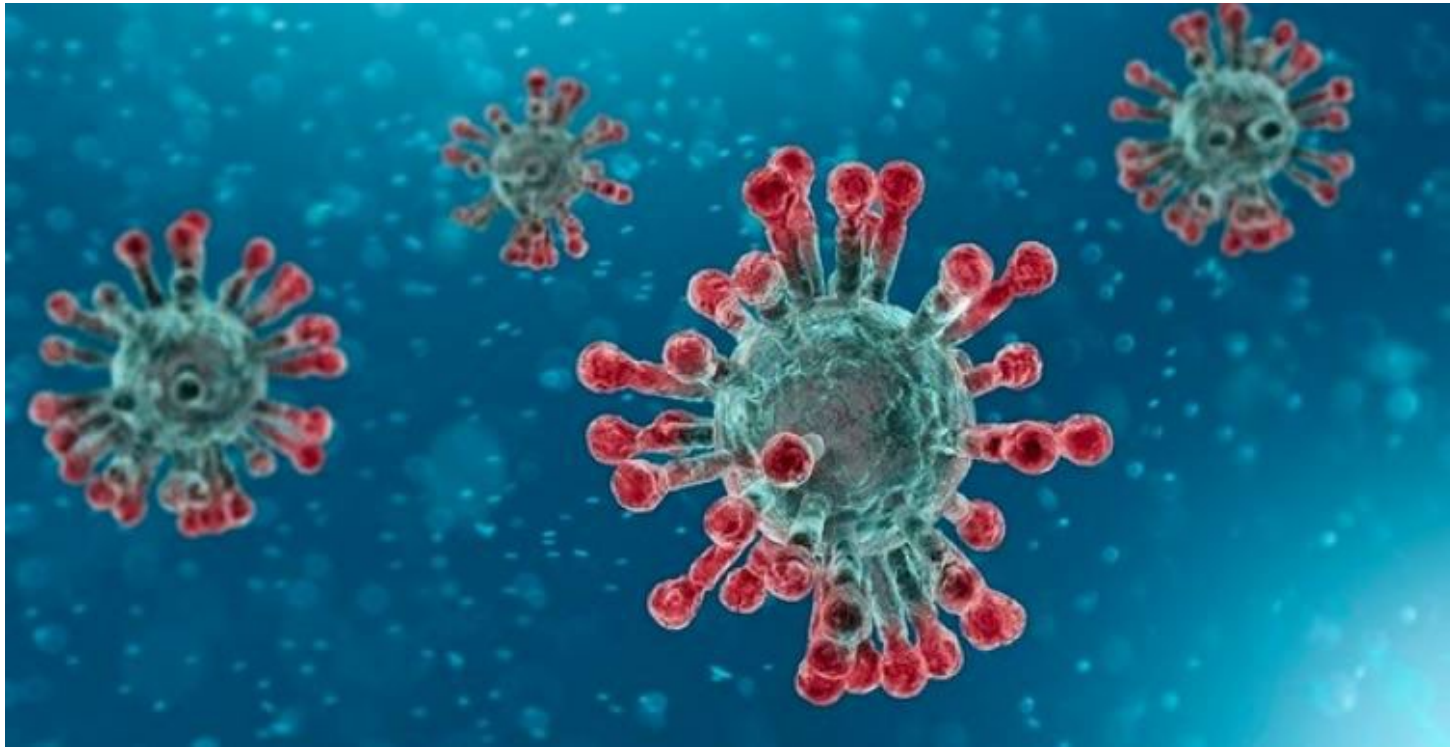
Novavax(Nuvaxovid™) COVID-19 Vaccine Orientation



Presented by
Provincial Population & Public Health
Provincial CDC Immunization Team
April 8 and 11, 2022

Objective

- To provide clinical information related to Novavax COVID-19 vaccine
  - **NOTE**: always use the online resources for up-to-date information
- Operational questions will NOT be addressed during this presentation (i.e., scheduling, vaccine distribution specifics)

Introduction

For more detailed information it is important to refer to additional program resources such as:

