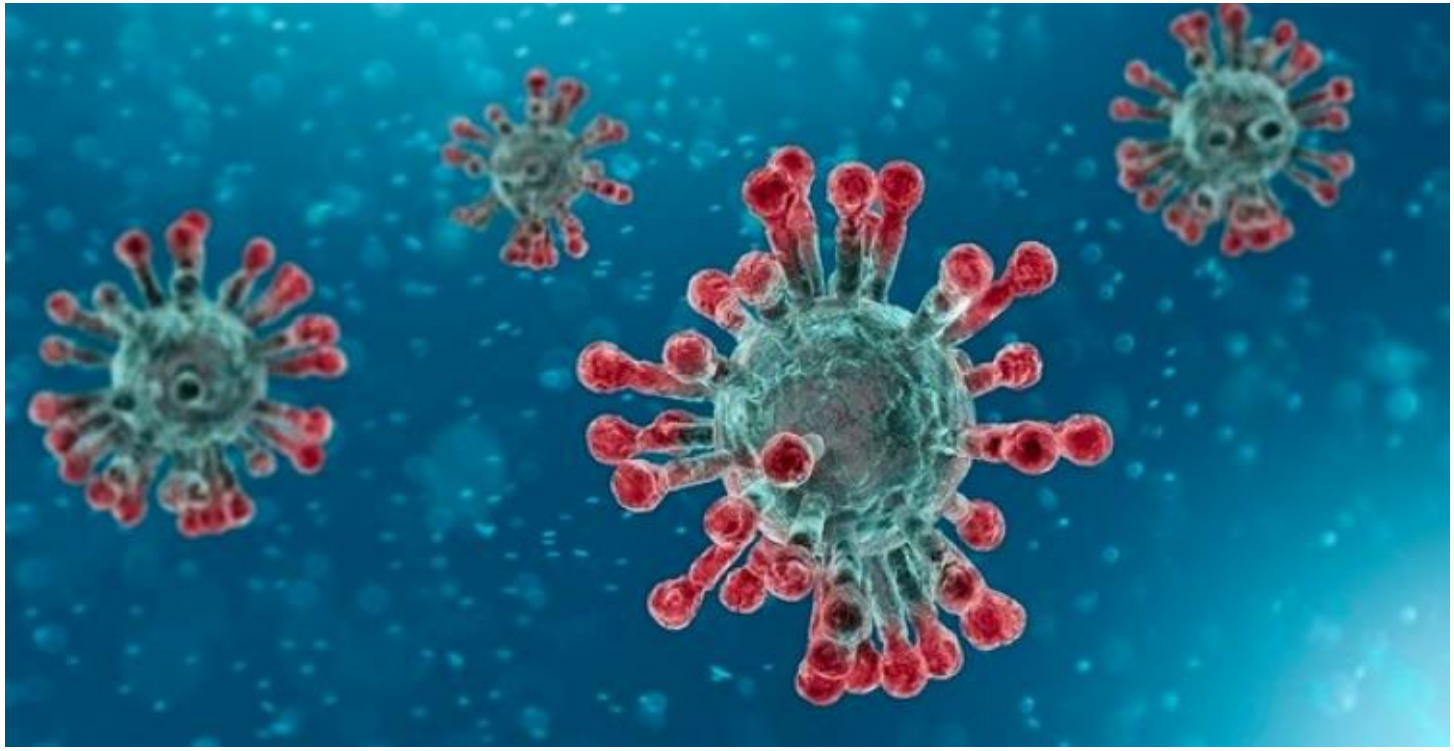
Moderna Bivalent (SpikeVax) COVID-19 Vaccine Orientation



Presented by
Provincial Population & Public Health
Provincial CDC Immunization Team
September 16, 2022

Objective

- To provide clinical information related to Moderna Bivalent 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**
  - Janssen (Johnson & Johnson)
- **mRNA**
  - Pfizer Ultra Frozen Vaccine
  - Moderna Frozen Vaccine
  - Moderna Bivalent Frozen Vaccine

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What are mRNA COVID-19 Vaccines?

