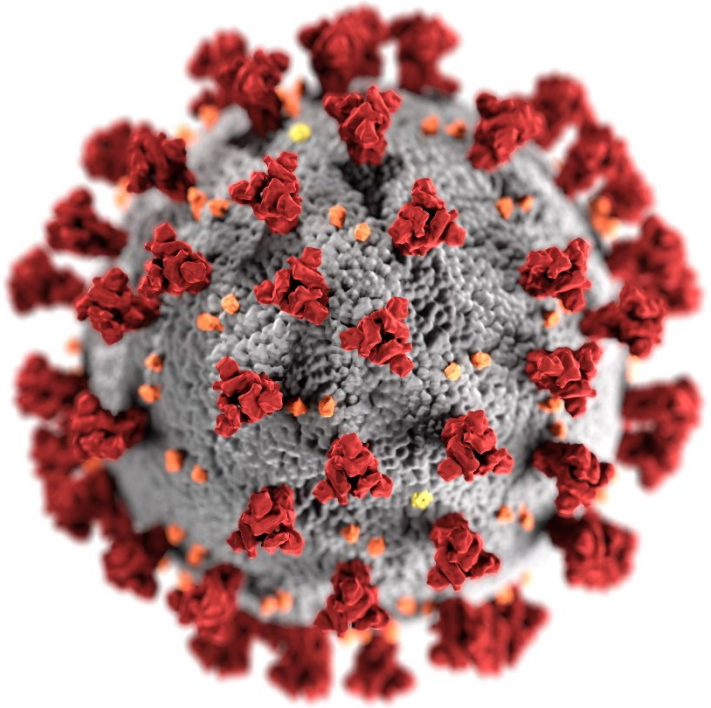
Interim Clinical Considerations for Novavax COVID-19 Vaccine

Elisha Hall, PhD

Clinical Guidelines Lead

Advisory Committee on Immunization Practices Meeting

July 19, 2022

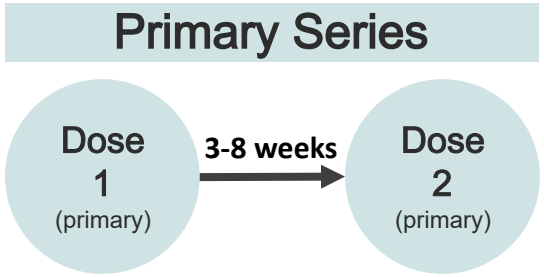


cdc.gov/coronavirus

Novavax COVID-19 Vaccination Schedule

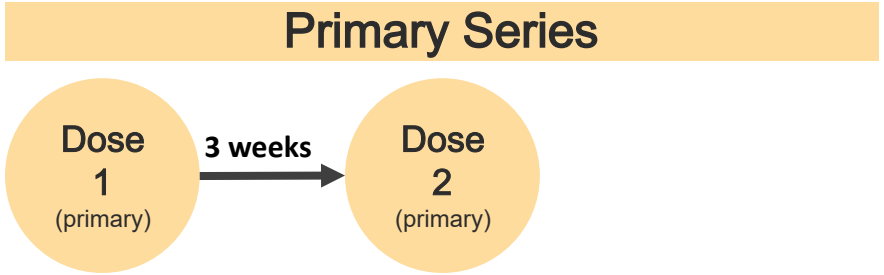
People who are **NOT** moderately or severely immunocompromised

Novavax
(18 years and older)



People who **ARE** moderately or severely immunocompromised

Novavax
(18 years and older)



Doses NOT Currently Authorized

- For people receiving a Novavax COVID-19 Vaccine primary series, the following are **NOT** currently authorized:
  - Third primary dose for people who are moderately or severely immunocompromised
  - Booster dose using ANY COVID-19 vaccine after a Novavax primary series
- CDC provides clinical guidance for what FDA authorizes; **once authorized**, these doses can be added to the COVID-19 vaccination schedule

Mixed Primary Series

- The **same** vaccine product should be used for all doses in the primary series.
- There are limited data on the safety and efficacy of a mixed primary series composed of any combination of Moderna, Novavax, and Pfizer-BioNTechCOVID-19 vaccines.
- If a mixed primary series is inadvertently administered
  - The series is complete, and doses do not need to be repeated
  - This is considered an error; report to the Vaccine Adverse Event Reporting System (VAERS)

Mixed Primary Series, Continued

- If a person starts but is unable to complete the primary series with the same COVID-19 vaccine **due to a contraindication**, any other age-appropriate COVID-19 vaccine may be administered to complete the series at a minimum interval of 4 weeks (28 days) from the last COVID-19 vaccine dose.
- This would not need to be reported to VAERS.

