CDC Panel Backs Novavax COVID Vaccine for Adults

- Unvaccinated are target population for two-dose, protein-based shot, ACIP member says

by Amanda D'Ambrosio, Enterprise & Investigative Writer, MedPage Today July 19, 2022

The CDC Advisory Committee on Immunization Practices (ACIP) voted unanimously to recommend Novavax's COVID-19 vaccine for individuals 18 and up.

With a vote of 12-0, the advisory panel endorsed a two-dose primary series of the adjuvanted, protein-based vaccine, which will be administered 3 weeks apart. The recommendation follows FDA's emergency use authorization last week.

Shortly after the meeting, ACIP's recommendation was endorsed by CDC Director Rochelle Walensky, MD, MPH.

The recommendation was expected, as the shot proved safe and effective in preventing mild, moderate, and severe illness in an ongoing randomized trial conducted in the U.S. and Mexico.

"The primary target population for Novavax will be the 10% to 13% of those that are unvaccinated," said ACIP member Oliver Brooks, MD, chief medical officer of Watts HealthCare in Los Angeles. "We really need to focus on that population with the hope that perhaps this protein subunit vaccine will change them over from being unvaccinated to being vaccinated."

CDC experts noted that there are disparities in vaccine coverage, with younger patients, and those who come from minority racial and ethnic backgrounds, less likely to be immunized against COVID-19. Additionally, people without health insurance or a primary care provider have a lower likelihood of COVID vaccination.

"As always, the top priority remains vaccination of unvaccinated individuals," said Evelyn Twentyman, MD, MPH, of the CDC. "An initial COVID-19 vaccine utilizing traditional, more long-standing vaccine technology will provide an additional option for unvaccinated people."

Still, some ACIP members expressed concerns about the uncertainty of a timeline for Novavax booster doses and confusion around vaccine labeling.

While the Novavax COVID vaccine had 93% effectiveness against variants of concern and variants of interest, initially high antibody titers declined after 6 months, as seen with other COVID-19 vaccines, according to the manufacturer.

ACIP member Pablo Sanchez, MD, of the Ohio State University and Nationwide Children's Hospital in Columbus, said that while he is glad to see a fourth vaccine option on the table, recommendations about booster doses before fall 2022 will be critical for potential Novavax recipients.

"We really need some guidance," Sanchez said. "I think there will be an urgency for those who do receive the Novavax vaccine to have some FDA comments, also, on the booster dose."

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ACIP designated federal officer Melinda Wharton, MD, MPH, explained that "we are expecting that there will be boosters in the fall," but that "what the timeframe will be for that is not completely clear yet."

And some ACIP members expressed disappointment over the labeling of the vaccine: Expiration dates will not be listed directly on the vial so healthcare providers are tasked with using an online expiry date checker tool, which may prove to be burdensome, cause confusion, and potentially be a barrier to patient access.

"We have been moving at warp speed... to make sure vaccines are available for everyone," acknowledged ACIP member Helen Keipp Talbot, MD, MPH, of Vanderbilt University in Nashville. "Hopefully, by the time we're talking about booster doses and immunocompromised doses for this vaccine, labels will be updated."

The committee recognized that additional meetings will be needed to clarify labeling issues and discuss a timeline for booster doses in Novavax recipients.

"Although we were able to approve this fourth vaccine candidate today, we obviously still have work ahead," stressed ACIP Chair Grace Lee, MD, MPH, of Stanford Medicine in California.

The Novavax vaccine is already authorized for use in other countries including the U.K. and Japan.

Amanda D'Ambrosio is a reporter on MedPage Today's enterprise & investigative team. She covers obstetrics-gynecology and other clinical news, and writes features about the U.S. healthcare system. Follow y