DHA-IHD
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INFORMATION PAPER
ON
NOVAVAX COVID-19 VACCINE

PURPOSE:

This paper is intended to provide information to medical providers within the Department of Defense (DoD) to become better informed of the Novavax COVID-19 vaccine recently authorized under emergency use to prevent COVID-19 caused by SARS-CoV-2.

SITUATION:

The Novavax COVID-19 vaccine has recently become available under a Food and Drug Administration Emergency Use Authorization (FDA-EUA) as a primary series to prevent COVID-19 disease caused by SAR-CoV-2 in those 18 years of age and older. This vaccine uses a different platform than the messenger RNA vaccines (Pfizer-BioNTech and Moderna) or the viral-vector vaccine (Janssen). The Novavax vaccine is a recombinant protein vaccine, comprised of the SARS-CoV-2 spike protein and a saponin-based Matrix-M adjuvant and has been proven to be safe and effective at preventing COVID-19 disease caused by the B.1.1.7 variant[1].

BACKGROUND:

Several vaccines have been developed safely to help protect individuals from COVID-19 disease caused by the SARS-CoV-2 virus. In the US, there are three main types of COVID-19 vaccines approved or authorized to prevent COVID-19: messenger RNA (mRNA) such as Pfizer and Moderna, viral vector vaccines such as Janssen and protein subunit vaccines such as Novavax. All 3 vaccine types either deliver a protein (Novavax) or cause our cells to manufacture proteins (Pfizer, Moderna and Janssen) similar to the ones found on the surface of SARS-CoV-2. These vaccines teach the immune system to recognize the virus spike protein. Shortly after completing a vaccine series, the primed immune system is then able to prevent infection, or minimize the severity of infection.

Protein subunit vaccines are a traditional platform of vaccines and have been used for decades to prevent disease. The current shingles (zoster) vaccine is an example of a recombinant protein with novel adjuvant. Other recombinant protein vaccines used to prevent disease include the previously mentioned shingles vaccine, Hepatitis B, Human Papilloma virus vaccine and others. The Novavax vaccine presents the pre-fusional form of the SARS-CoV-2 spike protein to the immune system (aided by the novel adjuvant) and the vaccine teaches our immune system to recognize the virus. The protein subunit/novel adjuvant platform, does not use mRNA or DNA technology, does not enter the nucleus of cells, and does not integrate with any human DNA.

The Novavax vaccine may play an important role among DoD service members and beneficiaries who have been hesitant with either mRNA or viral vector vaccine development or production[1].

DISCUSSION:

Multiple vaccines are now available within the US to prevent COVID-19 disease. Novavax is the most recent vaccine authorized under emergency use to prevent COVID-19 and, like the other available COVID-19 vaccines available in the US, was formulated against the original SARS-CoV-2 strain. The Novavax vaccine does not rely on mRNA or viral vectors; therefore, this vaccine provides another option for individuals seeking protection against COVID-19.

Also, some individuals may have a precaution or contraindication to mRNA or viral vector vaccines and may be eligible for the Novavax vaccine due to its different manufacturing platform and its associated excipients differ from other approved/authorized vaccines (see EUA fact sheet for complete listing and details)[2]. Novavax COVID-19 vaccine does not contain PEG, though is does contain polysorbate 80.

The Novavax COVID-19 vaccine is packaged as a ready-to-use liquid formulation in a vial containing ten doses. The vaccination regimen calls for two 0.5 ml doses (5 mcg antigen and 50 mcg Matrix-M adjuvant) given intramuscularly 3-8 weeks apart in healthy individuals and 3 weeks apart in those who are immunocompromised apart. The vaccine is stored at 2°- 8° Celsius, enabling the use of existing vaccine supply and cold chain channels. Use of the vaccine should be in accordance with official recommendations from CDC and DoD.

Safety of the Novavax COVID-19 vaccine has been assessed both in Phase 3 trials as well as post EUA in other countries. According to the US Phase 3 trial data the most commonly reported local adverse events were injection-site tenderness or pain after both the first dose (with 53.3% reporting tenderness and 29.3% reporting pain) and the second dose (76.4% and 51.2%, respectively), with most events being grade 1 (mild) or 2 (moderate) in severity and of a short mean duration of around 2 days. Local adverse events were more commonly reported in younger recipients (18-64 years) than older recipients (>64 years). The most commonly reported systemic adverse events were headache, muscle pain, and fatigue after either dose, with most events being grade 1 or 2 in severity and of a short mean duration.[1] As with other vaccines, rare adverse events may not be detected in preauthorization trials due to their limited size.

RECOMMENDATIONS:

Providers may consider the Novavax'COVID-19 vaccine in individuals 18 years of age and older as a primary series who remain unvaccinated. Thus, providers should become knowledgeable about this vaccine, its indications, precautions and contraindications as outlined in the EUA fact sheet for Health Care Providers.[3]

[1] Novavax memo, received July 22, 2022 https://www.health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/IHD-COVID-19-Vaccine-Resource-Center-for-Health-Care-Personnel

[1] Heath PT, Galiza EP, Baxter DN, Boffito M, Browne D, Burns F, Chadwick DR, Clark R, Cosgrove C, Galloway J, Goodman AL, Heer A, Higham A, Iyengar S, Jamal A, Jeanes C, Kalra PA, Kyriakidou C, McAuley DF, Meyrick A, Minassian AM, Minton J, Moore P, Munsoor I, Nicholls H, Osanlou O, Packham J, Pretswell CH, San Francisco Ramos A, Saralaya D, Sheridan RP, Smith R, Soiza RL, Swift PA, Thomson EC, Turner J, Viljoen ME, Albert G, Cho I, Dubovsky F, Glenn G, Rivers J, Robertson A, Smith K, Toback S; 2019nCoV-302 Study Group. Safety and Efficacy of NVX-CoV2373 Covid-19 Vaccine. N Engl J Med. 2021 Sep 23;385(13):1172-1183. doi: 10.1056/NEJMoa2107659. Epub 2021 Jun 30. PMID: 34192426; PMCID: PMC8262625.

[2] https://www.fda.gov/media/159897/download, last accessed July 19, 2022