Coadministration

- In general, COVID-19 vaccines may be administered without regard to timing of other vaccines.
  - ☑ Same day
  - ☑ Any time before
  - ☑ Any time after
- Routine administration of all age-appropriate doses of vaccines simultaneously is recommended for people for whom no specific contraindications exist at the time of the healthcare visit.
- There are additional considerations for orthopoxvirus vaccines.

Coadministration

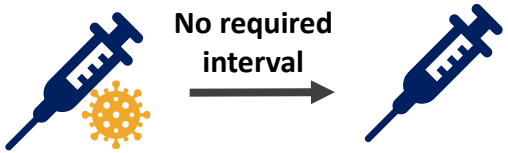
- When deciding whether to coadminister another vaccine(s) with COVID-19 vaccine, providers may consider:
  - ☑ Whether a person is behind or at risk of becoming behind on recommended vaccines
  - ☑ Likelihood of the person returning for another vaccination
  - ☑ Person's risk of becoming infected with a vaccine-preventable disease
  - ☑ Person's risk for severe disease if infected
  - ☑ Reactogenicity profile of the vaccines

Coadministration

- Additional consideration for orthopoxvirus vaccination:

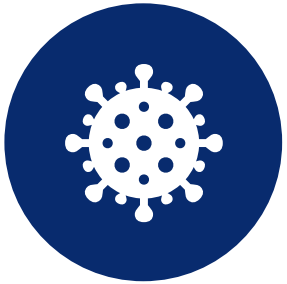
If orthopoxvirus vaccine administered first:
Might consider waiting 4 weeks before receiving a Moderna, Novavax, or Pfizer-BioNTech vaccine

If Moderna, Novavax, or Pfizer-BioNTech administered first :
No minimum interval necessary before receiving orthopoxvirus vaccination for prophylaxis in the setting of an outbreak



Novavax COVID-19 Vaccine: Preparation and Administration

Age indication:
18 years and older



Dose: 5 mcg SARS-CoV-2rS
50 mcg Matrix-M™ adjuvant

Injection volume:
0.5 mL

Preparation :
Do not dilute

Doses per vial:
10 doses

Injection route/site:
Intramuscular/deltoid

Novavax COVID-19 Vaccine: Storage

Storage:
Refrigerator 2° to 8°C
(36°to 46°F)

DO NOT
FREEZE

Beyond use time:
6 hours after first puncture

Expiration :
No expiration date is printed on the vial or carton

www.NovavaxCovidVaccine.com

Types of COVID-19 Vaccines

mRNA
- Moderna
- Pfizer-BioNTech

Adenovirus vector
- Janssen

Protein subunit
- Novavax

Contraindications & Precautions

- Contraindications
  - History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component Novavax COVID-19 Vaccine
  - History of a known diagnosed allergy to a component of Novavax COVID-19 Vaccine

Contraindications & Precautions

- People with an allergy-related contraindication to one type of COVID-19 vaccine have a contraindication or precaution to the other type of COVID-19 vaccines
  - Contraindication: People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen
  - In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types

Contraindications & Precautions

- Precautions
  - History of an immediate allergic reaction to any vaccine other than COVID-19 vaccine or to any injectable therapy
  - History of a non-severe, immediate (onset less than 4 hours) allergic reaction after a dose Novavax COVID-19 Vaccine
  - Moderate or severe acute illness, with or without fever
  - History of MIS-C or MIS-A
  - History of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

