Advisory Committee on Immunization Practices (ACIP) Emergency meeting
Center for Diseases Control and Prevention (CDC)
Virtual April 14, 2021
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Coronavirus Disease 2019 (COVID19) Vaccines

Outcome of Todays: ACIP Virtual Emergency meeting: ACIP will recommend to continue the pause for the Janssen COVID19 Vaccine. The ACIP wants more information before voting on Janssen COVID19 Vaccine and will reconvene in approximately one week to discuss further.

Problem: A possible link for Janssen's COVID19 Vaccine for a serious , but rare risk of clotting events in 6 US patients 1-2 weeks after receiving the Janssen COVID19 Vaccine.

Both the Janssen and AstraZeneca (AZ) COVID19 Vaccines are Adenovirus Vectors with Janseen's being a human and AZ's a Chimp adenovirus. Janseen's is a one dose and AZ's is a 2 dose. Both vaccines seem to have rare clotting issues after their use in humans.

In general, one of the clotting issues is a cerebral venous sinus thrombosis (CVST) involving the large vessels draining blood from the brain. Coagulation risks are mostly among 20-50 year-old females. Increase known risks include prenancy and oral contraceptives. Symptoms typically include headache, nausea, vominting and other neruologic symptoms and can be acute or over weeks or months.

Last week the European Medicine Agency (EMA) reported a strong association and probable causal link between the AZ COVID19 vaccine and rare clotting events. From the European Union there were 62 cases of CVST and 24 cases of splanchnic vein thrombosis with thrombocytopenia of which 18 were fatal. In the UK, 79 cases of thrombosis + thrombocytopenia of which 19 were fatal. There were another 44 cases of CVST with 14 fatalities and 35 cases of other clots with 5 fatalities. There were 20.2 million doses of vaccine given.

As of April 12, more than 6.8 million doses of Janssen Vaccine have been administered in the US. with 6 cases of CVST in combination with low platelets. Most cases in the US were reported to the Vaccine Adverse Events Reporting System (VAERS). Anyone can make a report and should if any questions about possible vaccine events. Here is how to report: go to https://vaers.hhs.gov/reportevent.html and fill out the report.

- **For clinicians**
  - Maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the Jansen 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 Jansen 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 Janssen COVID-19 vaccine with heparin, unless HIT testing is negative.
  - If HIT testing is positive or unable to be performed in patient with thrombotic events and thrombocytopenia following receipt of Jansen COVID-19 vaccine, non-heparin anticoagulants and high-dose intravenous immune globulin should be strongly considered.
  - Report adverse events to VAERS, 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.

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For questions and/ specific presentation slides, contact Stan Grogg, DO at stanley.grogg@okstate.edu.

ACIP Emergency Virtual Meeting May 5, 2021.