To: CAHAN San Diego Participants
Date: July 29, 2022
From: Public Health Services

Health Advisory Update #55: Coronavirus Disease 2019 (COVID-19) Vaccine Update: Novavax Vaccine

Key Messages

- Novavax is a protein-based COVID-19 vaccine similar to classic vaccines used in routine vaccination.
- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have authorized the Novavax COVID-19 primary series (two doses) for persons 18 years of age and older.
- CDC has updated its interim clinical considerations page, and a recording of Clinical Outreach and Communications Activity (COCA) held on July 28, 2022, is available here.
- COVID vaccines may be co-administered with other recommended vaccines; however, CDC suggests waiting four weeks after administration of orthopoxvirus vaccine (i.e., Jynneos) if other vaccines are due.

Situation

Following thorough evaluation and analysis of the safety and effectiveness data, federal agencies granted Novavax COVID-19 vaccine Emergency Use Authorization (EUA) and recommendations for primary series for adults (18 years of age and older).

Background

Vaccine and Administration

Novavax is an adjuvanted protein subunit vaccine. Other protein subunit vaccines include those for human papillomavirus (HPV), acellular pertussis, and hepatitis B vaccine. The Novavax primary series requires two doses given 3–8 weeks apart. An additional dose to the primary series for persons with moderate to severe immune compromise has not yet been authorized. As with other COVID-19 vaccines, the primary series should be completed using the same product. If this is not possible due to lack of availability or contraindication following the first dose, the primary series is considered completed after the subsequent dose of the alternate COVID-19 vaccine. COVID-19 vaccines may be co-administered with other vaccines. However, if an orthopoxvirus vaccine (i.e., Jynneos) has been administered, the Centers for Disease Control and Prevention (CDC) recommends delaying, if possible, other vaccinations for four weeks. If Moderna, Novavax, or Pfizer-BioNTech has recently been administered, there is no minimum interval necessary before receiving orthopoxvirus vaccination for post-exposure prophylaxis in the setting of an outbreak (Advisory Committee on Immunization Practices (ACIP) meeting, July 19, 2022, Interim Clinical Considerations for Novavax COVID-19 Vaccine).

Novavax COVID-19 vaccine was assessed in an ongoing randomized, blinded, placebo-controlled study conducted in the United States and Mexico. The effectiveness of the vaccine was assessed in clinical trial participants 18 years of age and older who did not have evidence of SARS-CoV-2 infection through six days after receiving the second vaccine dose. Among these participants, approximately 17,200 received the vaccine, and approximately 8,300 received a saline placebo. Overall, the vaccine was 90.4% effective in preventing mild, moderate, or severe COVID-19, with 17

cases of COVID-19 occurring in the vaccine group and 79 cases in the placebo group. No cases of moderate or severe COVID-19 were reported in participants who received the vaccine, compared with 9 cases of moderate COVID-19 and 4 cases of severe COVID-19 reported in placebo recipients. In the subset of participants 65 years of age and older, the vaccine was 78.6% effective. The clinical trial was conducted prior to the emergence of the Delta and Omicron variants.

Approval Process

On July 13, 2022, the Food and Drug Administration (FDA) authorized emergency use of the Novavax COVID-19 vaccine for persons 18 years of age and older. The FDA determined that the known and potential benefits of the Novavax vaccine outweighed the known and potential risks.

On July 19, 2022, following a meeting of the ACIP, the CDC updated its COVID-19 vaccine recommendations (presentations are available). A recording of a Clinical Outreach Communication Activity (COCA) held on July 28, 2022, discussing the Novavax data and recommendations (CME available) is available here.

Scheduling

MyTurn.ca.gov is currently being updated to include Novavax.

Actions Requested

1. If not already enrolled, providers can listen to the recorded webinar on how to enroll in the California COVID-19 vaccination program and participate in COVID-19 vaccination.
2. Remain up-to-date on COVID-19 vaccine clinical considerations, including contraindications and precautions.
   a. Delaying COVID-19 vaccination, including Novavax, for four weeks after orthopoxvirus vaccination (i.e., Jynneos) is suggested by the CDC.
3. Report vaccine-related adverse events and deaths, as well as vaccine administration errors, to the Vaccine Adverse Event Reporting System (VAERS) and the County Immunization Program at IZINFO.HHSA@sdcounty.ca.gov or Fax: (619) 692-5677.

Resources

- Novavax COVID-19, Adjuvanted Vaccine: Overview and Safety | CDC
- Fact Sheet for Recipients, Novavax |FDA
- Fact Sheet for Healthcare Providers, Novavax |FDA
- Safety of COVID-19 Vaccines | CDC
- COVID-19 Vaccination Clinical and Professional Resources | CDC
- Vaccine Resources and Guidance |San Diego County

Thank you for your participation.

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