COUNTY OF IMPERIAL
PUBLIC HEALTH DEPARTMENT

April 13, 2021

HEALTH ALERT

Health Officials Recommend Pause of J&J COVID-19 Vaccine Pending Investigation of Reports of Rare Blood Clots

Six U.S. cases of a rare and severe type of blood clot in individuals after receiving the Johnson & Johnson (J&J) COVID-19 vaccine are under investigation by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA).

CDC will convene an emergency meeting of the Advisory Committee on Immunization Practices (ACIP) to further review these cases and assess potential implications on vaccine policy. FDA will review that analysis. 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. This type of adverse event has not been reported for individuals who received Pfizer or Moderna COVID-19 vaccines.

The purpose of this Health Alert is to ensure that the health-care providers are 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.

In these reported 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 in women aged 18-48 years. The interval from vaccine receipt to symptom onset ranged from 6-13 days. One patient died.

Health-care providers should maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia in individuals who recently received the J&J COVID-19 vaccine. Symptoms include severe headache, backache, new neurologic

symptoms, severe abdominal pain, shortness of breath, leg swelling, petechiae, or new or easy bruising. Obtain platelet counts and screen for evidence of immune thrombotic thrombocytopenia.

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.

In patients with a thrombotic event and thrombocytopenia after the J&J COVID-19 vaccine, it is recommended to evaluate initially with a screening PF4 enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune heparin-induced thrombocytopenia (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 patients with a thrombotic event or thrombocytopenia following receipt of J&J COVID-19 vaccine, non-heparin anticoagulants and high-dose intravenous immune globulin should strongly be considered.

Report adverse events to VAERS, a national surveillance system jointly managed by CDC and FDA to monitor adverse events after vaccination. Adverse events include serious and life-threatening events and deaths in individuals following receipt of COVID-19 vaccines as required under the Emergency Use Authorizations for COVID-19 vaccines.

As of April 12, 2021, approximately 6.85 million doses of the J&J COVID-19 vaccine have been administered in the United States. To date, Imperial County has received more than 10,500 J&J COVID-19 vaccine doses through the State's vaccine program. This number does not include

those received through the Federal program. Of the J&J COVID-19 vaccine doses administered in Imperial County, no major side effects have been reported.

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)
- How to report to VAERS
- CDC materials on stroke and NIH materials on thrombocytopenia

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