- AHS COVID-19 Health Professional Immunization Information
  - Insite for AHS employees or External site for non-AHS employees
- AHS Immunization Program Standards Manual (IPSM) Vaccine Biological pages are located at
  - Insite for AHS employees or External site for non-AHS employees
- COVID-19 Vaccine Product Monographs
- AHS Vaccine Storage and Handling Standard and e-learning modules*
- Alberta Health Adverse Events Following Immunization (AEFI) Policy
- Site specific reporting requirements and data collection guidelines

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Refer to COVID-19 Vaccine Orientation to review:

- What is COVID-19
- Booster/additional dose indications
- Fit to Immunize Assessment
- Infection Prevention and Control
- Commitment to Comfort Principles
- Anaphylaxis
- Vaccine Recording
- Adverse Events Following Immunization Reporting
- Vaccine Administration
- Immunocompromised and Auto-Immune Disorders
- Administration with Other Products
- Tuberculin Skin Testing and COVID-19 vaccines
- Vaccine Storage and Handling Principles
- General Pregnancy Information
- General Breastfeeding Information

COVID-19 Vaccines Available in Alberta

- **Recombinant Protein Subunit**
  - Novavax (Nuvaxovid)
- **Viral Vector-based**
  - AstraZeneca/COVISHIELD
  - Janssen (Johnson & Johnson)
- **mRNA**
  - Pfizer Ultra Frozen Vaccine
  - Moderna Frozen Vaccine

What are Recombinant Protein COVID-19 Vaccines?

- Novavax Nuvaxovid consists of a purified full-length SARS-CoV-2 recombinant spike (S) protein nanoparticle administered as a co-formulation with the adjuvant Matrix-M.
- Matrix-M is a novel saponin-based adjuvant that facilitates activation of the cells of the innate immune system, which enhances the magnitude of the S protein-specific immune response.
- Matrix-M has been used in Novavax Nuvaxovid clinical trials and in pre-licensure studies targeting other pathogens, but has not previously been used in any licensed vaccine.

National Advisory Council on Immunization, Recommendations on the use of Novavax Nuvaxovid COVID-19 vaccine, 17 February 2022

Novavax Vaccine Summary

	Novavax COVID-19 Vaccine
Dosage/Route	0.5 mL / IM (deltoid or vastus lateralis)
Packaging	Multi-dose vial – 10 doses per vial
Diluent	No
Eligibility	As per indication
Indication	• Novavax vaccine may be considered for individuals 18 years of age and older ○ A complete series with an mRNA COVID-19 vaccine is preferentially recommended for individuals in the authorized age group without contraindications to the vaccine.
Composition	• NUVAXOVID is composed of purified full-length SARS-CoV-2 recombinant spike (S) protein nanoparticle • Adjuvanted with saponin-based Matrix-M
Schedule	**Primary Series: 2 doses** (refer to biological page for more details) • 8 weeks (56 days) apart • Optimal spacing between dose 1 and dose 2 is at least 8 weeks.. • Minimum interval: 21 days Booster dose indicated for specific eligible groups when mRNA vaccine contraindicated or refused (see Additional Dose Slides for more information)

Novavax Vaccine Storage

Nuvaxovid Vaccine	Storage temperatures and time limits
Pre-puncture storage:	Store at +2°C to +8°C for 9 months, not exceeding the original expiry date
Post-puncture storage:	+2°C to +25°C for 6 hours
Post-puncture usage limit:	Punctured vials (first dose is withdrawn) can be stored at +2°C to +25°C for up to 6 hours. Discard if not used within this time.
Check puncture date/time and storage time limits prior to administration DO NOT FREEZE PROTECT FROM LIGHT	

Novavax Vaccine Reactions

Common	Rare
• Pain, redness, warmth, and swelling at injection site • Fever, chills • Fatigue • Malaise • Headache, arthralgia, myalgia • Nausea, vomiting • Pain in extremity	• Allergic reaction • Anaphylaxis

As with any immunization, unexpected or unusual side effects can occur.
Refer to product monograph for more detailed information.

