Immunization Protocol for Moderna SPIKEVAX® COVID-19 Vaccine

On September 16, 2021, Moderna SPIKEVAX® transitioned to an authorization under the *Food and Drug Regulations*. This vaccine formulation was then approved for individuals who are 6 years of age and older on March 17, 2022.

Note: Please pay close attention to the dosing considerations outlined in this protocol prior to any COVID-19 vaccine administration as there are varying recommendations for both the primary series and booster doses of the Moderna SPIKEVAX® COVID-19 vaccine. The dosing considerations for a primary series in ages 6-11 is also different from 12 years of age and older. Tools and resources have been developed to assist frontline healthcare providers in COVID-19 vaccine administration. Please ensure that these tools are not used as a stand-in for a thorough review of this protocol.

While all COVID-19 vaccines currently offered in Nunavut are mRNA vaccines, there are key differences between the Moderna SPIKEVAX® and Pfizer BioNTech COMIRNATY® vaccines with respect to requirements for dilution/reconstitution, dosing, storage/transport, and temperature considerations. Please review each COVID-19 vaccine protocol carefully to ensure safe use of each vaccine.

Purpose	To provide information and guidance for the COVID-19 Immunization Program in Nunavut.
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 syndromic coronavirus 2 (SARS-CoV-2) virus in individuals 6 years of age and older.[1] Data on the efficacy of the Moderna SPIKEVAX® COVID-19 vaccine against emerging variants of concern is evolving.[2]
Eligibility	Individuals 6 years of age and older 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	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. These vials have a red cap. Do not use vaccine obtained from two or more vials to comprise a dose of vaccine.[1] Moderna SPIKEVAX® multidose vial contains a volume of 5mL supplied as a frozen dispersion that does not contain preservative. Ten (10) doses of 0.5mL volume each or a maximum of twenty (20) doses of 0.25mL volume each can be withdrawn from each multidose vial. It is possible that one vial may yield a mix and match of 0.5mL and 0.25mL doses as the dosing

	considerations vary for different populations. 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 should be stored between -25° 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 and 30 minutes**. 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 **1 hour**. • 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.[1] 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 20 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 to 11 Years of Age: The primary series is a two-dose regimen of 0.25mL (50mcg) each administered 8 weeks apart.[1]

Individuals equal to or greater than 12 Years of Age: The primary series is a two-dose regimen of 0.5mL (100mcg) each administered 8 weeks apart.[1]

Immunocompromised individuals equal to or greater than 6 Years of Age: The primary series is a three-dose regimen of 0.5mL (100mcg) each given 4 to 8 weeks apart.[1] Please refer to the *Additional Dose for Immunocompromised* section of this protocol for more information.

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 years 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 years 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 years 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

Please refer to the *Booster Dose(s)* section of this protocol for suggested intervals between COVID-19 infection and vaccination with booster doses.

Vaccine product	Minimum interval between doses of primary series	Optimal interval between doses of primary series	Interval between primary series and booster dose
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]

**Individuals 18 years of age and older who have completed their primary series and booster dose are now eligible for a second booster dose. The same interval applies between first and second booster doses for this population (4.5 months). Please refer to the *Booster Dose(s)* section for more information.

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)

Waning immunity over time and efficacy of vaccines against variants of interest and variants of concern are two factors that have been examined in the context of booster doses.

Dosing Considerations for a Booster Dose

Moderna SPIKEVAX® has been approved for use in Nunavut as a booster dose for individuals **12 Years of Age and older**. Individuals between the ages of 12-17 are eligible for a booster dose 6 months after completion of the primary series and individuals 18 years of age and older are eligible for a booster dose 4.5 months after completion of the primary series. Individuals in Nunavut 18 Years of Age and older are also now eligible for a second booster dose 4.5 months since their last booster dose.

Individuals 12-49 Years of Age (who are not immunocompromised): The booster dose is 0.25mL (50mcg).

Individuals 50-69 NOT* living in a long-term care home or other congregate setting *(who are not immunocompromised): The booster dose is 0.25mL (50mcg).

Individuals 50 Years of Age and older living in a long-term care home or other congregate setting: The booster dose is 0.5mL (100mcg).

Individuals 70 Years of Age and older: The booster dose is 0.5mL (100mcg).

Immunocompromised individuals equal to or greater than 12 Years of Age: The booster dose is a full dose at 0.5mL (100mcg).

COVID-19 infection timing relative to COVID-19 vaccination	Population	Suggested interval between COVID-19 infection and vaccination
Infection after primary series but before or between booster dose(s) (if eligible for booster dose)	Individuals 12 years of age and older currently eligible for a booster dose	**3 months** after symptom onset or positive test (if asymptomatic) and provided it is at least 4.5-6 months from the last dose

Please reach out to your RCDC if you have any questions about booster doses.

Vaccine Interchangeability

NACI suggests that:

- For adolescents and adults (12+), COVID-19 vaccines may be given at the same time as, or any time before or after, live or non-live vaccines.
- **For children 6-11 years of age, COVID-19 vaccines should not routinely be given simultaneously (i.e. same day) with other vaccines (live or non-live).**

	Those receiving Moderna SPIKEVAX® between the ages of 6 and 11 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 at the time of vaccination without delay or vaccine wastage), 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	**Pregnancy and Breastfeeding** It is recommended that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are pregnant or breastfeeding. Adolescents and adults who are pregnant or breastfeeding are included among those recommended to receive a booster dose.[2] **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 and Booster Doses)* 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	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. These include pain at the injection site, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever.[2]
Precautions and uncommon, rare and very rare adverse events	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. **Bell's Palsy** 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 in Canada and internationally. Bell's palsy is an episode of facial muscle weakness or paralysis. The condition is typically temporary. Symptoms appear suddenly and generally start to improve after a few weeks. Health care providers should consider Bell's Palsy in their evaluation if the patient presents with clinically compatible symptoms (e.g., uncoordinated movement of the muscles that control facial expressions, loss of feeling in the face, drooling, etc.) after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis. **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 and 11 years of age receiving 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 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: https://covid-vaccine.canada.ca/info/pdf/covid-19-vaccine-moderna-pm-en.pdf 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).
Approved by the Chief Public Health Officer on June 07, 2022 Department of Health, Government of Nunavut	

Department of Health
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Ministère de la Santé

Appendix A - Transporting and Logging Vials of Moderna SPIKEVAX® and Pfizer BioNTech COMIRNATY® COVID-19 Vaccines

Last updated: Jun 06, 2022

Contents

Background:

The product monograph for both the Moderna SPIKEVAX® and Pfizer-BioNTech COMIRNATY® COVID-19 vaccine(s) recommend that vials be transported in the frozen state due to the unstable nature of the vaccine. In the liquid or thawed state, the vaccine is susceptible to interfacial stresses from being shaken or jostled. If this happens, the vaccine would then be less effective, or perhaps even ineffective, in inducing production of antibodies in the vaccinated person. While vials are normally transported in the frozen state, there are limited circumstances in which refrigerator temperature vaccine would be transported. In addition:

- Vials should never be transported at room temperature between sites.
- Punctured vials should never be transported between sites.
- COVID-19 vaccine will be stored in the Regional Pharmacy Hubs in Iqaluit, Rankin Inlet and Cambridge Bay. These communities will act as regional distribution sites.
- It is important to ensure that the vial(s) are kept at the appropriate temperature. If there is a breach in the cold chain, this failure should be documented using the form: *Incident Report – Vaccine Cold Chain Failure*.

- For additional information on storage temperatures for the Moderna SPIKEVAX® and Pfizer-BioNTech COMIRNATY® COVID-19 vaccines, please see the respective *COVID-19 Immunization Protocols:* Manuals / Guidelines | Government of Nunavut

When vials of COVID-19 vaccine are transported, it is important to:

- Track the numbers of vials through vaccine logs signed by staff from vaccination program.
- Keep vials in original packaging for transport whenever possible.
- Pack the vials well in the transport container with packing materials such as packing peanuts, bubble wrap, blue pads or other materials to minimize any movement.
- Not shake or drop the vaccine.
- Use the TempTale temperature monitoring device (TMD) to monitor cold chain where feasible.

The purpose of this document is to provide information on transport of COVID-19 vaccine vials within the territory. For additional information on vaccine storage and handling refer to the Government of Nunavut's *Immunization Manual*.

Description of Vaccine Logs:

COVID-19 Vaccine Vial Shipping Log (Appendix 1):

This log is designed to track the number of vials which are transported to Regional Distribution Hubs and from these Regional Hubs to the communities – it tracks where a certain number of vials are going and has space for signatures of the shipper and receiver. This log is self-explanatory and further guidance is not provided in Appendix 1.

COVID-19 Vaccine Vial Inventory for Community Freezers or Vaccine Fridges Log (Appendix 2):

This log is designed to track how many vials are added to and removed from each of the health centre freezers or vaccine fridges, by date and by authorized person. This log is self-explanatory and further guidance is not provided in Appendix 2.

Transport into Territory:

Vaccine will be shipped as per the Federal, Provincial, and Territorial processes to either Cambridge Bay, Rankin Inlet or Iqaluit. Pharmacy staff are responsible for ordering and receiving inventory in compliance with National Operations Centre (NOC) guidelines, including documenting cold chain, and for confirming the orders through the NOC contact.

Transport from Regional Hubs to Community:

Except for Pediatric Pfizer Vaccine, all COVID-19 vaccine vials should be maintained at a temperature of **-25°C to -15°C** during transport from Regional Hubs to the health centre. Pediatric Pfizer is only stable at ultra low temperature or refrigerator temperatures; it is the only COVID-19 vaccine which will be removed from ULT freezer and packaged for transport, leaving the vaccine in a thawing state during transport. Transport at the appropriate temperature is achieved by transporting the vials in a portable Crēdo Cubes or coolers. The Cube(s) is returned to the Regional Pharmacy after transport. Pharmacy technicians are responsible to pack the vaccine in the Crēdo Cube or cooler for transport to communities.

Transporting the vials:

- Use the COVID-19 Vaccine Vial Inventory Log to document the number of vials taken out of the freezer in the Regional Hub.
- Vials are ideally transported in their original packaging and if this is not possible then remove from packaging, wrap in bubble wrap, and protect from light by placing in an opaque or amber bag.
- Vials are packed securely into a transport container with packing material around them so that they do not move at all during transit. Cold packs can also be placed around packing material in case of transportation delays or equipment failure (Appendix 3 for Transport Container Protocol).
- The TempTale TMD is packed with the vials in the container.
- Once the transport container is opened to access the vials - retrieve the TempTale TMD. This data will inform the temperature of the vials during transport. ***DO NOT STOP THE TMD***
- Appendix 4 provides instructions on downloading information from the TMD and sharing it with pharmacy technicians at regional pharmacy hubs.
- When the vials are moved into the freezer or vaccine fridge at the health centre, the TempTale TMD should be placed in the same freezer or fridge to continue recording temperature data.
- Check the number of vials received against the Vaccine Shipping Log.
- If the vaccine arrives frozen, with no breach of cold chain, and is placed directly in the freezer then it can be stored as follows:
    - Moderna SPIKEVAX®: until the expiry dates indicated on the label, unless otherwise advised by pharmacy. If there has been a breach of cold chain, it must be stored in the vaccine fridge (+2°C to +8°C) and used within 30 days or otherwise as directed by pharmacy. Thawed vials of vaccine cannot be moved to the next community. Determine if vaccine is thawing by checking TempTale TMD at arrival.
    - Pfizer BioNTech COMIRNATY®:
        i. For 14 days at **-25°C to -15°C**. Note that the time used for transport counts against the 14-day limit for frozen storage for Pfizer. If there has been a breach of cold chain, it must be stored in the vaccine fridge and used as directed by pharmacy. Thawed vials of vaccine cannot be moved to the next community. Determine if vaccine is thawing by checking TempTale TMD at arrival.
        ii. For 31 days at fridge temperature **+2°C to +8°C**. Note that this is in addition to the 14 days at **-25°C to -15°C.**

- **Pediatric** Pfizer BioNTech COMIRNATY ® will arrive between **+2°C to +8°C** (fridge temperature), if no breach of cold chain, and is placed directly in the fridge then it can be stored as follows:
    iii. For 10 weeks at fridge temperature **+2°C to +8°C**.
    iv. **DO NOT** store vials at -25°C to -15°C (freezer).

- **DO NOT** shake or drop the vaccine
- Use the COVID-19 Vaccine Vial Inventory Log to document the number of vials placed into the freezer or vaccine fridge.

Transporting Vials of COVID-19 Vaccine from Health Centre to Another Site in the Community for Administration.

This section provides the procedure for transporting both frozen and thawed vials of vaccine from the health centre to a site for administration. Please see the COVID-19 Immunization Protocol(s) for information on thawing frozen vials for Moderna SPIKEVAX®, Peds Pfizer COMIRNATY®, and Pfizer COMIRNATY®.

A frozen vial which is transported to a vaccination site and remains frozen in the cooler at the site can be returned to the health centre fridge not the freezer as it is assumed to be thawing. Thawed vials which are transported to a vaccination site cannot be returned to the health centre as this would mean moving a thawed vial twice. Plans should be made for vaccinating others in the event doses are available off-site to reduce wastage; this could include radio announcements.

Vials should not be transported between sites at *room temperature* and punctured vials should never be transported between sites.

Planning for transport:

When vials are moved from the freezer or vaccine fridge at the health centre to another location for vaccine administration, it is important to plan for transport.

- Notify the person in charge of ordering the vaccine that an identified number of vials will be required for administration of vaccine off-site so the vial(s) will be available in the freezer or vaccine fridge on that day.
- Take the minimum amount of vaccine required to the clinic to prevent any wastage. Document on the COVID-19 Vaccine Inventory Log the number of vials removed from the freezer of fridge.
- To transport *frozen* vaccine the cooling packs for the refrigeration pack are placed in a separate freezer – not the vaccine freezer - the day before transport.
- To transport *thawed* vaccine the cooling packs for the refrigeration pack are placed into the refrigerator the day before transport.

- Place the packing materials such as packing peanuts, bubble wrap, blue pads or other packing materials in the refrigerator (+2°C to +8° C) for conditioning the day before.
- Before the vial(s) is to be transported, the cooler is assembled to allow interior to cool (see Appendix E for details on assembling pack).
- *Frozen vial(s)* must stay at **-25°C to -15°C** throughout transportation.
- *Thawed vials* must stay at **+2°C to +8°C** throughout transportation.
- Room temperature is **+8°C to +25°C** – vaccine vials should not be transported at room temperature.

Transporting the vial(s):

- Vial(s) will be signed out on the COVID-19 Vaccine Vial Inventory Log.
- If transporting *frozen* vaccine, the frozen vial(s) should not be taken out of the freezer and put into the refrigeration pack until the health care team is ready to leave the health centre.
- If transporting *thawed* vaccine, the thawed vial should not be taken out of the refrigerator and put into the refrigeration pack until the health care team is ready to leave the health centre. Care must be taken to ensure the vial does not refreeze during transport - it is important to make sure the vial is not touching the cold pack.
- The manufacturer recommends transporting vials in their box or carton where possible. This may not be realistic as there are too many vials in a box or carton. In this case, each vial should be separately packed in bubble wrap and an opaque or amber bag before being placed into refrigeration pack.
- Be sure to use plenty of padding (packing peanuts, bubble wrap, blue pads or other materials), around vial(s) to reduce movement during transport.
- *Thawed* vials should be kept upright during transport (and storage).
- **The refrigeration cooler with the vial(s) should be secured in the vehicle. The cooler is not to be put on the floor or in the trunk of a car. Avoid sudden movements or braking of the vehicle as much as possible.**
- **Every attempt should be made to carry the cooler without jostling during transport. Be careful not to drop the container with the vial(s).**

Appendix 1 COVID19 Vaccine Vial Shipping Log

DATE/ TIME	QUANTITY OF DOSES	QUANTITY OF VIALS	ORIGINATING LOCATION	SHIPPER	SIGNATURE	DESTINATION	RECEIVER	SIGNATURE

Appendix 2: COVID19 Vaccine Vial Inventory for Freezers Log

DATE/ TIME	LOCATION	NUMBER OF VIALS ADDED	BALANCE OF VIALS	NAME (PRINT)	SIGNATURE
DATE/ TIME	**LOCATION**	**NUMBER OF VIALS REMOVED**	**BALANCE OF VIALS**	**NAME (PRINT)**	**SIGNATURE**

Appendix 3 Transport Container Protocol

1. Open the transport container and retrieve the TempTale Temperature Monitoring Device (TMD), and transfer vaccine to health centre fridge or freezer.
2. Download the data as per instructions for downloading information from the TMD. ***DO NOT STOP THE TMD* (Appendix D).**
3. When emailing the TMD data, please re-name the PDF document with community you are sending the data from and the date.
4. Once data has been downloaded, place the TMD with the vaccine to continue recording temperature data.
5. Send data daily during Mass Vaccination Clinics (MVC) and twice weekly if no MVC.
6. Transport containers and dataloggers are to be returned to the originating regional pharmacy once no longer needed to be reused.
7. When needed, take the minimum amount of vaccine required out of the freezer to prevent any wastage.
8. **DO NOT** shake or drop the vaccine!

Michael Gauvin (Iqaluit) mgauvin@gov.nu.ca (867)975-8600 Ext. 6352, pager (867)979-7646 pager #126.

Amanda Arsenault (Rankin Inlet) aarsenault@gov.nu.ca (867) 645-8334, On-call phone # (867)645-7978.

Lisa Wedge (Cambridge Bay) lwedge@gov.nu.ca (867) 983 4526

Appendix 4 - **Instructions for use of TempTale** Temperature Monitoring Device

If any issues or concerns, please contact technicians at the regional pharmacy hubs:

Michael Gauvin (Iqaluit) mgauvin@gov.nu.ca 1-867-8600 ext 2306, pager 1-867-979-7646 pager # 126

Amanda Arsenault (Rankin Inlet) aarsenault@gov.nu.ca 1-867-645-8334 On call phone 645-7978

Lisa Wedge (Cambridge Bay) lwedge@gov.nu.ca (867) 983 4526

PLEASE EXECUTE THE FOLLOWING STEPS:

1. Upon receipt, remove TempTale® from shipping container. "DO NOT STOP THE DEVICE"

2. Plug reader into a computer's USB port and send the files to the Regional Pharmacy Technician. (**Michael Gauvin** mgauvin@gov.nu.ca for the **Qikiqtaaluk** region and **Amanda Arsenault** aarsenault@gov.nu.ca for the **Kivalliq** and **Kitikmeot** regions.). These should be sent daily during mass vaccination clinics, any major transport, any temperature excursions, and at least every 72 hours. **Any major temperature excursions should be reported immediately to CPHO/DCPHO.**

3. Check TempTale® LCD display for alarm status:
   a) **If X** icon appears,
      i. Segregate product within appropriate temperature and do not use until disposition is provided from your Regional Pharmacy Technician.
      ii. Reference instructions below for alarming TempTale®.

   b) **If** icon appears, the product has stayed within the temperature and can be accepted. Return TempTale® to shipping freezer.

4. Place product in proper storage conditions according to product label.

No Alarm	Alarm
	

DOWNLOAD AND RETURN INSTRUCTIONS - For Alarmed TempTales® only if X icon appears

1. The device is a USB TempTale®, plug the USB connector of the TempTale® directly into a USB port on the computer.

2. Search and open either the TT4USBMA or TTULTRAUSB drive (removable storage) on the computer. **Call QGH at (867)975-8600 Ext 6352 or Kivalliq Health centre at (867)645-8334 if further instructions are needed.**

3. Select .TTV or .TTX file, right click on the file, and place the mouse over 'Rename' and change the name of the file to your community name and the date. Then place the mouse over 'Send To' and select 'Mail Recipient.' Email .TTV or .TTX file to Michael Gauvin at mgauvin@gov.nu.ca for Qikiqtaaluk region or Amanda Arsenault at aarsenault@gov.nu.ca for Kivalliq and Kitikmeot region.

Note: It will not be possible to open and view the data in the .TTV or .TTX file but the PDF file is readable.

Appendix 5: Immunization Manual 3.1.7 Maintaining Cold Chain during Transport

[Note that this guidance is adapted from the Nunavut Immunization Manual and is copied here for convenience. For updates, it is best to check the Immunization Manual.]

The following items are essential for ensuring that cold chain is maintained during transport and when conducting clinics outside of the health centre.

Hard-sided plastic insulated container

Refrigerator-conditioned cold packs

Newer Styrofoam cooler with walls at least 2 inches thick

Vaccines should be packed in layers to prevent shifting of the contents during transport. Be sure to place an insulating barrier between the refrigerated or frozen packs and the vaccines to prevent accidental freezing.

Container for transport

Vaccines should be transported in insulated containers. Soft-sided coolers, thin-walled coolers, and banged-up Styrofoam containers should not be used. Please note that Vaccines are double-boxed during the winter months (Oct.1 to May 31)

Cooling Packs

There are two main types of cooling packs: refrigerator-conditioned (refrigerated at +2°C to +8°C) and frozen packs available for packing vaccines. The use of these packs for transporting vaccines will depend on the ambient temperature, the amount and type of vaccine, and the size of the container.

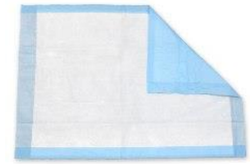
Frozen Packs

Insulating Barrier/Filler Materials and the Vaccine

Packing peanuts

Bubble wrap

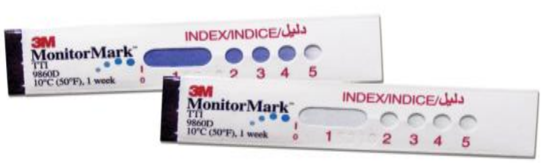
Blue pads



Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials from individual boxes – if multiple vials are in a single box the vial required for the home visit will need to be removed. Be sure to fill any spaces between vaccine boxes with crumpled paper or other filler to prevent shifting of contents in the insulated container.

Temperature Monitor

Warm/cold markers Min/max thermometer



Use a properly placed min/max thermometer or cold chain monitor near the vaccine. The temperature- monitoring device should be placed in the middle of the vaccines and should not come in contact with the refrigerated or frozen packs.

References:

1. Adapted from Nova Scotia Immunization Manual, by the Government of Nova Scotia, 2008. Adapted with permission.
2. Public Health Agency of Canada (2007). National Vaccine Storage and Handling Guidelines for Immunization Providers [PDF version]. Retrieved from http://www.phac- aspc.gc.ca/publicat/2007/nvshglp-ldemv/pdf/nvshglp-ldemv-eng.pdf.

Appendix B

Guidance on TSTs and COVID-19 Vaccines

Note: *This guidance for Nunavut is based on recommendations from the National Advisory Committee on Immunization (NACI- reviewed June 2022) and guidance from Nunavut's Tuberculosis Services in Nunavut during the COVID-19 Pandemic document (December 2021). It is subject to change as additional information becomes available.*

There is a theoretical risk that mRNA or viral vector COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin test (TST) or Interferon Gamma Release Assay (IGRA) results. However, these vaccines are not thought to cause false-positive TSTs/IGRAs. NACI[1] has recommended delaying TSTs in some situations until at least 4 weeks after the most recent COVID vaccine dose.

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.

The *Nunavut Tuberculosis Manual* and the *Nunavut Immunization Manual* are available online here: https://www.gov.nu.ca/health/information/manuals-guidelines

The guidance below outlines the appropriate action in various scenarios.

1. People with TB-compatible symptoms who have had a COVID-19 vaccine less than 4 weeks prior to assessment:

Investigate according to the usual Nunavut protocols for diagnosing active TB (e.g., chest-Xray, sputum for AFB/TB culture). If the person is TST-eligible, perform a TST. If the TST and/ or other tests are positive, then proceed to manage the client as you normally would.
If the TST/IGRA is negative and there is still concern about active TB, consult the RCDC/TB Case Manager who will, in consultation with the TB Physician, determine on a case-by-case basis, whether a repeat TST should be done 28 days or more after the vaccine dose.

2. People who are contacts of a person with active TB, who had COVID-19 vaccine less than 4 weeks ago:

Investigate contacts according to the usual Nunavut TB protocols. If a contact is TST-eligible, perform a TST. If the TST is positive, proceed to manage the client as you normally would (the vaccine should not cause a false-positive TST). If the TST is negative, consult the RCDC/TB Case Manager who will, in consultation with the TB Physician, determine on a case-by-case basis whether a repeat TST should be done 28 days or more after the vaccine dose.

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[1] https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a11.2

3. Asymptomatic people presenting for routine TB screening e.g. employment screening or ad hoc requests:
Whenever feasible, delay administering the TST until more than 4 weeks after the most recent dose of COVID-19 vaccine.

4. People scheduled for COVID vaccine who are also due for a TST:
If a TST is required, if possible it should be administered and read before COVID-19 vaccination. However, if COVID vaccination is a higher priority (e.g. unvaccinated person during community transmission of COVID) vaccination should not be delayed because a TST is also needed.

Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed. A TST given prior to or at the time of vaccination does not affect either the response to the COVID-19 vaccine or the risk of adverse reactions to the vaccine.

5. People who have had a recent TST and present for COVID-19 vaccination:
Proceed with COVID-19 vaccination according to the applicable protocol in the *Nunavut Immunization Manual*. A TST given and read prior to vaccination does not affect either the response to the COVID-19 vaccine or the risk of adverse reactions to the vaccine.