Johnson & Johnson (Janssen) Update

April 13, 2021

DCHD Statement

The DuPage County Health Department (DCHD) is pausing the use of the Johnson & Johnson (Janssen) COVID-19 vaccine following guidance from the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and as required by the Illinois Department of Public Health (IDPH). DCHD has shared the CDC and FDA recommendation with all COVID-19 vaccine providers who have received vaccine from DCHD. DCHD officials are closely monitoring this situation and learning more from IDPH and CDC.

The pause of the Johnson & Johnson (J&J) vaccine was done out of an abundance of caution due to six cases of a rare and severe type of blood clot in individuals who received the Johnson & Johnson vaccine in the United States, out of over 6.8 million doses given. Currently, there are no reported cases in DuPage County. These events appear to be extremely rare, and COVID-19 vaccine safety continues to be a top priority.

Based on CDC and FDA guidance, individuals who received the J&J vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should contact their health care provider. Health care providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at **https://vaers.hhs.gov/reportevent.html**.

For more information, visit www.cdc.gov/media/releases/2021/s0413-JJ-vaccine.html.

Johnson & Johnson Pause Key Messages

Key message 1: As required by IDPH and out of an abundance of caution, the DuPage County Health Department is pausing vaccinations with the Johnson & Johnson COVID-19 vaccine in DuPage County, under the guidance of the CDC, FDA, and IDPH.

- On April 13, 2021, the CDC and FDA recommended and IDPH required pausing the use of Johnson & Johnson's COVID-19 vaccine after six recipients developed a rare and severe type of blood clot.
- All six cases occurred among women between the ages of 18 and 48 years, and symptoms occurred 6 to 13 days after vaccination.
- Adverse reactions to the vaccine are extremely rare. As of April 12, six cases of this rare blood clotting disorder were identified out of more than 6.8 million doses of the J&J vaccine administered in the United States.
- The CDC and FDA are reviewing these cases, as well as data from other countries, and are taking these events very seriously.
- A key reason for the pause is to prepare the health care system to recognize and treat patients appropriately, to report severe events they may be seeing in people who have received the J&J vaccine.
  - This pause also will allow CDC's expert committee to review the situation.
  - 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 health care 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.

Key Message 2: The safety of COVID-19 vaccines is a top priority and is being closely monitored.

- There are multiple monitoring systems in place – including the Vaccine Adverse Event Reporting System (VAERS), v-safe, and others – where any adverse reactions are reported. The CDC is closely reviewing this data for patterns.
- This pause illustrates the value of public health vaccine monitoring. It is normal procedure to take a pause to review adverse event data and then make public health decisions going forward.
- We expect to know more about the situation soon and will keep our community informed.

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Frequently Asked Questions (FAQs)

Q: Why are you pausing J&J vaccinations?

A: We are following the guidance of the CDC, FDA, and the IDPH-required pause for Johnson & Johnson vaccinations. The CDC and FDA are reviewing data for six cases of a rare blood clotting disorder that occurred out of 6.8 million people who received the J&J vaccine.

Q: Is DCHD cancelling vaccination appointments?

A: The DuPage County Health Department is using the Pfizer vaccine for appointments that are scheduled at the DuPage County Community Vaccination Site. At this time, we do not anticipate having to cancel appointments. Our partners are also being asked to pause any use of the Johnson & Johnson/Janssen COVID-19 vaccine and use other vaccine brands if available until we receive the recommendation to resume.

Q: I received the J&J vaccine recently; do I need to worry?

A: We understand that this news may cause concern. Millions of people have received the Johnson & Johnson vaccine with no serious side effects. Serious reactions are extremely rare. The CDC has shared that if you got the vaccine several weeks ago, the risk of a reaction is very low. People who have received the Johnson & Johnson vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should contact their health care provider and share their recent vaccination history. Patients with other clinical questions should contact their health care provider.

Q: Will use of the J&J vaccines resume in the future?

A: Johnson & Johnson vaccinations will resume once the CDC, FDA, and IDPH make a recommendation to do so. In the meantime, DCHD and local vaccine providers continue offering vaccinations using Pfizer and/or Moderna vaccine.

Q: How likely is it that someone would have an adverse reaction to J&J?

A: Adverse reactions to the vaccine are extremely rare. There were six reports of a rare type of blood clot called cerebral venous sinus thrombosis (CVST) in combination with low levels of blood platelets (thrombocytopenia) out of 6.8 million doses given in the United States using the Johnson & Johnson vaccine.