questions, please contact the department through the COVID VAX resource account at ra-dhccovidvax@pa.gov.

If you have questions about this guidance, please call your local health department or **1-877-PA-HEALTH (1-877-724-3258)**.

Individuals interested in receiving further PA-HANs are encouraged to register at <https://han.pa.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.

This information is current as of April 13, 2021 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.