Novavax Vaccine Efficacy & Effectiveness

- Vaccine Effectiveness estimates against Delta and Omicron are not yet available in regards to infection and hospitalization

Novavax COVID-19 & Myocarditis

- Myocarditis was identified in two teenage males shortly after receiving a second dose of Novavax COVID-19 vaccine in the clinical trial, however the information currently available is insufficient to determine a causal relationship with the vaccine. Post-market safety surveillance is required to determine whether this is an adverse event of interest associated with NovavaxCOVID-19 vaccine.
- It is unknown if individuals with a history of previous myocarditis and/or pericarditis are at higher risk of vaccine associated myocarditis and/or pericarditis.
  - Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA or Novavax vaccines.
  - If these individuals have questions or concerns about their prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines.

Novavax COVID-19 & Myocarditis

- Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of Novavax COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can be re-immunized when they are symptom free and at least 90 days have passed since previous immunization.
- In most circumstances, further doses of Novavax COVID-19 vaccine should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an Novavax COVID-19 vaccine.
    - However, further doses may be offered if individuals with confirmed myocarditis or pericarditis with abnormal cardiac investigation choose to receive another dose of vaccine after discussing the risks and benefits with their clinician.
    - Informed consent should discuss the unknown risk of recurrence of myocarditis and/or pericarditis following additional doses of Novavax COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of Novavax COVID-19 vaccine.

Novavax COVID-19 & Myocarditis

- Anyone receiving a Novavax COVID-19 vaccine should be informed of the potential risk of myocarditis and pericarditis and advised to seek medical attention if they develop related symptoms including shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.
- Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with Novavax COVID-19 vaccine.

Novavax COVID-19 Vaccine – Contraindications

- Less than 18 years of age
- Have a known **severe hypersensitivity** to any component of the vaccine:
  - One non-medicinal ingredient in the vaccine that has the potential to cause type 1 hypersensitivity reactions is polysorbate 80. Polysorbate 80 may be found in medical preparations (e.g., vitamin oils, tablets, anticancer agents) and cosmetics.
  - Anaphylaxis to previous dose of Novavax COVID-19 vaccine. See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations.
- Known severe hypersensitivity to a previous dose of Novavax COVID-19 vaccine

Novavax COVID-19 Vaccine – Precautions

- Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.
- Administration should be postponed in individuals suffering from acute severe febrile illness.

COVID-19 Vaccine – Other Considerations

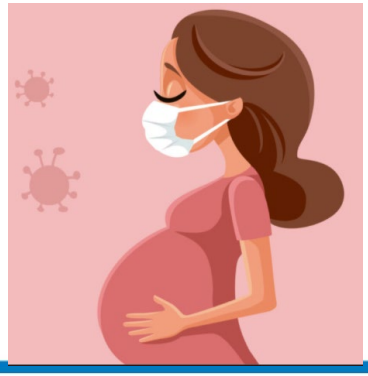
- For individuals with a history of confirmed COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization.

Infection prior to initiation or completion of a primary COVID-19 immunization series	**Individuals without certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C),**	**8 weeks after symptom onset or positive test (if asymptomatic).**
	Individuals **with** certain immunocompromising conditions (as listed above) AND no history of MIS-C,	4 to 8 weeks after symptom onset or positive test (if asymptomatic).
	History of MIS-C (regardless of immunocompromised status)	Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer.
Infection after primary series	Individuals eligible for booster doses	3 months after symptom onset or positive test (if asymptomatic) AND at least 5 months from last dose.

COVID-19 Vaccine – Other Considerations

- Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
- Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.
- However, individuals with COVID-19-like symptoms, should not go to an immunization venue in order to minimize the risk of COVID-19 transmission and their immunization should be deferred. They should isolate, seek testing and get immunized as per guidance in the 'Interval between previous COVID-19 infection and COVID-19 immunization' section.
- Individuals within facilities who are isolated due to COVID-19-like symptoms can be provided COVID-19 vaccine as long as they are well enough to be immunized.
- It is not recommended that serology testing be completed to determine if an immune response to the COVID-19 vaccine has been mounted in individuals. It is still unknown what antibody level correlates with protection against COVID-19, and serology testing in many labs may also not detect antibodies developed as a response to vaccine. Serology testing should not be used as evidence to inform whether vaccine doses have been effective.

