Ohio | Department of Health

Mike DeWine, Governor
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April 23, 2021

To Enrolled Provider Partners,

Today, April 23, 2021, following a thorough safety review including two meetings of the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP), the U.S. Food and Drug Administration and the CDC have recommended that use of the Johnson & Johnson (Janssen) COVID-19 vaccine can resume. The panel says the benefits of the vaccine in preventing COVID-19 outweigh the risks of rare blood clotting that has occurred in a small number of people who have received the Janssen COVID-19 vaccine.

Healthcare providers administering the vaccine and vaccine recipients or caregivers must review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers, which have been revised to include information about the risk of rare blood-clotting events. Updated interim recommendations for the vaccine's emergency use authorization (EUA) add a warning about the potential for the blood clots.

Background

On April 13, the FDA and the CDC recommended a pause in the use of the Johnson & Johnson vaccine out of an abundance of caution following six reported cases of a blood clot called cerebral venous sinus thrombosis (CVST) seen in combination with low levels of blood platelets (thrombocytopenia) in people who had received the vaccine. More than 6.8 million Americans had received the Johnson & Johnson vaccine since its EUA was granted on Feb. 27, 2021. On April 14, the ACIP held an emergency meeting to discuss these rare but potentially life-threatening cases of thrombosis with thrombocytopenia syndrome (TTS), but determined that more information was needed before a recommendation on policy options could be made. ACIP reconvened today, April 23, to assess the data and make a recommendation to the CDC.

Today, the agencies confirmed that a total of 15 cases of TTS have been reported to the Vaccine Adverse Event Reporting System (VAERS), including the original six reported cases. All of these cases occurred in women between the ages of 18 and 59, with a median age of 37 years. Reports indicated symptom onset between six and 15 days after vaccination.

Information and recommendations for vaccine providers, healthcare providers

- Use of the Johnson & Johnson (Janssen) COVID-19 vaccine can resume. Ohio providers who have available Johnson & Johnson vaccine supply can resume vaccinations immediately. ODH will share information with providers about future shipments as soon as that information is available.
- 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 continue to investigate this risk.
- **Ongoing education of vaccine recipients about signs and symptoms of TTS:** According to the FDA, people who have received the Johnson & Johnson COVID-19 vaccine and develop shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms (including severe or persistent headaches or blurred vision), or petechiae beyond the site of vaccination should seek immediate medical care. These patients should disclose their vaccination history to medical providers to ensure proper care.

- **Treatment of TTS:** Recommended treatment of TTS is different from the treatment that might typically be administered for a blood clot, according to the CDC. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this case, administration of heparin could worsen symptoms and should not be used to treat this condition. Alternative anticoagulant treatments need to be given with a TTS diagnosis.
- **Moderna or Pfizer vaccines:** The CDC says there haven't been any reports of TTS among the 182 million doses of the Pfizer and Moderna vaccines that had been administered in the United States. The Moderna and Pfizer vaccines use a different vaccine technology than the Johnson & Johnson vaccine.
- **Vaccine adverse events** must be reported through VAERS. VAERS, managed by the CDC and FDA, is part of the larger vaccine safety system in the United States that helps make sure vaccines are safe. A report to VAERS does not mean that a vaccine caused an adverse event. FDA and CDC will investigate reports and take action as needed.

CDC and FDA resources

- UPDATED: Fact Sheet for Healthcare Providers Administering Vaccine
- UPDATED: Fact Sheet for Recipients and Caregivers
- CDC Health Alert for Health Care Providers
- Johnson & Johnson Granting EUA Amendment (April 23, 2021)

Officials at the Ohio Department of Health will continue to follow this situation closely and share updates.

Sincerely,

Ohio Department of Health COVID-19 Vaccination Provider Relations Team