Summary from the Advisory Committee for Immunization Practices

Johnson and Johnson COVID-19 Vaccine ‘Pause’ Update
April 15, 2021

On April 14, the Advisory Committee on Immunization Practices (ACIP) met to review the safety profile of the Johnson and Johnson COVID-19 vaccine due to reports of cerebral venous sinus thrombosis (CVST) after vaccination which compelled CDC and FDA to issue a joint recommendation on April 13 to pause the use of the subject vaccine. Current data suggests that the risk of CVST following vaccination is rare; however, the observed cases appear to exceed expected cases among women aged 20 - 50 years (three-fold or greater). There was not enough data to draw conclusions about additional risk factors such as race, gender, or comorbidities. ACIP determined that there is not enough information to alter current recommendations for the authorized use of the vaccine, and decided not to vote, but to maintain the pause to conduct a more robust risk benefit analysis. Johnson and Johnson and CDC will continue to collect and analyze more data. Reports of additional suspected cases are emerging and being investigated, which is expected. ACIP members cautioned against an indefinite pause and urged the creation of a clear timeframe, plan to resume, and messages to combat emerging vaccine hesitancy due to the pause.

ACIP will reconvene next week to revisit the issue following the collection of more data. The recommended pause on ordering and administering Johnson and Johnson vaccine is likely to remain in effect until the investigation is concluded and ACIP makes further recommendations. The use of the vaccine has not been revoked by FDA and in theory can still be used based on provider-recipient discussions and decisions.

Guidance to Jurisdictions
- Jurisdictions should consider alternative approaches for how to address special groups that would benefit from the Johnson and Johnson vaccine.
- Notwithstanding the current situation, there should be enough vaccine supply from the other two manufacturers, Pfizer and Moderna, to meet the demand for all adults by the end of May and this incident should not impact the current plan to open up eligibility for all adults.
- Jurisdictions may consider convening safety review boards or working groups to review information provided by the federal government.
- Jurisdictions should encourage providers to report adverse events to the Vaccine Adverse Event Reporting System.
- Jurisdictions should order all doses allocated and redouble efforts to schedule and administer all available vaccine to meet demand.
- This week, a total of 28 million doses of Pfizer and Moderna will be made available (up from last week), which includes 17.75 million doses to the states, tribes, and territories.

Key Messages

General messages:
- COVID-19 vaccine safety is a top priority, and we take all reports of health problems following COVID-19 vaccination very seriously.
- This is an extraordinarily rare event that needs to be reviewed further.
While a pause may seem concerning, it should be considered a success that the current safety surveillance systems are working properly and as intended.

This pause will allow experts to further review the data. Until that process is complete, we are recommending a pause in the use of this vaccine out of an abundance of caution.

This is important, in part, to ensure that the healthcare provider community is aware of the potential for these adverse events and can plan for proper recognition and management due to the unique treatment required with this type of blood clot.

**For individuals receiving Johnson and Johnson vaccine:**
- For people who got the vaccine more than a month ago, the risk is very low at this time.
- People who recently got the vaccine—within the last few weeks—should be aware of any symptoms.
  - If you have received the vaccine and develop severe headache, abdominal pain, leg pain, or shortness of breath, you should contact your healthcare provider and seek medical treatment.
- At present, there are three vaccines available in the United States. We are not seeing these events in the case of the other two vaccines.
- People who have appointments for the other two vaccines should continue with their appointment. Our partners will work with those scheduled to receive the Johnson and Johnson vaccine in the days ahead to reschedule.

**For clinicians:**
- Treatment of this specific type of blood clot, CVST, is different from the treatment that might typically be administered. Usually, the anticoagulant drug heparin is used to treat blood clots. In these cases, administration of heparin may be dangerous, and alternative treatments need to be given.
- Healthcare providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at [https://vaers.hhs.gov/reportevent.html](https://vaers.hhs.gov/reportevent.html).

**Additional Information**
- ACIP
  - Slides from the April 14, 2021 ACIP meeting
  - Another ACIP meeting will be held next week.
- Johnson and Johnson
  - Press statement (April 13, 2021)
  - Press statement (April 14, 2021)
- White House:
  - Statement from Jeff Zients, White House COVID-19 Response Coordinator on Johnson & Johnson Vaccine
- FDA:
  - Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine
- CDC:
  - Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine
  - HAN ALERT: Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine