Immunization Protocol for Pediatric (6 months of age to <5 years) Moderna SPIKEVAX® COVID-19 Vaccine

On July 14, 2022, Moderna SPIKEVAX® (blue cap indication) was approved for use in the pediatric population 6 months of age to less than 5 years of age. Prior to July 14, 2022, mRNA COVID-19 vaccines have been previously authorized by Health Canada in other pediatric populations (< 12 years of age) as follows:

- Pfizer BioNTech COMIRNATY® authorized on November 19, 2021 for individuals 5 to 11 years of age (2 dose primary series; 10 mcg per dose);
- Moderna SPIKEVAX® authorized on March 17, 2022 for individuals 6 to 11 years of age (2 dose primary series; 50 mcg per dose).

Note: SPIKEVAX® is available in two presentations within Nunavut. Dose volume will be different based on which presentation is being administered. Pay careful attention to the vial cap colour and the corresponding dose volume. **Please note that the blue cap indication of Moderna SPIKEVAX® (25 microgram [mcg] dose) mRNA COVID-19 vaccine is the first COVID-19 vaccine authorized in Canada for use in pediatric populations under the age of 5 years.**

Purpose	To provide information and guidance for the COVID-19 Immunization Program in Nunavut.
Objective	To minimize serious illness and death while minimizing societal disruption as a result of the COVID-19 pandemic and to transition away from the crisis phase towards a more sustainable approach to long term management of COVID-19.
Indication	Active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndromic coronavirus 2 (SARS-CoV-2) virus in individuals 6 months of age to 5 years of age.[1] Data on the efficacy of the Pediatric Moderna SPIKEVAX® COVID-19 vaccine against emerging variants of concern is evolving.[2]
Eligibility	Individuals 6 months of age to 5 years of age without contraindications to the vaccine. Please refer to the *Contraindications* section of this protocol for more information on the very rare instances when this vaccine should be avoided.
Product	Pediatric Moderna SPIKEVAX® COVID-19 vaccine (mRNA SARS-CoV-2 vaccine)
Vaccine Type	Elasomeran mRNA vaccine (for more information, please see references). Note: mRNA vaccines are not live vaccines and cannot cause infection in the host. mRNA vaccines also cannot alter a person's DNA.[2]
Vaccine Components	*Medicinal ingredients:* Elasomeran (mRNA), encoding the pre-fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2).[1] *Non-medicinal ingredients:* Acetic acid, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), lipid SM-102, PEG2000-DMG (1,2-dimyristoyl-rac-glycerol, methoxy-polyethyleneglycol), sodium acetate trihydrate, sucrose, trometamol, trometamol hydrochloride, water for injection.[1]
Formats Available	Moderna SPIKEVAX® is supplied in a multi-dose 10R type I glass vial with a 20 mm Fluro Tec-coated chlorobutyl elastomer stopper, 20 mm flip-off aluminum seal. The vial stopper does not contain natural rubber latex. The 0.10 mg/mL multi-dose vial is supplied with a royal blue flip-off plastic cap (pediatric indication). This is different from the 0.20 mg/mL multi-dose vial that is supplied with a red flip-off plastic cap (12 years of age and older indication). Do not use vaccine obtained from two or more vials to comprise a dose of vaccine.[1] Pediatric Moderna SPIKEVAX® does not contain preservative. Each vial must be thawed prior to administration.[1] The vaccine has special storage and handling requirements. It should be transported frozen to remain stable. Follow the storage, thawing and handling instructions in this protocol to ensure the vaccine is effective.

Manufacturer	ModernaTX, Inc. 200 Technology Square Cambridge, MA, USA, 02139
Storage of vials prior to use	Moderna SPIKEVAX® vials (both pediatric and adolescent/adult) should be stored between -50° to -15°. Store in the original carton to protect from light. Vials can be stored: • -25°C to -15°C (frozen) until the expiration date • 2°C to 8°C (refrigerated) for up to 30 days • 8°C to 25°C (room temperature) for a total of 24 hours
Thawing	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.
Thawed, unpunctured vials	Unpunctured vials may be stored between 8°C to 25°C (room temperature) for **up to 24 hours**.
Thawed, punctured vials	Once the vial has been entered (needle-punctured), it can be stored at room temperature or refrigerated, but must be discarded after 24 hours. Do not refreeze. **Thawed vials and filled syringes can be handled in room light conditions.** Any unused vaccine should be placed in a biohazard sharps container and disposed of using usual regional organizational processes.
Consent	Consent forms (updated with this protocol revision) must be reviewed and signed prior to vaccination.
Administration	**Administration** Moderna SPIKEVAX® must not be reconstituted, mixed with other medicinal products, or diluted. No dilution is required prior to administration. Moderna SPIKEVAX® is a white to off-white dispersion. It may contain white or translucent product-related particulates. Visually inspect the vials for foreign particulate matter and/or discolouration prior to administration. If either of these conditions exists, the vaccine should not be administered.[1] Administer SPIKEVAX® intramuscularly (IM) only. The preferred site is the deltoid muscle of the upper arm for children over 12 months of age and the vastus lateralis for children under 12 months of age as per the Nunavut Immunization Manual.[4] Do not inject the vaccine intravascularly, subcutaneously or intradermally. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. Withdraw each dose of vaccine from the vial using a new sterile needle and syringe (preferentially a low-dead volume syringe and/or needle) for each injection. Pierce the stopper preferably at a different site each time**. Do not puncture the vial more than 10 times.**[1] Swirl the vial gently after thawing and between each withdrawal. Do not shake. Shaking the vial can make the vaccine less or not effective.[1]
Dose Series (Primary)	**Dosing Considerations for a Primary Series** ***Individuals 6 Months of Age to 5 Years of Age:*** The primary series is a two-dose regimen of 0.25mL (25 mcg) each administered 8 weeks apart.[1] The National Advisory Committee on Immunization (NACI) has suggested intervals between previous COVID-19 infection and COVID-19 vaccination. Please inquire about an individual's COVID-19 infection history (whether detected via Rapid Antigen Test, Polymerase Chain Reaction (PCR) test, Point of Care test (POCT) at the health centre, or diagnosed based on symptoms) and the timing of infection prior to administration of a COVID-19 vaccine.

COVID-19 infection timing relative to COVID-19 vaccination	Population	Suggested interval between COVID-19 infection and vaccination
Infection prior to initiation or completion of a primary vaccination series	Individuals 6 months of age and older who are **not** considered moderately to severely immunocompromised and with no previous history of multisystem inflammatory syndrome in children (MIS-C)	Receive the vaccine **8 weeks** after symptom onset or positive test (if asymptomatic)
	Individuals 6 months of age and older who are moderately to severely immunocompromised and with no previous history of MIS-C	Receive the vaccine dose **4 to 8 weeks** after symptom onset or positive test (if asymptomatic)
	Individuals 6 months of age and older with a previous history of MIS-C (regardless of immunocompromised status)	Receive the vaccine dose when clinical recovery has been achieved or ≥ 90 days since the onset of MIS-C, whichever is longer

Vaccine product	Minimum interval between doses of primary series	Optimal interval between doses of primary series	Interval between primary series and booster dose
Pediatric Moderna SPIKEVAX® (when used in 6 months to 5 years of age)	28 days	8 weeks*	Booster dose currently not authorized in this age group.
Moderna SPIKEVAX® (when used in 6-11 years)	21 days	8 weeks*	Booster dose currently not authorized in this age group.
Moderna SPIKEVAX® (when used for 12+)	21 days	8 weeks*	4.5 months for 18+ **
Moderna SPIKEVAX® (when used for immunocompromised individuals)	21 days	4 to 8 weeks	6 months for 12 to 17 Years of Age

*There is emerging evidence that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness. Balancing this enhanced protection from a longer interval with simultaneously minimizing the time at risk of infection due to having protection from only 1 dose, an 8-week interval for mRNA vaccine is recommended.[2]

Additional Dose for Immunocompromised

It is recommended that for moderately to severely immunocompromised individuals, a primary series of 3 doses with an mRNA COVID-19 vaccine should be preferentially offered. Immunocompromised individuals, including those receiving immunosuppressive therapy, are at increased risk for prolonged infection and serious complications from SARS-CoV-2 infection.[2]

	As immunocompromised individuals may have a reduced immune response to COVID-19 vaccines, an additional dose provides another opportunity for these individuals to develop a better immune response, completing their primary series.[2] To qualify as immunocompromised, individuals must meet the moderately to severely immunocompromised criteria: an individual has one of the following conditions (Please note: other jurisdictions may have a slightly different list of medical conditions to qualify an individual for an additional dose). a. Active treatment for solid tumour or hematologic malignancies; b. Receipt of solid-organ transplant and taking immunosuppressive therapy; c. Receipt of hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy); d. Receipt of chimeric antigen receptor (CAR)-T-cell therapy; e. Moderate to severe primary immunodeficiency with associated humoral and/or cell-mediated immunodeficiency or immune dysregulation; f. HIV with AIDS-defining illness or HIV with TB diagnosis in last 12 months before starting vaccine series, or severe immune compromise with CD4<200 cells/uL or CD4%<15%, OR without HIV viral suppression; g. Active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids, alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive. A vaccine series should ideally be completed at least 2 weeks before initiation of immunosuppressive therapies where possible. Please reach out to your Regional Communicable Disease Coordinators (RCDCs) if you have any questions about additional dose(s) for immunocompromised individuals.
Booster Dose(s)	This age group is currently not eligible for booster doses.
Vaccine Interchangeability	Those receiving Pediatric Moderna SPIKEVAX® between the ages 6 months and 5 years of age need to wait for a period of at least **14 days before or after** the administration of another vaccine before administering a COVID-19 vaccine.[2] NACI also recommends that if readily available (i.e., easily available and approved for this age range) 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, 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.[2] Please reach out to your RCDC if you have any questions about vaccine interchangeability (e.g., completing a series for an individual who received a non-mRNA vaccine out of territory).
Special Populations	**Individuals previously infected with SARS-CoV-2** It is recommended that mRNA COVID-19 vaccines should be offered to individuals with precious SARS-CoV-2 infection without contraindications to the vaccine.[2] Please see *Dose Series (Primary)* section for more information on suggested intervals between previous infection and COVID-19 vaccination prior to and after completion of the primary series.[2] **Persons with an Autoimmune Condition** It is recommended that an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group with an autoimmune condition.

	Persons new to Canada It is recommended that people who are planning to live, work or study in Canada who have had only a complete or incomplete series of non-Health Canada authorized vaccines, should be offered an additional dose of an mRNA vaccine, unless they have already received 3 doses of a COVID-19 vaccine.[2]
Contraindications	Pediatric Moderna SPIKEVAX® 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.
Side Effects	Some adverse events are commonly reported (defined as 10% or more) among all vaccine recipients. However, they are mild or moderate and transient, resolving within a few days. The most frequently reported solicited local and systemic adverse reactions were irritability/crying, pain, sleepiness, and loss of appetite. Fatigue was the most frequently reported systemic adverse reaction in those 37 months to 5 years of age. Some additional side effects include pain at the injection site, redness and swelling at the injection site, headache, muscle pain, chills, joint pain, and fever.[2]
Precautions and uncommon, rare and very rare adverse events	Overall, the safety profile of Pediatric Moderna SPIKEVAX® (25 mcg) vaccine was consistent with the known safety and reactogenicity profile of the 50 mcg and 100 mcg SPIKEVAX formulations authorized for use in those 6 years of age and older. Events reported in the vaccine group were consistent with events commonly reported for other pediatric vaccines authorized for use in children 6 months to 5 years of age.[1] Evidence on vaccine safety that informs precautions and additional notes for mRNA vaccines is available from COVID-19 clinical trials and post-licensure COVID-19 vaccine pharmacovigilance, which is ongoing. Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients and rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively.[2] **Hypersensitivity and Allergies** **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 (e.g., PEG), consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. Please refer to *Anaphylaxis* section for more information. In individuals with mild to moderate immediate allergic reactions (defined as 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, 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.[2] **Acute illness** 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 all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine. **Hematologic** 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.

	Myocarditis and Pericarditis 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. Cases following mRNA vaccination are consistently reported to have occurred more often after the second dose, usually within a week after vaccination, more often in males 12 to 29 years of age. Surveillance data suggests a higher rate of myocarditis/pericarditis cases reported after vaccination with Moderna SPIKEVAX® compared to Pfizer-BioNTech COMIRNATY® vaccine especially among 12 to 29 year old males following a second dose of vaccine. While long-term follow-up is ongoing, available data indicate that the majority of individuals who reported myocarditis/pericarditis after mRNA COVID-19 vaccination, while hospitalized, have responded well to conservative therapy and tend to recover quickly.[2] Healthcare providers should consider myocarditis/pericarditis in their evaluation if the patient presents with clinically compatible symptoms (e.g., chest pain, shortness of breath, palpitations) after an mRNA COVID-19 vaccine regardless of timing from vaccination to symptom onset. Please reach out to the community physician if you have any questions regarding investigation for myocarditis and pericarditis. Consultation with a cardiologist, infectious disease specialist, internal medicine specialist and/or rheumatologist may be advisable to assist in this evaluation, particularly to investigate the many potential causes of myocarditis and pericarditis. Investigations may include diagnostic testing for acute COVID-19 infection, prior SARS-CoV-2 infection and consideration of other potential infectious and non-infectious etiologies including auto-immune conditions.[2] 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 (CPHO) for instructions on how to proceed. **Multisystem Inflammatory Syndrome in Children (MIS-C)** For children with a previous history of MIS-C, vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.
Anaphylaxis	Anaphylaxis is a very rare, severe, life-threatening allergic reaction typically with a rapid onset that involves multiple organ systems and can progress rapidly. Symptoms and signs of anaphylaxis may include but are not limited to generalized urticaria; wheezing; swelling of the mouth, tongue, and throat; difficulty breathing; vomiting; diarrhea; hypotension; decreased level of consciousness; and shock.[2] Very rare cases of severe immediate allergic reactions (e.g., anaphylaxis) following vaccination with mRNA COVID-19 vaccines has been reported at an incidence between 2 to 10 cases per million doses of vaccine administered. 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. Studies have shown that individuals with a severe immediate allergic reaction after a previous dose of mRNA vaccine can be re-vaccinated with the same vaccine or another mRNA vaccine following an appropriate medical assessment. Emerging evidence also suggests that most of the reported severe immediate allergic reactions following mRNA COVID-19 vaccines are likely not Immunoglobulin E (IgE)-mediated and therefore, have a low risk of recurrence following future vaccine doses.[2]
Administration of other drugs or biological products	There have been no drug interaction studies performed to date. It is recommended that COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.