Myocarditis and Pericarditis

- Myocarditis or pericarditis after a dose of an mRNA or Novavax:
  - Precaution to a subsequent dose of any COVID-19 vaccine
  - Considerations for subsequent vaccination include:
    - Whether myocarditis or pericarditis was considered unrelated to mRNA or Novavax vaccination
    - Personal risk of severe acute COVID-19
    - Timing of immunomodulatory therapies
  - For people ages 18 years and older who choose to receive a subsequent COVID-19 vaccine, some experts advise using Janssen
    - People choosing Janssen should be informed of the risk of thrombosis with thrombocytopenia syndrome; the highest risk is in females ages 30–49 years

Myocarditis and Pericarditis

- History of myocarditis or pericarditis prior to COVID-19 vaccination
  - Not a precaution
  - May receive any currently authorized or approved vaccine after the episode of myocarditis or pericarditis has resolved

Extended Interval Between Dose 1 & 2

- No specific data on extended interval between dose 1 & 2 of Novavax
- Evidence of benefits of an extended interval in mRNA recipients
  - The small risk of myocarditis and/or pericarditis associated with mRNA COVID-19 vaccines might be reduced and peak antibody responses
  - Vaccine effectiveness may be increased
- Therefore an 8-week interval may be used between dose 1 & 2 to potentially reduce the risk of myocarditis and/or pericarditis

Considerations for Extended Interval Between Dose 1 & 2

3-week interval

- People who are moderately or severely immunocompromised
- People ages 65 years and older
- When protection needs to be achieved soonest
  - High risk for severe disease
  - Living, working, or traveling to an area with high COVID-19 community levels

8-week interval

- Reduced myocarditis risk
  - Young adult males
- Optimize vaccine effectiveness

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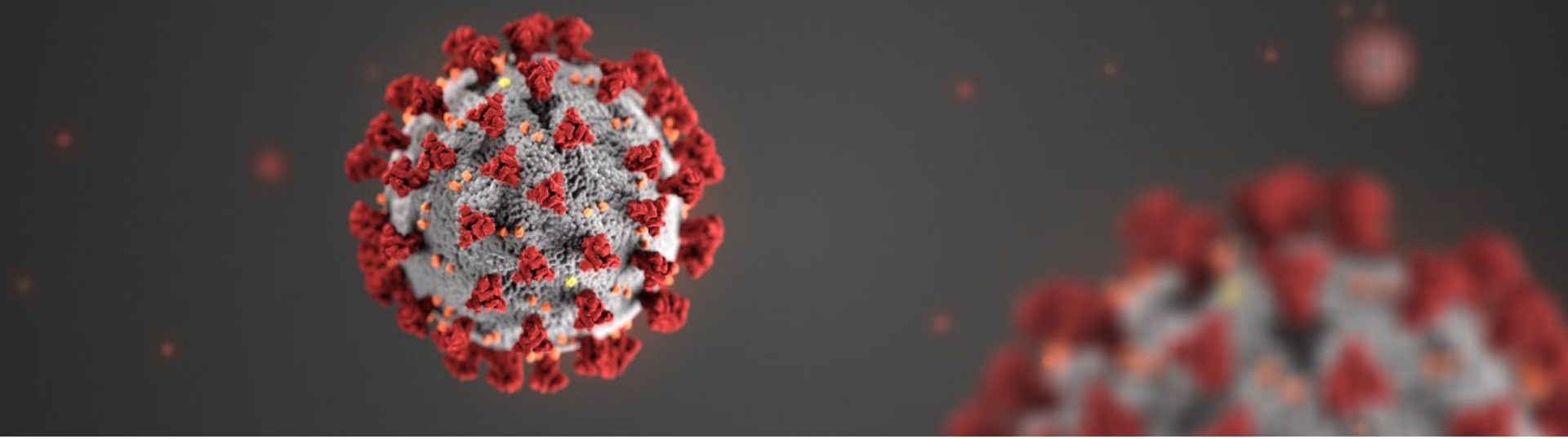
Acknowledgements

- Karen Broder
- Mary Chamberland
- Margaret Cortese
- Laura Daniel
- Megan Freedman
- Sue Goldstein
- Lauren Hughes
- Joy Hsu
- Sarah Meyer
- Sarah Morales
- Valerie Morelli
- Sara Oliver
- Evelyn Twentyman
- JoEllen Wolicki



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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