- **Moderna** COVID-19 vaccines use the messenger RNA (mRNA) manufacturing platform.
- mRNA (messenger ribonucleic acid) vaccines contain the genetic instructions for making the COVID-19 spike protein. This protein is found on the surface of the virus that causes COVID-19.
- When a person is given the vaccine, their cells will read the genetic instructions like a recipe and produce the spike protein.
- After the protein piece is made, the cell breaks down the instructions and gets rid of them.
- The cell then displays the protein piece on its surface. Our immune system recognizes that the protein doesn't belong there and begins building an immune response and making antibodies.
- mRNA vaccines do not affect, interact with or alter your DNA in any way

Moderna Bivalent Vaccine Summary

	Moderna Bivalent COVID-19 Vaccine
Dosage/Route	0.5 mL / IM (deltoid or vastus lateralis)
Packaging	Multi-dose vial – 5 doses per vial
Diluent	No
Eligibility	As per indication
Indication	• Moderna Bivalent vaccine may be considered for individuals 18 years of age and older after completion of a primary series and/or previous COVID-19 booster
Composition	• mRNA (new technology) – nucleoside-modified mRNA (modRNA) platform, original and Omicron BA.1 • formulated in lipid nanoparticles (LNPs) • no adjuvants, preservatives and antibiotics
Schedule	**Booster dose** (refer to biological page for more details) • At least 5 calender months after the last COVID-19 vaccine received, whether that was the final dose in the primary series or a booster dose (regardless of vaccine type) • A shortened interval of at least 3 calendar months between the last dose or infection and the bivalent booster may be considered for individuals at higher risk for severe outcomes.

Moderna Bivalent Vaccine Storage

Moderna Bivalent mRNA Vaccine	Storage temperatures and time limits
Primary storage: Freezer	-50°C to -15°C until expiration date
Storage: Thawed, Unpunctured	+2°C to +8°C for 30 days **OR** +8°C to +25°C for 24 hours
Usage Limit: Thawed, Punctured	+2°C to +25°C for 24 hours
DO NOT REFREEZE OR STORE ON DRY ICE OR BELOW -50°C DO NOT SHAKE PROTECT FROM LIGHT	

Moderna Bivalent Vaccine Reactions

Common	Rare
• Pain, redness, warmth, and swelling at injection site • Fever, chills • Fatigue • Lymphadenopathy • Headache, arthralgia, myalgia • Nausea, vomiting • Hypoaesthesia (decreased sense of touch or sensation, numbness) or paraesthesia (tingling, itching or prickling sensation) • Dizziness	• Allergic reaction • Anaphylaxis • Facial swelling/Bell's Palsy* • Myocarditis/pericarditis* • Erythema multiforme* *There were no cases of facial swelling/Bell's palsy, myocarditis/pericarditis, and erythema multiforme following Moderna Bivalent immunization during the study period, however these were reported post-market following Moderna (Original).

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

Moderna Bivalent Vaccine Efficacy

When administered as a second booster dose, Moderna SpikeVax Bivalent (50 mcg) elicited higher neutralizing antibody responses against the original strain, Omicron BA.1 and Omicron BA.4 and BA.5 among individuals with and without prior infection when compared to a second booster dose of Moderna SpikeVax original (50 mcg). This effect was consistent across age groups studied, in individuals 18-65 years of age and individuals >65 years of age.

- Recommendations on the use of Bivalent Omicron-Containing mRNA COVID-19 Vaccines, National Advisory Committee on Immunization, September 1, 2022

Moderna Bivalent COVID-19 & Myocarditis

- There were no vaccine-related cases of myocarditis or pericarditis in the bivalent vaccine clinical trial. However, given the number of participants enrolled in the bivalent clinical trial it is unlikely that rare adverse events would be detected.
- Anyone receiving an mRNA COVID-19 vaccine should be informed of the 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 an mRNA COVID-19 vaccine.

Moderna Bivalent COVID-19 & Myocarditis

- 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 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.
- Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of an mRNA 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.

