CDC Panel Unanimously Decides to Demote J&J's COVID Vaccine Over Blood Clots

A panel of vaccine advisors to the Centers for Disease Control and Prevention (CDC) voted 15 – 0 to "preferentially recommend" mRNA COVID vaccines Pfizer and Moderna, over Johnson & Johnson (J&J) for adults 18 years and older.

The Advisory Committee on Immunization and Practices (ACIP) said the interim recommendation applies to both primary series vaccine doses and the booster dose. Panel members requested more forceful language be included in the guidance, but CDC officials said the strength of the recommendations would be made clear in the clinical considerations.

The ACIP looked at data from CDC officials on thrombosis with thrombocytopenia syndrome (TTS) and acknowledged 54 cases of the condition among J&J recipients, including nine deaths.

The median time from vaccination to symptom onset was 9 days and all patients were hospitalized – including 36 who were

admitted to the ICU. The median age of cases was about 45 but ranged in age from 18 to 70. Thirty-seven cases were in women and more than half (54%) of cases had cerebral venous sinus thrombosis (CVST). All cases occurred after the initial vaccine dose.

"The additional TTS cases and reported deaths are concerning," said Dr. Helen Keipp Talbot, an infectious-disease specialist at Vanderbilt University Medical Center and member of the ACIP.

The rate of cases is higher than previously estimated in both men and women, and in a wider age range, officials said. Although the CDC's COVID-19 Vaccine Task Force excluded "reports where [the] only thrombosis is ischemic stroke or myocardial infarction," which significantly reduced the number of coagulopathy disorders.

Cases were also excluded if the individual had concurrent COVID infection.

Among the nine deaths, all had features of severe CVST – a condition that occurs when a blood clot forms in the brain's venous sinuses and prevents blood from draining out of the brain. Seven cases had confirmed CVST and four received a craniectomy or craniotomy for a brain hemorrhage.

"We've been struck when we've been doing these cases by how quickly the patient deteriorates," said Isaac See of the CDC, who noted the median time from admission to death was 1 day.

See added that in most cases, the condition is too rapid "for much more to be done."

FDA updates fact sheet for J&J over

blood clots

The U.S. Food and Drug Administration (FDA) on Dec. 14, updated their fact sheets for emergency use authorization (EUA) of the J&J vaccine, marketed under the company's Janssen subsidiary, adding a contraindication to the shot for adults with a history of TTS following J&J or any other adenovirus-vectored vaccine.

Yet, the agency did not add a contraindication for people with pre-existing conditions, including coagulation disorders, or for those who may have experienced blood clots after receiving an mRNA vaccine.

The FDA noted TTS was reported in men and women, in a wide range of ages, with the highest rate in women aged 30 to 49. The agency noted approximately 15% of TTS cases were fatal.

ACIP stops short of pulling J&J vaccine

The ACIP did not recommend removing the J&J vaccine from the market over concerns it would leave some adults without protection. J&J is used most often in individuals who are homeless, prisoners or from rural areas — population groups that one ACIP member noted are least likely to have informed consent.

Other panel members felt that J&J's vaccine should remain available to anyone who is appropriately informed of the risks, an approach not taken with other products like hydroxychloroquine and ivermectin — FDA-approved drugs with strong safety profiles, that many scientists and patients desire to use off-label for the treatment of COVID.

"I cannot recommend a vaccine that's associated with a condition that may lead to death," said Pablo Sánchez,

principal investigator in the Center for Perinatal Research at The Research Institute and a professor of pediatrics at Ohio State University College of Medicine.

“I’m not recommending it to any of my patient’s parents. I tell them to stay away from it,” Sánchez added.

The CDC temporarily paused J&J’s COVID vaccine in April while scientists investigated reports of rare blood clots. The pause was lifted when health officials decided the benefits of the shot outweighed the risks. However, new data released by the FDA this week showed more cases occurred during the summer and fall prompting the emergency meeting.

The recommendations made by the ACIP are not considered final until they are published in the Morbidity and Mortality Weekly Report.