Society for Maternal•Fetal Medicine
High-risk pregnancy experts

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

April 13, 2021

Today, the US FDA and CDC are jointly recommending a pause to the use of the Johnson & Johnson (Janssen) vaccine due to reports of a rare, severe type of blood clot in 6 women aged 18 to 48 following receipt of the vaccine. This form of blood clot, known as cerebral venous sinus thrombosis (CVST), was accompanied by thrombocytopenia (low levels of blood platelets), and occurred 6 to 13 days after vaccination. 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. Alternative treatments are therefore necessary.

More than 6.8 million doses of the J&J vaccine have been administered in the United States, making this adverse effect extremely rare. Nevertheless, out of an abundance of caution and with safety concerns a top priority, the CDC and FDA recommend pausing administration of the J&J vaccine while they analyze the cases and determine their potential impact. They also recommend that anyone who has received the J&J vaccine and develops symptoms of severe headache, abdominal pain, leg pain, or shortness of breath seek medical attention. Health care professionals are urged to be aware of these symptoms in persons who have received the vaccine in the past month and the potential for CVST with thrombocytopenia.

These safety concerns do not apply to the mRNA vaccines (Moderna and Pfizer). The J&J vaccine is an adenoviral-vector vaccine. The Moderna and Pfizer vaccines are still recommended, and the administration of these vaccines is continuing.

Because the adverse effects appear to have occurred in women of reproductive age, the Society of Maternal-Fetal Medicine is following these events closely. Of particular interest is whether the affected individuals were pregnant, breastfeeding, or taking hormonal contraception. This information was not disclosed by the FDA and CDC but is expected to be an area of inquiry as the analysis proceeds. SMFM will update its vaccine guidance as more information becomes available.

This announcement, while concerning, highlights the effectiveness of surveillance efforts to ensure the safety of vaccines and the transparency with which the FDA and CDC are communicating about possible adverse events.

More information will be available following a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday, April 14 (please keep checking the ACIP web page for details).