Immunization Protocol for Moderna SPIKEVAX® XBB.1.5 COVID-19 Vaccine

Age: 6 months and older
Packaging: Royal blue vial cap, coral blue label border
Presentation: 0.10 mcg/mL multi-dose vial

Note: Moderna SPIKEVAX® may be available in multiple presentations within Nunavut. Pay careful attention to the vial cap and label border colour.

Purpose	To provide information and guidance for the COVID-19 Immunization Program in Nunavut. Refer to the Canadian Immunization Guide (CIG) and product monograph for specific information.
Objective	To decrease severe illness and death related to COVID-19 infection while also minimizing adverse societal impacts from COVID-19 and the pandemic response.
Indication	Active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 6 months of age and older.
Eligibility	Individuals 6 months of age and older without contraindications to the vaccine and as per administration schedule below
Product	Moderna SPIKEVAX® XBB.1.5 COVID-19 vaccine (mRNA SARS-CoV-2 vaccine)
Vaccine Type	Andusomeran mRNA vaccine [COVID-19 mRNA vaccine, Monovalent]
Vaccine Components	*Medicinal ingredients:* Andusomeran (mRNA) encoding the pre-fusion stabilized conformation variant (K982P and V983P) of the SARS-CoV-2 Spike glycoprotein (Omicron subvariant XBB.1.5). *Non-medicinal ingredients:* acetic acid, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), PEG2000-DMG (1,2-dimyristoyl-rac-glycerol,methoxy-polyethyleneglycol), lipid SM-102, sodium acetate trihydrate, sucrose, trometamol, trometamol hydrochloride, water for injection. The vial vial stopper does not contain natural rubber latex.
Formats Available	Moderna SPIKEVAX® XBB.1.5 multidose vial of the 0.10 mg/mL formulation contains a volume of 2.5mL supplied as a frozen dispersion that does not contain preservative. Each vials contains enough vaccine for 5 doses of 0.5mL volume or 10 doses of 0.25 mL. This product does not need to be diluted.
Manufacturer	Moderna Biopharma Canada Corp. 155 Wellington St. W, Suite 3130 Toronto, ON M5V 3L3
Storage & Handling Storage of vials prior to use	Moderna SPIKEVAX® XBB.1.5 vials should be stored between -50° to -15° until needed. Store in the original carton to protect from light. **Unpunctured vials can be stored:** • **-50°C to -15°C (frozen) until the expiration date**

	• **2°C to 8°C (refrigerated) for up to 30 days prior to first use** • **8°C to 25°C (room temperature) for a total of 24 hours**
Thawing vials	Thaw each vial before use: • Thaw in refrigerated conditions between 2°C and 8°C for 2 hours. Let each vial stand at room temperature for 15 minutes before administering. • Alternatively, thaw at room temperature between 15°C to maximum 25°C for 45 minutes. • Do not re-freeze vials after thawing.
Storing and handling thawed punctured vials	Once the vial has been entered (needle-punctured), it can be stored at **room temperature or refrigerated for 24 hours**. Do not refreeze. Thawed vials and filled syringes can be handled in room light conditions.
Disposal of unused vaccine	Any unused vaccine should be placed in a biohazard sharps container and disposed of using usual regional organizational processes.
Consent	Informed verbal consent must be obtained from the client or parent/guardian and appropriately documented in Meditech prior to vaccination. Refer to the Nunavut Immunization Manual (for routine immunizations) – Section 3.2 to review the principles of informed consent.
Administration	Review the Nunavut Immunization Manual (for routine immunizations) – Section 3.3 Administration of Biological Products for guidance on preparing and administrating immunizing agents. Moderna SPIKEVAX® XBB.1.5 must not be reconstituted, mixed with other medicinal products, or diluted. No dilution is required prior to administration. Visually inspect the vials for foreign particulate matter and/or discolouration prior to administration. Moderna SPIKEVAX® XBB.1.5 is a white to off-white dispersion. It may contain white or translucent product-related particulates. If either of these conditions exists, the vaccine should not be administered. Swirl the vial of Moderna SPIKEVAX® XBB.1.5 gently after thawing and between each withdrawal. Do not shake. **Administer Moderna SPIKEVAX® XBB.1.5 intramuscularly (IM) only.** The preferred site is the deltoid muscle of the upper arm, or in infants and young children, the anterolateral aspect of the thigh. A needle length of ≥1 inch should be used as needles <1 inch may be of insufficient length to penetrate muscle tissue in some adults. Do not inject the vaccine intravascularly, subcutaneously or intradermally.

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<tr><td></td><td></td></tr>
<tr><td>Dose</td><td>
Moderna SPIKEVAX® XBB.1.5 has been approved for use in both primary series and additional booster doses in individuals 6 months of age and older.

