

## **Statement on the US Food & Drug Administration and Centers for Disease Control Recommendation to Pause Administration of the Johnson & Johnson (Janssen) Vaccine**

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On April 13, 2021, the US FDA and CDC [jointly recommended](#) a pause to the use of the Johnson & Johnson (Janssen) vaccine due to reports of a rare, severe type of blood clot in six women aged 18 to 48 (median age 33 years) occurring 6 to 13 days after vaccination. In addition to the pause, the CDC has also issued an official [Health Alert](#).

This form of blood clot, known as a cerebral venous sinus thrombosis (CVST), was accompanied by thrombocytopenia (low levels of blood platelets) in all six cases. Thrombosis does not usually occur in the presence of thrombocytopenia, which makes these cases atypical. Although the incidence of CVST plus thrombocytopenia following the J&J vaccine is very low (a reported incidence of 0.87 per million), the observed rate is 3.8 to 15 times higher than the background rate in women aged 20 to 50 years.

Clinical features of the J&J cases are similar to those associated with the AstraZeneca COVID-19 vaccine in Europe. CVST plus thrombocytopenia has not been observed in people receiving the mRNA vaccines.

On April 14, 2021, the [Advisory Committee on Immunization Practices \(ACIP\)](#) met to discuss the six cases and to determine next steps. After reviewing more detailed information about the cases, the Committee declined to change the current pause on the distribution of the J&J vaccine in the United States. Within the next 7 to 14 days, the Committee will further investigate the data and conduct a risk/benefit analysis, at which time they will reconvene and present their recommendations regarding use of the J&J vaccine.

Medical details about the cases that were presented at the ACIP meeting are as follows:

- 3 had obesity
- 1 had hypothyroidism
- 1 had asthma
- 1 had hypertension
- 1 was currently taking estrogen/progesterone

None had preexisting coagulation disorders. None were pregnant or postpartum. One of the patients died; three remain hospitalized; and two have been discharged to home.

ACIP stresses that physicians need to maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia in those who have recently received the J&J vaccine, including severe headache, backache, new neurologic symptoms,

severe abdominal pain, shortness of breath, leg swelling, petechiae, or new or easy bruising. Platelet counts should be obtained and screening for evidence of immune thrombotic thrombocytopenia should be performed. Clinicians are encouraged to report any adverse events to the [Vaccine Adverse Event Reporting System \(VAERS\)](#), including serious and life-threatening adverse events and deaths, in patients following receipt of COVID-19 vaccines.

Treatment is different with this type of blood clot than what is typically given. Heparin, the usual treatment for blood clots, can cause serious harm when used to treat CVST with thrombocytopenia. Patients with a thrombotic event and thrombocytopenia after the J&J vaccine should be screened initially with a PF4 enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune HIT. Consultation with a hematologist is strongly recommended. If results of such testing are positive, or if the test cannot be performed, alternative treatments, such as non-heparin anticoagulants and high-dose intravenous immune globulin, are indicated. The American Society of Hematology has recently added an [overview of treatment considerations](#) of vaccine-induced thrombocytopenia to its website.

Anyone who develops symptoms of severe headache, abdominal pain, leg pain, or shortness of breath within 3 weeks of receiving the J&J vaccine should seek prompt medical attention. People scheduled to receive the J&J vaccine should contact their health care professional or vaccination location to learn about additional vaccine availability.

The announcement by the FDA and CDC, while concerning, highlights the effectiveness of surveillance efforts to ensure the safety of vaccines and the transparency with which the agencies are communicating about possible adverse events. The Society for Maternal-Fetal Medicine continues to closely follow these events and will update its [vaccine guidance](#) as more information becomes available.