Indian Health Service
National Pharmacy and Therapeutics Committee

Pharmacovigilance Drug Safety Alert

FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination.[1]

Most cases of thrombosis with thrombocytopenia reported following the Janssen COVID-19 Vaccine have occurred in females ages 18 through 49 years; some have been fatal. **The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia.** In individuals with suspected thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine, the use of heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended.[1]

During the pause, medical and scientific teams at the FDA and CDC examined available data to assess the risk of thrombosis involving the cerebral venous sinuses, or CVST (large blood vessels in the brain), and other sites in the body (including but not limited to the large blood vessels of the abdomen and the veins of the legs) along with thrombocytopenia, or low blood platelet counts. The teams at FDA and CDC also conducted extensive outreach to providers and clinicians to ensure they were made aware of the potential for these adverse events and could properly manage and recognize these events due to the unique treatment required for these blood clots and low platelets, also known as thrombosis-thrombocytopenia syndrome (TTS).[1]

The two agencies have determined the following:[1,2]

- Use of the Janssen COVID-19 Vaccine should be resumed in the United States.
- The FDA and CDC have confidence that this vaccine is safe and effective in preventing COVID-19.
- The FDA has determined that the available data show that the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older.
- At this time, the available data suggest that the chance of TTS occurring is very low, but the FDA and CDC will remain vigilant in continuing to investigate this risk.
- Health care providers administering the vaccine and vaccine recipients or caregivers should review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers, which have been revised to include information about the risk of this syndrome, which has occurred in a very small number of people who have received the Janssen COVID-19 Vaccine.

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. FDA and CDC Lift Recommended Pause on Johnson & Johnson (Janssen) COVID-19 Vaccine Use Following Thorough Safety Review, https://www.cdc.gov/media/releases/2021/fda-cdc-lift-vaccine-use.html.
2. Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers).
3. Advisory Committee on Immunization Practices (ACIP). ACIP Presentation Sides. (2021, April 23). Retrieved April 23, 2021 from https://www.cdc.gov/vaccines/acip/meetings/slides-2021-04-23.html.