	Please reach out to the Office of the CPHO if there is a need to assess timing of COVID-19 vaccines after administration of anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma.[2] Please note that those 6 months of age to 5 years of age receiving Pediatric Moderna SPIKEVAX® (or other COVID-19 vaccine) must wait for a period of at least **14 days before or after** the administration of another vaccine[2]
Tuberculin Skin Testing (TST) or interferon gamma release assay (IGRA)	There is a theoretical risk that mRNA vaccines may temporarily affect cell-mediated immunity, resulting in a false-negative tuberculin skin test (TST) or Interferon Gamma Release Assay (IGRA) results. However, the vaccines are not thought to cause false-positive TSTs/IGRAs.[2] In general, Nunavummiut at high risk for active or latent TB infection should continue to be investigated and managed according to the usual practices as outlined in the Nunavut TB manual. However, for low-risk people only, TSTs should be delayed until at least 4 weeks after COVID vaccine.[3] In cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed since these are theoretical considerations. However, re-testing (at least 4 weeks post immunization) of individuals with negative results for whom there is high suspicion of tuberculosis infection may be prudent in order to avoid missing cases due to potentially false-negative results. Please refer to Appendix B titled, *Guidance on TSTs and COVID-19 Vaccines* for additional guidance on TSTs and COVID-19 vaccines.
Post-vaccination counselling	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.[2] 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 following vaccination. The COVID-19 Vaccine After Care Sheet (translated in all 4 languages) 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. Review section 3.5 *Management and Reporting of Adverse Events* in the Nunavut Immunization Manual: https://www.gov.nu.ca/sites/default/files/3.0_practice_guidelines_complete_may2020.pdf The AEFI form is available here: https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/aefi-form-october-2021-eng.pdf Once the AEFI form has been submitted to the RCDC, the Public Health Officer will provide public health recommendations according to current best practice (e.g., if another dose is permitted). Please also see guidance document on the *Management of COVID-19 Vaccine Errors.* Complete an AEFI form and submit it to the RCDC only if the inadvertent vaccine administration error results in an AEFI.
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. Please refer to Appendix A *Transporting and Logging Vials of Moderna SPIKEVAX® and Pfizer BioNTech COMIRNATY® COVID-19 Vaccines.*
Documentation	To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health care professionals should record 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.[1] The consent form is completed

	and stored according to health centre processes. Update the recipient's Personal Immunization Record (if feasible) and follow operational team guidance on processes to track and call clients back for follow up doses.
Materials and resources	Nunavut Immunization Manual Guidance Document on the Management of COVID-19 Vaccine Errors Summary Table(s) of mRNA Vaccine Recommendations Pediatric Moderna SPIKEVAX® COVID-19 Vaccine Consent Form Moderna SPIKEVAX® COVID-19 Vaccine Information Sheet COVID-19 Vaccine After Care Sheet Adverse Events Following Immunization (AEFI) Reporting Form: https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/aefi-form-october-2021-eng.pdf Vaccine protocols and materials (available on the Department of Health website): https://gov.nu.ca/health/information/manuals-guidelines
Appendices	Appendix A Transporting and Logging Vials of Moderna SPIKEVAX® and Pfizer BioNTech COMIRNATY® COVID-19 Vaccines Appendix B Guidance on TSTs and COVID-19 Vaccines
References	1. Moderna Product Monograph (2022). *SPIKEVAX®* (Elasomeran mRNA vaccine). Moderna: 2022. Available: covid-19-vaccine-moderna-pm-en.pdf (canada.ca) 2. COVID-19 Vaccine: Canadian Immunization Guide (2022). Available: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html 3. Tuberculosis Services in Nunavut During the COVID-19 Pandemic (V2 2021.12.13). 4. Nunavut Immunization Manual. Available: https://www.gov.nu.ca/sites/default/files/3.0_practice_guidelines_complete_may2020.pdf
Approved by the Chief Public Health Officer on July 20, 2022 Department of Health, Government of Nunavut	