

FOR IMMEDIATE RELEASE 4/13/2021

TO: Grant County healthcare providers, infection control staff, supervisory nursing staff, clinic management, school nurses.

FOR INFORMATION CONTACT

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Health Advisory: Effective Immediately Statewide Pause on Use of Johnson & Johnson - Covid-19 Vaccine

The Washington State Department of Health is immediately pausing use of the Johnson & Johnson - Janssen (J & J) vaccine statewide starting immediately, while the federal government begins an investigation into fully understanding recent safety events. There will be no state allocations for Johnson & Johnson vaccine this week. Grant County Health District is instructing all medical providers to follow this recommendation and halt any administration of the J & J vaccine until further notice.

This action is being taken out of an abundance of caution based on the appearance of a rare but serious side effect including serious brain blood clots (CVST) combined with low platelet counts in six patients, all women under 50, associated with the Johnson & Johnson vaccine. This is very rare; 6 people out of 6.8 million doses given in the U.S. so far, but safety is the highest priority when it comes to all COVID-19 vaccines. About 149,000 doses of J & J vaccine have been administered in Washington. At this time, we have no knowledge of the six patients who experienced these blood clots being Washington residents

The CDC's Advisory Committee on Immunization Practices (ACIP) will review these cases in the days ahead and will recommend guidance going forward. This is being considered a temporary pause until more is learned from these reviews. The investigation into an event that takes place less than 1 in 1 million times is a sign that our safety monitoring system is working well. The safety concern was identified quickly, and vaccines were paused to allow for further investigation.

For those who got the vaccine over 3 weeks ago, the risk of this complication is very low at this time. However, about 90,000 doses of the J&J vaccine have been administered in Washington in the past two weeks. As providers consider reaching out proactively to all patients who received J & J vaccine from you in the past three weeks and advise them to watch for the following symptoms and contact you if they develop:

—severe headache—leg pain—shortness of breath

No definitive cause has been identified yet, but the FDA said today that a probable cause is a rare immune response generated by an individual after receiving the vaccine. DOH will continue to monitor the situation related to J & J vaccine and update on its use as the pause is reviewed and once it is lifted.

Recommendations for Providers:

- 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,

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- petechiae (tiny red spots on the skin), or new or easy bruising. Obtain platelet counts and screen for evidence of immune thrombotic thrombocytopenia.
- 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.
- Do not treat patients with thrombotic events and thrombocytopenia following receipt of J&J COVID-19 vaccine with heparin, unless HIT testing is negative.
- 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.
- 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 More Information

- Link to CDC here.
- 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 <u>VAERS FAQs (hhs.gov)</u>
- How to report to VAERS
- CDC materials on <u>stroke</u> and NIH materials on <u>thrombocytopenia</u>

Further information will be provided to Grant County health care providers as it becomes available.

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