Pharmacovigilance Drug Safety Alert

Rare and Serious Adverse Vaccine Events Potentially Associated with the Johnson & Johnson/Janssen COVID-19 Vaccine

Cerebral venous sinus thrombosis (CVST) in combination of low levels of blood platelets (thrombocytopenia) have been observed in a small number of patients who have received the Johnson & Johnson/Janssen COVID-19 vaccine.

CVST is a rare type of thrombotic event that is estimated to occur in 0.22-1.57 per 100,000 people each year.

Six adverse vaccine events of CVST with thrombocytopenia have been reported after the administration of approximately 6.85 million doses of the Johnson & Johnson/Janssen COVID-19 vaccine in the United States.

All six cases have occurred in women ranging from 18 and 48 years of age, and between 6 to 13 days after receiving the vaccination. One case was fatal.

The specific association between the vaccine and thrombotic thrombocytopenia including CVST remains unknown. Similar adverse events have occurred with the AstraZeneca/Oxford COVID-19 vaccine (also a viral vector vaccine) in Europe. Based on analysis of the European cases, researchers speculate that there may be an association with heparin platelet factor 4 (PF4) antibody, which causes heparin induced thrombocytopenia (HIT).

When evaluating for and/or treating thrombotic thrombocytopenia (including CVST) after the Johnson & Johnson/Janssen COVID-19 vaccine, the CDC recommends the following:

- **Maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia** 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, evaluate with a screening PF4 enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune HIT.
- **Do not treat patients with heparin, unless HIT testing is negative.**
- If HIT testing is positive or unable to be performed, non-heparin anticoagulants and high-dose intravenous immune globulin should be strongly considered.

The CDC and FDA recommend that clinicians temporarily stop using the Johnson & Johnson/Janssen COVID-19 vaccine until further analysis is performed. To date, there have been no reports of CVST with thrombocytopenia among patients who have received the Pfizer-BioNTech or Moderna COVID-19 vaccines. **Continue to vaccinate patients using the Pfizer-BioNTech or Moderna COVID-19 vaccines.**

Report all significant or unusual Adverse Vaccine Events (AVE) to the VAERS program as described in the Indian Health Manual. Instructions for submitting an AVE can be found on the IHS Pharmacovigilance website. Please ensure that you document “IHS” in field #26 of the form.

References:

1. Advisory Committee on Immunization Practices (ACIP). ACIP Presentation Sides. (2021, April 14). Retrieved April 14, 2021 from https://www.cdc.gov/vaccines/acip/meetings/slides-2021-04.html
2. CDC Health Information Network. HAN archive - 00442. (2021, April 13). Retrieved April 14, 2021, from https://emergency.cdc.gov/han/2021/han00442.asp