Moderna Bivalent COVID-19 & Myocarditis

- In most circumstances, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA 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 COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine.

Moderna Bivalent 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 known to cause type 1 hypersensitivity reactions is polyethylene glycol (PEG). This potential allergen may be found in bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens solutions, products such as ultrasound gel, laxatives, cough syrup, and some food and drinks.
  - Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications.
  - Anaphylaxis to previous dose of 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 Moderna Bivalent COVID-19 vaccine

Moderna Bivalent 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.

Moderna Bivalent COVID-19 Vaccine – Other Considerations

Interval between previous COVID-19 infection and COVID-19 immunization

- It is expected that individuals who have been infected with SARS-CoV-2 may optimize their benefit from future vaccine doses by timing them according to the interval since infection, using similar immunological principles to those informing intervals between vaccine doses.
- Emerging evidence indicates that a longer interval between SARS-CoV-2 infection and immunization is associated with improved immune responses to COVID-19 vaccines.
- Previously infected individuals are recommended to receive a booster dose 5 months after symptom onset or positive test (if asymptomatic) AND 5 months after the last COVID-19 vaccine dose. A shortened interval of at least 3 calendar months between the last dose or infection and the bivalent booster may be considered for individuals at higher risk for severe outcomes.

Moderna Bivalent 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.

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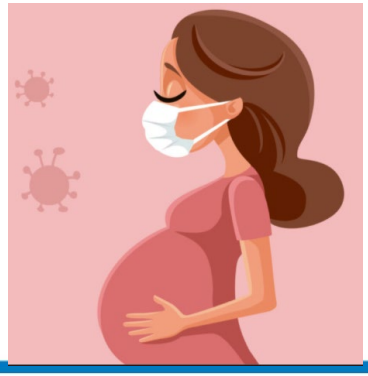
Pregnancy



- mRNA COVID-19 vaccine is preferentially recommended for pregnant individuals in the authorized age group without contraindications to the vaccine.
- The safety and efficacy of this bivalent COVID-19 mRNA vaccine in pregnant women have not yet been established in the clinical trials. However, data available so far on monovalent mRNA vaccines administered in pregnancy did not detect safety signals from post-marketing surveillance.
- Moderna Bivalent vaccine may be offered to individuals in the eligible group who are pregnant as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals 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 Moderna Bivalent 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

Breastfeeding

- It is unknown whether Moderna Bivalent 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.
- Moderna Bivalent 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 Moderna Bivalent COVID-19 vaccine. Breastfeeding individuals can be immunized following routine informed consent discussion.

Administration with Other Products

- No participants in the bivalent clinical trial were concurrently administered other vaccines. Data with regard to the safety and immunogenicity of other authorized COVID-19 vaccines (including original monovalent mRNA vaccines) when given concurrently with other vaccines, are currently limited. However, no specific safety concerns have been identified to date.
- Moderna Bivalent 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.
- 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.

Administration with Other Products

- Deferral of COVID-19 immunization is not recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment or prophylaxis of COVID-19 just because they received these pharmacological interventions. This applies to people who received these before receiving any COVID-19 vaccine dose or between doses.
  - A study among nursing home residents and staff demonstrated that recipients of a SARS-CoV-2 monoclonal antibody (bamlanivimab), mounted a robust immune response to mRNA immunization, regardless of age, risk category or vaccine type.
  - Although antibody response was numerically lower in people who received monoclonal antibodies, they were still considered to be high and the clinical significance of the reduction is unknown.
  - There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients.
  - Intervals between previous COVID-19 infection and COVID-19 immunization outlined in this document would still apply to individuals who got the monoclonal antibodies or convalescent plasma for their infection.

Administration with Other Products

- Individuals who are to receive Evusheld (tixagevimab and cilgavimab) as pre-exposure prophylaxis should wait at least 2 weeks following COVID-19 immunization to minimize interference.

Note: Anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma should not be administered concomitantly with COVID-19 vaccines (i.e. administer on different days).

- Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment or prophylaxis 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.

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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