Moderna Spikevax® (XBB.1.5) Administration Schedule*
<table>
<tr><th>Age</th><th># of doses</th><th>Interval</th><th>Dose Volume</th></tr>
<tr><td>12 years of age and older</td><td>1 dose:
50 mcg</td><td>Minimum 6 months~ after receipt of previous COVID-19 vaccine dose
OR
Minimum 6 months since known COVID-19 infection (whichever is later)</td><td>0.5 mL</td></tr>
<tr><td>5 to 11 years of age</td><td>1 dose:
25 mcg</td><td>Minimum 6 months~ after receipt of previous COVID-19 vaccine dose
OR
Minimum 6 months since known COVID-19 infection (whichever is later)</td><td>0.25 mL</td></tr>
<tr><td rowspan="2">6 months to 4 years of age</td><td>2 doses:
25 mcg</td><td>Minimum 4 weeks between dose 1 and 2</td><td rowspan="2">0.25 mL</td></tr>
<tr><td>1 dose:
25 mcg</td><td>Minimum 6 months~ after receipt of previous COVID-19 vaccine dose
OR
Minimum 6 months since known COVID-19 infection (whichever is later)</td></tr>
</table>

The above refers to individuals who have previously received COVID-19 vaccine. If someone has not been previously vaccinated for COVID 19, they can receive one dose of Moderna SPIKEVAX® XBB.1.5 if older than 5 years (dose as per age above). If 6 months to 4 years of age and no previous COVID-19 vaccine, then they require a 2 dose primary series. If any questions, please consult Regional Communicable Disease Coordinator (RCDC) who will consult territorial team.

*Refer to section 4.3 in Part One of the Nunavut COVID-19 Immunization Manual for guidance on administration for immunocompromised individuals and the list of immunocompromising conditions.
~The recommended interval of 6 months provides a better immune response however booster doses may be offered at a shorter interval of a minimum of 3 months under special circumstances with CPHO, DCPHO, or MHO approval (e.g. upcoming travel or operational considerations for efficient vaccine deployment).
</td></tr>
<tr><td>Vaccine Interchangeability</td><td>If readily available, the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine product is not readily available, or is unknown,</td></tr>
</table>

	another mRNA COVID-19 vaccine product recommended for use in that age group can be considered interchangeable and should be offered to complete the vaccine series.
Concurrent administration with other vaccines	COVID-19 vaccines may be given concurrently with (i.e. same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines). Refer to section 6.1 in Part One of the Nunavut COVID-19 Immunization Manual for more information.
Contraindications	Moderna SPIKEVAX® XBB.1.5 is contraindicated in individuals who are hypersensitive to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container.
Common adverse events	Some adverse events are commonly reported among vaccine recipients. However, they are mild or moderate and transient, usually resolving within a few days. These include pain at the injection site, redness and swelling at the injection site, lymphadenopathy, fatigue, headache, muscle pain, chills, joint pain, and fever.
Uncommon, rare and very rare adverse events	For clarity on the terms used below: • Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. • Rare adverse events occur in 0.01% to less than 0.1% of vaccine recipients. • Very rare adverse events occur in less than 0.01% of vaccine recipients. **Severe immediate allergic reactions (e.g., anaphylaxis) following vaccination with COVID-19 vaccines** As with other vaccines, very rare cases of severe immediate allergic reactions (e.g., anaphylaxis) have been reported following vaccination with mRNA COVID-19 vaccines. Individuals tend to recover quickly with appropriate treatment and there have been no fatalities nor long-term morbidity observed with any of these severe immediate allergic reactions in Canada. Most of the reported cases have occurred within 30 minutes of vaccination. **Myocarditis or pericarditis following vaccination with an mRNA COVID-19 vaccine** Rare cases of myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the lining around the heart) have been reported following vaccination with COVID-19 mRNA vaccines. These have been reported more often after the second dose; usually within a week after vaccination; and more often in males aged 12 to 29 years of age. While long-term follow-up is ongoing, available data indicate that the majority of individuals who reported myocarditis/pericarditis after mRNA COVID-19 vaccination, though requiring hospitalization, have responded well to conservative therapy and tend to recover quickly. **Bell's palsy following vaccination with an mRNA COVID-19 vaccine** Very rare cases of Bell's palsy (typically temporary weakness or paralysis on one side of the face) have been reported following vaccination with COVID-19 mRNA vaccines. Symptoms of Bell's palsy appear suddenly and generally start to improve after a few weeks. It is not clear if the Bell's palsy is associated with having received COVID-19 vaccine. COVID-19 infection may also trigger Bell's palsy. **Multisystem inflammatory syndrome in adults (MIS-A) following vaccination with an mRNA COVID-19 vaccine** Very rare cases of MIS-C or MIS-A have been reported following vaccination with COVID-19 mRNA vaccines.