Pregnancy



- mRNA COVID-19 vaccine is preferentially recommended for pregnant individuals in the authorized age group without contraindications to the vaccine.
- Novavax vaccine may be offered to individuals in the eligible group who are pregnant if a risk assessment with their primary health care provider or obstetrician determines that the benefits outweigh the potential risks for the woman and fetus.
- However, the individual may also be immunized without consulting their primary health care provider or obstetrician following their acknowledgment of the absence of evidence on the use of a viral vector COVID-19 vaccine in this population and the preference for an mRNA vaccine due to published safety data
    - Additional resource: Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy

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Breastfeeding

- It is unknown whether Novavax COVID-19 vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to the newborns/infants cannot be excluded.

- Novavax COVID-19 vaccine can be offered to individuals in the eligible group who are breastfeeding.

- It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions or concerns.

- However, consultation with a primary health care provider or medical specialist is not required to receive Novavax COVID-19 vaccine. Breastfeeding individuals can be immunized following routine informed consent discussion.

Immunocompromised & Auto-Immune Disorders

- Novavax vaccine may be considered for individuals 18 years of age and older with immunocompromising and auto-immune disorders,

Refer to COVID-19 Vaccine Orientation to review additional information re: immunocompromising and auto-immune disorders.

Additional Dose Recommendations for Travel Purposes

- Receiving an additional dose for travel purposes is not considered clinically necessary.
- Albertans who received a viral vector vaccine series or a mixed vaccine series may be eligible for up to two additional doses of COVID-19 vaccine to meet international travel requirements. It is up to the traveler to know the COVID-19 vaccine requirements for their destination.
- Individuals traveling to countries where a booster dose is required within a certain timeframe (e.g. 6 months) following a primary series are eligible to receive an additional dose of COVID-19 vaccine to meet those requirements. In some circumstances this may be a fourth dose or fifth dose of COVID-19 vaccine.
- For additional doses the spacing needs to be at least 28 days after the previous dose.

Interchangeability

- Novavax vaccine can be used to complete a series if mRNA vaccine is contraindicated and/or individuals who experience anaphylaxis from a previous COVID-19 vaccine, based on consultation with an allergist or other appropriate physician.

Administration with Other Products

- Novavax COVID-19 vaccines may be co-administered with, or at any time before or after other vaccines (including, live, inactivated, adjuvanted, or unadjuvanted vaccines).

- Currently there is no data on the impact of the COVID-19 vaccines on tuberculin skin testing or IGRA (QFT) test results. There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results.

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- Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment of COVID-19 infection are currently unknown and the primary health care provider or medical specialist should be consulted on a case-by-case basis.

- COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including RhIg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.

Informed Consent

- Clients must give informed consent before immunization

- Prior to immunizing the immunizer must:
  - Determine that the client is eligible (based on current phase and/or eligibility requirements)
  - Review the disease being prevented
  - Review vaccine
  - Discuss:
    - risks and benefits of getting the vaccine and not getting the vaccine
    - side effects and after care
    - how the vaccine is given
  - Provide the opportunity to ask questions
  - Affirm verbal consent

Questions?

- Clinical immunization questions should first be directed to your Site Lead. You may be asked to contact CDCIMM@ahs.ca

- Process and operational questions should be directed to your Site Lead

References

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2. Centers for Disease Control and Prevention. (2021, September). Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination

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9. Novavax. February 17, 2022. Nuvaxovid COVID-19 Vaccine (recombinant, adjuvanted) Product Monograph. https://covid-vaccine.canada.ca/info/pdf/nuvaxovid-pm-en.pdf

10. Shimabukuro, T., Kim, S., et al. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. American Journal of Medicine. (2021 April 21) https://www.nejm.org/doi/full/10.1056/NEJMoa2104983