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Further analysis of J&J COVID-19 vaccine data warranted: CDC advisory panel

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Editor's note:*For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

The pause on the Ad26.COV2.S Johnson & Johnson (J&J, Janssen) COVID-19 vaccine remains while a federal vaccine advisory group further analyzes data before making a recommendation to the director of the Centers for Diseases Control and Prevention (CDC) on use of the vaccine moving forward.

Use of the J&J vaccine was paused on Tuesday following reports of cerebral venous sinus thrombosis (CVST) in combination with thrombocytopenia in six women ages 18-48 who received the vaccine, including one who died.

Workgroup leaders from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) and representatives from Janssen Pharmaceuticals presented data and answered questions from ACIP members and liaisons Wednesday.

The ACIP agreed to reconvene in about a week to obtain more data if available as well as to allow more time to review reports. This will allow additional time to monitor for new data in individuals who received the vaccine and are within a six- to 13-day window of symptom onset observed for the six women who experienced CVST.

On April 13, the CDC issued a health alert that recommended pausing use of the vaccine in the U.S. "out of an abundance of caution" after cases of six women with CVST in combination with thrombocytopenia were reported to the Vaccine Adverse Event Reporting System (VAERS).

CVST with thrombocytopenia is very rare and not well-understood, but the rare and unusual events may be associated with platelet-activating antibodies against platelet factor-4 (PF4), according to the CDC.

ACIP members agreed that any decision on the vaccine must be made based on robust data and emphasized the importance of preserving vaccine confidence.

"I would speak in favor of a pause until we have a better data," said ACIP member Sarah S. Long, M.D., FAAP. "I think that we can't parcel out groups that are more or less at risk because we don't have enough information."

The J&J COVID-19 vaccine was recommended for people ages 18 years and older under a Food and Drug Administration (FDA) emergency use authorization (EUA) on Feb. 28.

Between March 19 and April 12, reports of adverse events were submitted to the CDC, the FDA, Janssen Pharmaceuticals and VAERS.

All six women were white; one had current estrogen/progesterone use; none were pregnant or postpartum. Known preexisting conditions included obesity (three), hypothyroidism (one), hypertension (one) and asthma (one). No known coagulation disorders were reported. The median onset was eight days after receiving the vaccine (range, six-13 days).

Also unusual was the formation of clots in vessels in the presence of low platelets, said Tom T. Shimabukuro, M.D., M.P.H., M.B.A., of the CDC National Center for Emerging and Zoonotic Infectious Diseases. Thrombosis usually does not occur in the presence of a low platelet count. In three patients, thromboses were not limited to the cerebral venous drainage system.

The CDC recommends that health care providers:

- Maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia in patients who recently received the J&J COVID-19 vaccine, including 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.
- In patients with a thrombotic event and thrombocytopenia after the vaccine, consultation with a hematologist is strongly recommended. Initial evaluation with a screening PF4 enzyme-linked immunosorbent assay may be indicated as would be performed for autoimmune heparin-induced thrombocytopenia (HIT).
- Do not treat patients with thrombotic events and thrombocytopenia following receipt of the vaccine with heparin, unless HIT testing is negative.

- 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.
- 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 EUA for COVID-19 vaccines.

Last week, European safety officials issued a report concluding a strong association and probable causal link between the AstraZeneca vaccine and rare clotting events. Both the J&J and AstraZeneca vaccines use a replication incompetent adenovirus vaccine platform.

Pediatricians are invited to participate in a CDC Clinician Outreach and Communication Activity (COCA) Call at 2 p.m. EDT April 15. Speakers will present the latest evidence on CVST with thrombocytopenia associated with the administration of the Johnson & Johnson/Janssen COVID-19 vaccine. In addition, they will discuss what is known about CVST, the importance of early detection and updated vaccine recommendations. Information on how to access the call can be found at https://emergency.cdc.gov/coca/calls/2021/callinfo_041521.asp.