Indiana Health Alert Network Notification

Statement on Johnson & Johnson Vaccine

April 13, 2021

The Indiana Department of Health advises all healthcare providers to evaluate, treat and report potential adverse effects from the Johnson & Johnson (Janssen) COVID-19 vaccine following an announcement made today by the Centers for Disease Control and Prevention (CDC) and the U.S. FDA. The CDC has also issued a Health Alert Network notification.

The statement from Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research and Dr. Anne Schuchat, principal deputy director of the CDC, says:

> "As of April 12, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S. CDC and FDA are reviewing data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine. In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred among women between the ages of 18 and 48, and symptoms occurred 6 to 13 days after vaccination. Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this setting, administration of heparin may be dangerous, and alternative treatments need to be given.
>
> "CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday to further review these cases and assess their potential significance. FDA will review that analysis as it also investigates these cases. 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.
>
> "Right now, these adverse events appear to be extremely rare. COVID-19 vaccine safety is a top priority for the federal government, and we take all reports of health problems following COVID-19 vaccination very seriously. People who have 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."

The Indiana Department of Health is following the CDC and FDA recommendation to pause Johnson & Johnson vaccine administration to ensure safety. The pause is expected to last a matter of days, according to the ACIP and FDA, as their thorough and expeditious review of the available information is completed.

This rare adverse event is related to only the Johnson & Johnson viral vector vaccine. The FDA has advised that typical flu-like symptoms are expected in the first few days after vaccination. Symptoms of this rare event occurred at least a week after vaccination and not longer than three weeks, with a median of nine days.

Anyone with an appointment in the next two days for that vaccine should call 211 to schedule an appointment for a different vaccine.

More information will be shared as it becomes available after additional study and review.

Please email questions to Chief Medical Officer Dr. Lindsay Weaver at lweaver@isdh.in.gov.