

J&J vaccine and brain blood clots: What physicians should know

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Editor's note: After a thorough review, ACIP lifted the J&J vaccine pause April 23. Dr. Bailey commended ACIP that day for “reaffirming its recommendation on the use of the Janssen COVID-19 vaccine” for those 18 or older under the FDA’s emergency use authorization. “The population-level data presented during ACIP’s meeting today clearly demonstrates that the benefits of this approach outweigh the risks,” she said.

“The pause on the Janssen COVID-19 vaccine has demonstrated the strength of our nation’s vaccine safety monitoring system and the transparent and careful deliberations by the ACIP should raise confidence in FDA-authorized and CDC-recommended COVID-19 vaccines,” Dr. Bailey added. “The AMA continues to encourage everyone who is eligible for COVID-19 vaccines to get vaccinated as soon as possible.”

When federal agencies in charge of protecting Americans’ health recommended that there should be a pause in the administration of the Johnson & Johnson (J&J) COVID-19 vaccine, state health leaders listened and suspended its use.

The FDA didn’t recommend the pause “because we felt that the number of cases was growing out of control, but because we wanted to educate providers to know what to do,” said Peter Marks, MD, PhD, director of the FDA’s Center for Biologics Evaluation and Research, during an AMA-hosted webinar.

This also includes informing doctors that standard treatments—such as administering heparin—can worsen a patient’s condition.

“One of the individuals who received heparin clearly had complications related to the receipt of heparin,” Dr. Marks told AMA President Susan R. Bailey, MD, in the seventh installment of the AMA-hosted “COVID-19: What Physicians Need to Know” webinar series to discuss current issues and next steps in SARS-CoV-2 vaccine safety and delivery.

Nearly 7 million doses of the J&J vaccine have been administered, but the FDA and Centers for Disease Control and Prevention (CDC) are reviewing data involving six reported cases in the U.S. of a brain blood clot—cerebral venous sinus thrombosis in combination with thrombocytopenia—in people getting the J&J vaccine. All were in women between 18 and 48, with symptoms developing six to 13 days after vaccination.

One of the women died. Another is hospitalized in critical condition.

The pause also gives the FDA and CDC time to ascertain whether there are other cases that the agencies were not aware of, whether women 18–48 are at higher relative risk for blood clots after receiving the vaccine and, if so, develop appropriate mitigation strategies.

The Advisory Committee on Immunization Practices (ACIP) met April 14 and sought more data to review on the J&J vaccine and these rare blood clots, including why they're happening and how often. ACIP said it would meet again within 10 days to determine next steps, which could include resuming administration of the vaccine, continuing the pause, or allowing it for certain subgroups of patients.

Signs to look for

People who develop a severe headache, abdominal pain, leg pain or shortness of breath within six to 13 days after J&J vaccination are being advised to contact their physician to assess them for the treatment required for this type of blood clot.

“If the patient has those symptoms, I assume we send them to the emergency room?” Dr. Bailey asked.

Dr. Marks agreed, adding, “If you have little speckle spots on your hands and your shins, time to go to the emergency room.”

Both noted that people may experience a mild headache after vaccination. Dr. Marks noted that headaches associated with the blood clot occur one to three weeks after the shot and are more severe.

Dr. Marks recommended asking patients, “Is this like headaches you've had before? Or is the quality of the headache something that you've never experienced before?”

While the reported adverse events all involve women, Dr. Marks said there was one instance of a man developing cerebral vein thrombosis with thrombocytopenia in the clinical trial conducted by J&J-owned Janssen Pharmaceuticals.

“My plea is don't dismiss a male who says, ‘Well, I got Janssen a week ago and I have a headache that's nothing like I've ever had before,’” he said. “That person probably should be evaluated.”

Doctors should obtain platelet counts and screen for evidence of immune thrombotic thrombocytopenia. Patients should be evaluated initially with a screening PF4 enzyme-linked immunosorbent (ELISA) assay, as would be performed for autoimmune heparin-induced thrombocytopenia. In such cases, the CDC strongly encourages consulting with a hematologist.

Learn more about these events and how to respond in the CDC's April 13 health alert, “Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine.”

Open communication's key

Still, Dr. Bailey asked him if the recommendation to pause administering the J&J vaccine would fuel vaccine hesitancy and perhaps engender hesitancy where it didn't exist prior to the FDA and CDC's announcement.

“I share your pain about this because it's pain we all felt,” Dr. Marks replied. “The best thing we can do to make sure we engender vaccine confidence is to communicate openly.”

He noted that the FDA also received safety signals involving severe allergic reactions to the two authorized messenger RNA-based vaccines from Pfizer-BioNTech and Moderna and quickly instituted mitigation measures that serve as a paradigm for addressing issues as they arise.

“We know now to ask people about whether they've had previous allergic reactions to medications and particularly to vaccines,” he said. “We know to have anaphylaxis kits onsite, and we know not to wait until someone has full-blown anaphylaxis to start to use those management kits.”

Dr. Marks acknowledged that federal health officials are under fire for the J&J vaccine pause, but he said they wouldn't waiver in their commitment to safety.

“I've had every epithet hurled at me in my email,” Dr. Marks said. “Overall, we should be very confident that the systems are working, and the fact that they're picking up rare adverse events is actually what they were designed to do—and now we just have to deal with them.”