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**DEPARTMENT OF
HEALTH AND HUMAN SERVICES**
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH
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Technical Bulletin

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Contact: Pamela Forest, MD, Vaccine Safety Coordinator

To: All Health Care Providers and Facilities, Local Health Districts, and Pharmacists

On April 23, 2021, the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) [lifted the recommended pause](#) on the Johnson & Johnson (Janssen/J&J) COVID-19 Vaccine following a thorough safety review, including two meetings of the Advisory Committee on Immunization Practices (ACIP).

The pause was recommended after six cases of a rare and severe type of blood clot occurred in individuals following administration of the J&J COVID-19 Vaccine. The teams at FDA and CDC also conducted extensive outreach to providers to ensure they were aware of the potential for these adverse events and could properly manage and recognize these events due to the unique treatment required for these blood clots coupled with low platelets, also known as thrombosis with thrombocytopenia syndrome (TTS).

CDC and FDA have determined the following:

- **Use of the J&J COVID-19 Vaccine should be resumed in the U.S. for everyone 18 years and older.**
- **Enrolled providers may submit new orders for J&J vaccine weekly.**
- **The agencies are confident this vaccine is safe and effective in preventing COVID-19.**
- These clotting events are rare; available data show the vaccine's known and potential benefits outweigh its known and potential risks in people 18 years and older.
- At this time, available data suggest the chance of TTS occurring is very low, but the FDA and CDC will remain vigilant in continuing to investigate this risk.
- Healthcare providers administering the J&J COVID-19 Vaccine and vaccine recipients and caregivers should review the [Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#) and [Fact Sheet for Recipients and Caregivers](#), which have been revised to include information about the risk of TTS, which has occurred in a very small number of people who have received the J&J COVID-19 Vaccine.

The agencies have confirmed a total of 15 cases of TTS have been reported to the Vaccine Adverse Events Reporting System (VAERS), including the original six reported cases. All these cases occurred in women between the ages of 18 and 59 years with symptom onset between 6 and 15 days after vaccination. The Emergency Use Authorization (EUA) for the Janssen COVID-19 Vaccine now includes a warning for rare clotting events, primarily occurring among women aged 18-49 years. The safety profile of the Janssen vaccine remains like that observed in clinical trials.

Women younger than 50 years should be aware of the rare but increased risk of this adverse event following receipt of the J&J vaccine and that there are other COVID-19 vaccine options available for which this risk has not been seen. Women in the higher risk group (7 cases per million in women 18-49 years) should be made aware of the potentially increased risk of TTS and, when possible, should be offered the option to receive the Moderna or Pfizer COVID-19 vaccines.

For **three weeks after administering the vaccine**, providers and patients should be on the lookout for symptoms indicating a possible blood clot with low platelets, including:

- o Severe or persistent headaches or blurred vision
- o Shortness of breath
- o Chest pain
- o Leg swelling
- o Persistent abdominal pain
- o Easy bruising or tiny blood spots under the skin beyond the injection site

If the patient develops one or more of the symptoms listed above, immediate medical attention should be received.

Current vaccine safety monitoring systems in place are working and TTS reports were detected early. The Nevada State Immunization Program (NSIP) would like to take this opportunity to emphasize the importance of reporting severe adverse events after vaccine administration to the VAERS: <https://vaers.hhs.gov/reportevent.html>.

VAERS gives vaccine safety experts valuable information so they can assess possible safety concerns related to vaccines. It is especially useful for quickly detecting unusual or unexpected patterns of health problems or adverse events that might indicate a possible safety problem with a vaccine. Additionally, patients experiencing adverse symptoms after receiving a COVID-19 vaccine should be encouraged to report the symptoms to [V-safe](#), a smart phone-based tool that uses text messaging and web surveys to provide personalized health check-ins after the receipt of a COVID-19 vaccine. COVID-19 vaccines have undergone and will continue to undergo intensive safety monitoring.

Review the official CDC health alert which includes details about how to assess and care for a patient that presents with thrombosis or thrombocytopenia: [Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine](#)

Questions: For updated guidance, please review the DPBH Technical Bulletin website and Nevada’s COVID-19 response website regularly. ^{1,2} If you have other questions regarding the COVID-19 Vaccine Response, please email dpbh covid19vax@health.nv.gov.



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¹ http://dpbh.nv.gov/Resources/Technical_Bulletins-New/

² <https://nvhealthresponse.nv.gov/>