

What doctors wish patients knew about the Novavax COVID-19 vaccine

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There's a fourth COVID-19 vaccine option in town: Novavax. The availability of the Novavax COVID-19 vaccine offers another option for people who may have been hesitant about getting vaccinated. But with its approval so late in the pandemic, some may wonder what distinguishes the Novavax option from other COVID-19 vaccines. Knowing those differences may be a deciding factor for hesitant individuals.

The AMA's What Doctors Wish Patients Knew™ series provides physicians with a platform to share what they want patients to understand about today's health care headlines, especially throughout the COVID-19 pandemic.

In this installment, Sandra Fryhofer, MD, an Atlanta general internist and chair of the AMA Board of Trustees, discusses the Novavax COVID-19 vaccine. Dr. Fryhofer also serves as the AMA's liaison to the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and is a member of ACIP's COVID-19 Vaccine Work Group.

For primary vaccination only

"We now have a third type of vaccine in the fight against COVID," Dr. Fryhofer said during an episode of the "AMA COVID-19 Update" about the Novavax vaccine. "A two-dose series of Novavax protein subunit COVID vaccine is now recommended for unvaccinated" individuals who are 12 or older "for primary vaccination against COVID-19."

But it is important to note that "Novavax has to be used for both doses in the primary series," she said. "You can't mix and match with a different product or type."

It's not new technology

“This vaccine contains harmless spike protein subunits with an adjuvant added to boost immune response. And, unlike mRNA vaccines, protein-based vaccines do not contain any genetic material,” said Dr. Fryhofer. “Our vast experience with protein subunit vaccines should be reassuring to those who worry about the newness of mRNA vaccine technology.”

“This protein-based platform is new for COVID vaccines but it's not really new. This technology has been around for more than 30 years,” she said, noting “it's already been used in making other vaccines, for example, for flu, hepatitis B and whooping cough.”

Novavax is not available for boosters yet

“Novavax can only be used as a primary series” because the Food and Drug Administration (FDA) “has not authorized it as a booster yet,” said Dr. Fryhofer. “However, there's a lot of interest in the prospect of using Novavax as a booster, especially since mRNA vaccines don't seem to be that durable.”

But Novavax has submitted booster data to the FDA. Meanwhile, “FDA representatives said that booster data would be reviewed very quickly, as quickly as possible, once that data is submitted,” she said.

“The company also announced that it started a study in May looking at Novavax boosters after an mRNA primary vaccine series,” Dr. Fryhofer explained. “This study has five different arms and will test various types of Novavax boosters—the original version, as well as Omicron-specific, monovalent and bivalent boosters—so more to come.

Effectiveness of Novavax is tricky

“The study data submitted to FDA says, overall, it was about 90% effective at preventing COVID,” said Dr. Fryhofer. “However, it did not seem to work quite as well in those 65 and older. Vaccine efficacy in this older group was 79%.

“And for some unexplained reason for which it doesn't make any physiological sense, vaccine efficacy in those of Hispanic ethnicity was also a little lower at 77%,” she added, noting “here's the catch: The studies submitted to FDA were done before Omicron started circulating.”

Because of that, “we just don’t know how it will work against Omicron,” Dr. Fryhofer said. “The Omicron surge started in December 2021 and still dominates. Omicron's BA.5 sublineage now makes up” 80% and BA.4 makes up a little more than 5% “of specimens tested, and who knows what variant is next on the menu.”

“The Novavax studies were done during a time when the Alpha variant was predominant, and the South Africa study showed that Novavax was only 51% effective against the Beta variant,” she said, adding that “we really can't compare vaccine effectiveness of Novavax to that of mRNA vaccines based on the data that we currently have available.”

Expect typical side effects

“Just like the mRNA vaccines, these vaccines are reactogenic, so expect fatigue, muscle pain, joint pain, headache, maybe some nausea, vomiting, maybe a little fever,” said Dr. Fryhofer. “These side effects usually go away within one to two days.”

“Unfortunately, as we've seen with the mRNA vaccines, there have been reports of myocarditis and pericarditis after Novavax during the clinical trials and also in early post-authorization data,” she said. “We know that the risk of heart complications is higher after COVID disease than after mRNA COVID vaccination among males and females of all ages.

“However, we can't directly compare myocarditis rates between Novavax and mRNA vaccines based on currently available data,” Dr. Fryhofer added. “Now, in the Novavax clinical safety study, there were only four to six cases identified out of more than 40,000 vaccine recipients. “As of the beginning of May of 2022, nearly 750,000 doses of Novavax had been administered in other countries and global post-marketing safety data have revealed 36 cases of myocarditis or pericarditis.”

“Myocarditis risk was addressed by the FDA in its guidance fact sheets, and FDA explains the chance of myocarditis is very low, but it can occur usually within 10 days following vaccination,” she explained. “It also says patients who have chest pain, shortness of breath, the fast heartbeat, heart fluttering or a pounding heart should seek medical care right away.”

“Post-authorization safety monitoring will continue and will be so important in further defining myocarditis risk,” Dr. Fryhofer noted.

Novavax is easy to store and use

“It comes in 10-dose vials, and it's preservative free. A dose is half a cc and contains 5 micrograms of protein subunit antigen along with 50 micrograms of a proprietary adjuvant Matrix-M, which boosts the immune response,” said Dr. Fryhofer, adding it is given “intramuscularly in the deltoid muscle.”

“Novavax has several logistical advantages. It's easy to store, easy to prepare and easy to administer,” she said. “You store it at regular refrigerator temperatures but don't freeze it. No dilutions necessary, but vaccine has to be discarded if it's not used within six hours after the first puncture of the vial.”

You can wait longer between doses

“In the study, vaccine doses were administered three weeks apart. However, CDC guidance says you can extend the interval between doses to as long as eight weeks,” said Dr. Fryhofer. “This extended interval guidance is based on data from mRNA vaccines. There are no specific data on extended intervals for Novavax and this is all based on the mRNA vaccine studies.”

“Some studies of mRNA vaccines have indicated a lower risk of myocarditis and greater immune response with that extended interval,” she said. “The eight-week interval could be considered, especially in young adult males, to reduce potential for myocarditis and at the same time optimize vaccine effectiveness.

“This extended interval recommendation does not apply to those with immunocompromised conditions,” Dr. Fryhofer added. “CDC recommends sticking to that three-week interval for patients with immunocompromised conditions so we can get their immune protection built up as quickly as possible.”

Be mindful of vaccine coadministration

There's some “good news” about coadministration of flu and COVID-19 vaccines, said Dr. Fryhofer. “It's fine to give flu shots and COVID vaccines at the same time, and that also goes for the Novavax vaccine.

“Also, there's no problem giving Novavax or any of the other COVID vaccines with other vaccines with one exception: orthopoxvirus vaccines,” she added, noting that while “we're in the middle of a monkeypox outbreak ... ACAM2000 and JYNNEOS are the two vaccines available for orthopoxvirus viruses.”

Unfortunately, “ACAM2000 has been linked to myocarditis. We don't know if there's an increased risk of myocarditis with JYNNEOS yet, but if you've received a dose of one of these orthopox vaccines, CDC suggests waiting four weeks to get a COVID vaccine dose,” Dr. Fryhofer explained. “However, if you've already received a COVID vaccine and you're now at risk of monkeypox due to exposure, no need to wait. Go ahead and get the monkeypox vaccine dose now.

“And remember, Novavax and other COVID vaccines are reactogenic and can have significant side effects,” she said. “The shingles vaccine—Shingrix—also is very reactogenic, so you might want to think twice about getting both shingles vaccine and COVID vaccine on the same day.”