Precautions	**<u>Hypersensitivity and Allergies</u>** **Severe immediate allergic reaction (e.g., anaphylaxis) and/or confirmed allergies to a component of a COVID-19 vaccine** In individuals with a confirmed severe, immediate (≤4h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container, consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. **Mild to moderate immediate allergic reactions to previous doses of an mRNA COVID-19 vaccine or vaccine components** A mild to moderate immediate allergic reaction is limited in the scope of symptoms and involvement of organ systems or even localized to the site of administration to a previous dose of mRNA COVID-19 vaccine or any of its components. In these cases, re-vaccination may be offered with the same vaccine or the same platform (i.e., mRNA). Individuals should be observed for at least 30 minutes after re-vaccination if known confirmed allergies to a component of the COVID-19 vaccine. Please consult with your Regional Communicable Disease Coordinator (RCDC) prior to re-immunization after an allergic reaction to a previous dose of a COVID-19 vaccine. **<u>Acute illness</u>** As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until symptoms of an acute illness are resolving before vaccinating with a COVID-19 vaccine. **<u>Bleeding disorders</u>** In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy. **<u>Myocarditis and pericarditis</u>** If an individual with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA vaccine would like to receive another dose of vaccine, please reach out to the Office of the Chief Public Health Officer (OCPHO) via your RCDC for instructions on how to proceed. Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If the diagnosis is remote and they are no longer followed clinically for cardiac issues, they should receive the vaccine. <CIG> **<u>Guillain-Barrré syndrome (GBS)</u>** Individuals with past history of GBS unrelated to COVID-19 vaccination should receive an mRNA COVID-19 vaccine.

	Individuals who developed GBS after a previous dose of a COVID-19 vaccine may receive an mRNA COVID-19 vaccine, after consultation with the OCPHO (via your RCDC) if it is determined that the benefits outweigh the risk and informed consent is provided. **Bell's Palsy** Individuals should seek medical attention if they develop symptoms compatible with Bell's palsy following receipt of mRNA COVID-19 vaccines. Healthcare providers should consider Bell's palsy in their evaluation if the patient presents with clinically compatible symptoms after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis.<CIG>
Managing Anaphylaxis	Refer to the Nunavut Immunization Manual Section 3.7: Management of Anaphylaxis for guidance on identifying and managing anaphylaxis that occurs post-immunization.
Pre and post vaccination counselling	Refer to section 3.4 in PART ONE of the Nunavut COVID-19 Immunization Manual for guidance on pre vaccination assessment. Vaccine recipients should wait in the clinic for 15 minutes post vaccination and be advised to report any symptoms of adverse events. All vaccine recipients should be instructed to seek medical care if they develop signs or symptoms of a serious adverse event or an allergic reaction as described above after leaving the clinic following vaccination. Oral analgesics or antipyretics may be considered for the management of vaccine side effects (e.g., pain or fever, respectively), if they occur after vaccination. The COVID-19 Vaccine After Care Sheet should be given to clients following vaccination.
Reportable Adverse Events/ Administration Errors	Report all serious adverse events requiring medical attention, unusual/expected events, or vaccine errors to the RCDC. Refer to section 3.6 in PART ONE of the Nunavut COVID-19 Immunization Manual for procedure and forms for reporting adverse events following immunization (AEFIs) and immunization errors.
Vaccine supply and distribution	Review section on vaccine ordering in the *Policy and Procedure* section of the Nunavut Drug Formulary located here: https://www.gov.nu.ca/sites/default/files/gn_drug_formulary_binder_1_final_dec_2021.pdf Questions or concerns surrounding vaccine supply and distribution should be forwarded to the Regional Pharmacies.
Documentation	Health care professionals need to document COVID-19 vaccination in Meditech, including the time and date of administration, quantity of administered dose, anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date in Meditech. Informed consent form is documented according to current territorial requirements. Update the recipient's Personal Immunization Record (i.e. immunization card) and follow operational team guidance on processes to track and call clients back for follow up doses.
References	Canadian Immunization Guide. Accessed September 2023 from: COVID-19 vaccines: Canadian Immunization Guide - Canada.ca National Advisory Committee on Immunization. COVID-19 vaccine statements. Accessed September 2023 from: National Advisory Committee on Immunization (NACI): Statements and publications - Canada.ca

	Nunavut Immunization Manual (2013). Accessed September 2023 from: Manuals / Guidelines | Government of Nunavut Health Canada. COVID-19 Vaccines: Authorized Vaccines - Moderna Spikevax XBB.1.5 COVID-19 vaccine product monograph. Accessed September 2023 from: Microsoft Word - 275936 PM EN.docx (canada.ca)
Approved by the Chief Public Health Officer on October 3, 2023. Department of Health, Government of Nunavut	