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Use of J&J COVID-19 vaccine allowed to resume after investigation of rare blood clots

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Editor's note:*For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

Vaccine providers can resume using Johnson & Johnson's (J&J's) COVID-19 vaccine for everyone 18 years and older following a pause to investigate rare but serious cases of blood clots, health officials said Friday.

"After a thorough review of all available data, the FDA (Food and Drug Administration) and CDC (Centers for Disease Control and Prevention) have concluded that the possibility of a so-called thrombosis thrombocytopenia syndrome occurring is very low but the investigation into the level of potential vaccination-related risk will continue to be ongoing," said Acting FDA Commissioner Janet Woodcock, M.D. "Together, both agencies have full confidence that this vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older."

The FDA and CDC recommended a pause last week after confirming six women experienced cerebral venous sinus thrombosis (CVST) in combination with low platelet levels (thrombocytopenia). One of the women died. Officials have been continuing to gather data, which they presented to the CDC's Advisory Committee on Immunization Practices (ACIP) during a six-hour meeting Friday.

Officials broadened the cases they were investigating to include clots in other areas, including the abdomen and legs. They have confirmed 15 such cases of thrombosis with thrombocytopenia syndrome (TTS) following administration of nearly 8 million doses of the J&J vaccine.

Thirteen of the cases were in females ages 18-49 and two were in women ages 50 to 64 with a median age of 37, according to the CDC. Three of the women died, and seven remain hospitalized. Symptoms began a median of eight days after vaccination. Twelve of the cases were CVST with thrombocytopenia. Experts were not able to pinpoint risk factors outside of age and gender. They noted two women had used oral contraceptives, seven had obesity, two had hypothyroidism and two had hypertension. None had diabetes or coagulation disorders.

CDC modeling showed resuming use of the J&J vaccine for everyone 18 years and older could mean 26 to 45 more TTS cases over the next six months. However, it also could prevent 800 to 3,500 intensive care unit admissions and 600 to 1,400 deaths from COVID-19 during that time.

Because the vaccine requires only one dose and does not have onerous storage and handling requirements, it has been touted as an important tool for vaccinating hard-to-reach and vulnerable populations. Delaying or eliminating the use of the J&J vaccine would be especially detrimental to people who are homeless, homebound or incarcerated, vaccine experts said.

ACIP members discussed use of the vaccine in the context of potential harms and benefits, public confidence, rising COVID-19 cases, feasibility of use and equity. They ultimately voted 10-4, with one abstention, that use of the J&J vaccine should resume for all adults.

“The three COVID-19 vaccines currently authorized in the U.S. are amazingly safe and effective,” said Henry H. Bernstein, D.O., M.H.C.M, FAAP, professor of pediatrics at the Zucker School of Medicine at Hofstra/Northwell. “In my mind, their benefits far outweigh identified or perceived risks. We need as many people to be vaccinated as possible in order to reach community immunity and put the pandemic behind us. The J&J vaccine will help us do just that.”

Members showed almost no interest in permanently stopping use of the vaccine or restricting its use to people ages 50 and older. Instead, most of the debate focused on whether the language in their recommendation should mention the TTS cases and that women could choose another vaccine. Proponents of including the additional language said they wanted to make sure women have the information they need to make an informed choice, while others said they were concerned it could be interpreted as meaning all vaccine providers had to have several different types of vaccine on hand.

“I think if someone makes informed consent after having and knowing the risks involved, that’s fine, let them get it,” said Pablo J. Sanchez, M.D., FAAP. “But I think just making a blanket recommendation knowing the risks that seem to have biological plausibility and severity, I think we have to have stronger language and make sure people are informed appropriately.”

Information about TTS has been added to the FDA’s emergency use authorization for the vaccine and to clinician and patient information (see resources). Patients should seek medical attention if they experience severe or persistent headache, shortness of breath, chest pain, leg swelling, persistent abdominal pain or easy bruising beyond the injection site.

Clinicians are being warned that heparin may be harmful when treating patients with suspected TTS after COVID-19 vaccination, and they should consult with hematology specialists. Cases of TTS should be reported to the Vaccine Adverse Event Reporting System.

Resources

- The CDC will hold a webinar on the J&J vaccine and thrombosis with thrombocytopenia syndrome at 2 p.m. EDT on April 27
- Fact sheet for health care providers administering J&J vaccine
- Fact sheet for recipients and caregivers
- Information on J&J's amended emergency use authorization
- American Society of Hematology considerations relevant to the diagnosis and treatment of thrombosis with thrombocytopenia following vaccination with the J&J COVID-19 vaccine