

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Ron DeSantis
Governor

Scott A. Rivkees, MD
State Surgeon General

Vision: To be the **Healthiest State** in the Nation

Important Updates for Health Care Providers Regarding Johnson & Johnson's Janssen COVID-19 Vaccine

April 13, 2021

Health Alert Network Update Regarding Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson's Janssen COVID-19 Vaccine

The Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) are reviewing data involving six U.S. cases of a rare type of blood clot in individuals after receiving Johnson & Johnson's Janssen COVID-19 vaccine that were reported to the Vaccine Adverse Events Reporting System (VAERS). 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).

The CDC will convene an emergency meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday, April 14, 2021, to further review these cases and assess potential implications on vaccine policy. FDA will review that analysis as it also investigates these cases. Until that process is complete, the CDC and FDA are recommending a pause in the use of the Johnson & Johnson Janssen COVID-19 vaccine out of an abundance of caution. The purpose of this Health Alert is, in part, to ensure that the health care provider community is aware of the potential for these adverse events and can provide proper management due to the unique treatment required with this type of blood clot. Please visit CDC's website [here](#) for more information on the health alert.

CDC and FDA Updates for Clinicians

1. Pause the use of the Johnson & Johnson Janssen COVID-19 vaccine until the ACIP is able to further review these CVST cases in the context of thrombocytopenia and assess their potential significance.
2. Maintain a high index of suspicion for symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the Johnson & Johnson Janssen COVID-19 vaccine, including severe headache, backache, new neurologic symptoms, severe abdominal pain, shortness of breath, leg swelling, petechiae (tiny red spots on the skin), or new or easy bruising. Obtain platelet counts and screen for evidence of immune thrombotic thrombocytopenia.
3. In patients with a thrombotic event and thrombocytopenia after the Johnson & Johnson Janssen COVID-19 vaccine, evaluate initially with a screening PF4 enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune heparin-induced thrombocytopenia. Consultation with a hematologist is strongly recommended.
4. Do not treat patients with thrombotic events and thrombocytopenia following receipt of Johnson & Johnson Janssen COVID-19 vaccine with heparin, unless heparin-induced thrombocytopenia testing is negative.
5. If heparin-induced thrombocytopenia testing is positive or unable to be performed in patient with thrombotic events and thrombocytopenia following receipt of Johnson & Johnson Janssen

COVID-19 vaccine, non-heparin anticoagulants and high-dose intravenous immune globulin should be strongly considered.

Health Care Providers Reporting Adverse Events

Health care providers who diagnose patients with any adverse reactions to the Johnson & Johnson Janssen COVID-19 vaccine should report to the [Vaccine Adverse Event Reporting System](#), a national program managed by the CDC and the FDA to monitor the safety of all vaccines licensed in the United States. For more information on the VAERS, please click [here](#).

Updated Health Care Provider Telephone Conference Call Information

On Tuesday, April 20, 2021, a health care provider telephone conference call will be held at 5:30 p.m. Participants are asked to email questions in advance to Provider.COVID19@flhealth.gov no later than close of business on the Monday preceding the call. All participants will be muted during these calls to help streamline information delivery. The State Surgeon General, Dr. Scott A. Rivkees, will provide updates from the Department of Health on the COVID-19 response efforts and address questions submitted from health care providers. This call is not transcribed or recorded. If you are interested in joining this telephone conference call, please see the updated call-in information below:

Date: Tuesday, April 20, 2021

Time: 5:30 p.m., ET

Call-In Number: 888-585-9008

Conference Room ID: 208-305-233

Submit Questions in Advance: Provider.COVID19@flhealth.gov

Helpful Resources

- Health care provider notifications - www.flhealthsource.gov/covid19
- Florida Department of Health Immunization Section COVID-19 vaccine webpage - <http://www.floridahealth.gov/programs-and-services/immunization/COVID-19VaccineInfo/index.html>
- Florida Department of Health COVID-19 webpage - www.floridahealthcovid19.gov
- Official CDC Health Alert - <https://emergency.cdc.gov/han/2021/han00442.asp>