



## 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>