Yale NewHaven Health

Information & Guidance regarding management of individuals who have received the Janssen/J&J COVID-19 Vaccine

Concerns about blood clots associated with the Janssen (Johnson & Johnson, J&J) COVID-19 vaccine

Administration of the Janssen (Johnson & Johnson, J&J) COVID-19 vaccine was "paused" on 4/13/21 out of an abundance of caution due to six reported U.S. cases of cerebral venous sinus thrombosis (CVST) in combination with thrombocytopenia. Key facts summarized from CDC, FDA, and CT-DPH include:

- All six cases occurred among women ages 18–48 years, and all had onset 6–13 days after vaccination.
- The CDC and FDA recommend that individuals contact a healthcare provider for severe headache, abdominal pain, leg pain, or shortness of breath, which develop within three weeks of vaccination with the Janssen/J&J vaccine.
- These events are rare. There are 6 cases, of which one was fatal, reported out of 6.8 million doses administered and there have been no cases reported in Connecticut.
- Rapid identification of such a rare side effect demonstrates success of the Vaccine Adverse Event Reporting System (VAERS).
- The CDC began conducting their formal review on 4/14/21.

Key recommendations at this time from the CDC and the CT DPH for clinicians include:

1. 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 any of the following:

   - Neurological symptoms suggestive of CVST:
     - New onset headache*, especially if severe or worsening
     - Blurred vision
     - Syncope or loss of consciousness
     - Loss of control over movement in part of the body, or
     - Seizures
   - Systemic symptoms suggestive of blood clotting at other sites and/or thrombocytopenia:
     - Pain or swelling in one leg
     - Shortness of breath
     - Severe backache
     - Abdominal pain
     - Petechiae, or
     - New or easy bruising

*Note that headaches and flu-like symptoms are common during days 0-2 after vaccination and typically do not require evaluation. Severe headache that does not improve should be evaluated.

2. In patients with a confirmed 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 heparin-induced thrombocytopenia (LAB7878 or LAB766). Consultation with a hematologist is strongly recommended.

3. ***Do <u>NOT</u> treat patients with thrombotic events and thrombocytopenia following receipt of J&J COVID-19 vaccine with heparin, unless HIT testing is negative***.

Additional Recommendations from our YNHHS Vaccine Clinical Advisory Group for Ambulatory Clinicians include:

1. Patients who received the J&J vaccine within the past three weeks should CALL 911 for new onset headache which occurs 3 to 21 days post-vaccination (especially if severe or worsening) or other neurological symptom listed above.

2. For any systemic symptom listed above, patients should contact their regular clinician or go to the ED.

3. In all cases the patient should be reminded to notify the evaluating clinician that they recently received the J&J vaccine.

4. Definitive medical care considerations should include the following:
   - **In the ambulatory setting, patients with a new onset mild headache that developed 3-21 days after the J&J COVID-19 vaccine WITHOUT acute neurologic findings may be evaluated urgently with CT Head Venogram (IMG4938). Include "J&J vaccine" in test indication field and CBC w/platelets**
   - **If a patient has any acute neurological findings, they should instead be immediately referred to the ED instead for emergent evaluation and testing.**
   - **If concerned about DVT or other clotting event, evaluate with the appropriate imaging and CBC w/platelets. Consultation with a hematologist is strongly recommended.**
   - **Any patient confirmed to have thrombosis and thrombocytopenia should be admitted to the hospital for further evaluation and treatment. Ambulatory treatment with heparin/anticoagulation is absolutely contraindicated pending further testing as noted above.**

Additional notes/reminders:
1. There are no reports of CVST with thrombocytopenia among persons who received either of the two mRNA-based COVID-19 vaccines.
2. There are reports of vaccine-induced immune thrombotic thrombocytopenia (ITP) following administration of the Astra-Zeneca vaccine in Europe.

3. Recipients of any COVID-19 vaccine are strongly encouraged to send data to CDC about post-vaccine effects via the smartphone-based system v-safe (cdc.gov). Clinicians are encouraged to document the post-vaccine effects in RL Solutions or by following the instructions in the Agile "COVID vaccine delayed adverse reaction pathway" which will be available in the patient's Epic storyboard following vaccination or is searchable in the "Pathways" Epic tab. This will initiate YNHHS review and VAERS reporting (https://vaers.hhs.gov/reportevent.html).
4. YNHHS will continue to follow CDC & CT-DPH guidance with regards to how and when the Janssen/J&J is determined to be safe enough to resume vaccination.
5. The YNHHS COVID-19 Vaccine Enterprise has communicated directly with all scheduled patients to substitute Pfizer or Moderna vaccinations at the scheduled appointments.
6. Use "Immunization Registry" button under Immunization tab to refresh COVID Vaccine information for those vaccines administered outside YNHHS to clarify vaccination history.