MedStar Health

Provider Alert – Johnson and Johnson Vaccine Update

Effective April 23, 2021, CDC and FDA recommend that use of the Janssen COVID-19 Vaccine resume in the United States. However, women younger than 50 years old should be made aware of a rare risk of blood clots with low platelets following vaccination and the availability of other COVID-19 vaccines where this risk has not been observed. Read the CDC/FDA statement.

On April 13th, the FDA and CDC, out of an abundance of caution, recommended pausing administration of the Johnson and Johnson (J&J) COVID-19 vaccine after 6 reports of cavernous venous sinus thrombosis (CVST) were reported among women age 18-48 within 6-13 days post-vaccination. It's unclear whether these cases are linked to the vaccine product. The administration of the J&J vaccine across the US was paused immediately. **This does not affect Moderna or Pfizer administration and scheduling.** We want to emphasize that this pause reflects the incredible amount of scrutiny these vaccines undergo to ensure continued safety.

Patients who have received the J&J vaccine and develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should be evaluated by a health care provider. Below are the full CDC recommendations:

- 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, 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 the 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 thrombotic events and thrombocytopenia following receipt of the J&J COVID-19 vaccine, non-heparin anticoagulants and high-dose intravenous immune globulin should be strongly considered.
- Report adverse events to VAERS (https://vaers.hhs.gov/reportevent.html), 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. The MSH Safety Team (MSHSafetyTeam@medstar.net) can help facilitate these submissions.

Additional information will be provided as it becomes available from the FDA and CDC.