

Immunization Protocol for Moderna SPIKEVAX® COVID-19 Vaccine

As of September 16, 2021, the Moderna vaccine is no longer under an Interim Order and has been officially authorized for use in Canada by Health Canada under Food and Drug Regulations. It was previously authorized for use in Canada under the *Interim Order* on December 23, 2020 for adults 18 years of age and older, and on August 27, 2021 for adolescents 12-17 years of age.

NOTE: The Pfizer-BioNTech COMIRNATY® COVID-19 vaccine is also in use in Nunavut. While both are mRNA vaccines, there are key differences between the Moderna SPIKEVAX® and Pfizer-BioNTech COMIRNATY® vaccines with respect to requirements for dilution/reconstitution, storage/transport, and temperature considerations.

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 syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 12 years of age and older. ¹
Eligibility	Individuals age 12 years and older without contraindications to the vaccine. *As of October 4, 2021, the age eligibility criteria is based on date of birth; review is underway to assess change in eligibility criteria based on birth year.
Product	Moderna SPIKEVAX® COVID-19 vaccine (mRNA-1273 SARS-CoV-2 vaccine)
Vaccine type	Elasomeran mRNA-1273 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	<i>Medicinal ingredients:</i> Elasomeran (mRNA), encoding the pre-fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2) ¹ <i>Non-medicinal ingredients:</i> Acetic acid, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), Lipid SM-102, PEG2000-DMG (1, 2-dimyristol-rac-glycerol, methoxy-polyethyleneglycol), sodium acetate trihydrate, sucrose, trometamol, trometamol hydrochloride, water for injection. ¹
Formats available	Multi-dose vial (10 doses), preservative-free. No dilution is required. ¹ Moderna SPIKEVAX® is supplied in a multi-dose 10R type I glass vial (each of 5 mL) 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 vial contains overfill to ensure ten 0.5 mL doses per vial. If additional doses can be obtained from a single vial, there is no prohibition on using the additional dose(s). Do not use vaccine obtained from two or more vials to comprise a dose of vaccine. ¹

Manufacturer	<p>Moderna: Moderna Therapeutics Inc. 200 Technology Square Cambridge, MA, USA, 02139</p>
Administration	<p>Intramuscularly (IM) in the deltoid muscle.</p> <p>Do not shake. Swirl the vial gently after thawing and between each withdrawal. Shaking the vial can make the vaccine less or <u>not</u> effective.</p> <p>This 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 and in the <i>Moderna SPIKEVAX® and Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine Transport Protocol (Appendix E)</i> carefully in order to ensure the vaccine is effective.</p> <p>Moderna SPIKEVAX® is a white to off-white suspension. It may contain white or translucent product-related particulates. Inspect SPIKEVAX® vials visually for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered. SPIKEVAX® does not contain any preservatives, antibiotics, adjuvants, or human- or animal-derived materials.¹</p> <p>Once a dose is withdrawn from the vial, it should be administered immediately (less than 5 minutes), or in special circumstances within 15 minutes. <u>Once the vial has been entered (needle-punctured), it should be discarded after 24 hours.</u> Do not refreeze. Thawed vials and filled syringes can be handled in room light conditions.¹</p> <p>To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health 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.</p>
Dose series	<p>The Moderna SPIKEVAX® COVID-19 vaccine is administered IM as a primary series of two doses (0.5 mL each) 28 days (1 month) apart. The minimum interval is 21 days. The extended interval is 16 weeks (up to four months). If an individual is given a dose of mRNA vaccine outside of these parameters, an incident report should be filed on Meditech and the Regional Communicable Disease Coordinator (RCDC) should be consulted for additional dosing guidance.</p> <p>Canada’s National Advisory Committee on Immunizations (NACI) has recommended that an additional dose of an authorized mRNA vaccine be provided as part of the primary series to moderately or severely immunocompromised (see section of protocol on additional dose for immunocompromised).²</p> <p>NACI has also recommended that a booster dose of an authorized mRNA vaccine be provided for long-term care residents and seniors living in other congregate settings (see section of protocol on booster dose for long-term care residents and seniors living in other congregate settings).²</p>

Mechanism of Action	<p>The Moderna SPIKEVAX® COVID-19 vaccine uses messenger RNA (mRNA) genetic material that our cells read to make proteins. It consists of the genetic instructions for building the Spike (S) protein that is found on the surface of the COVID-19 virus. To protect the vaccine from the body's natural enzymes, the vaccine mRNA is wrapped in oily bubbles made of lipid nanoparticles. After intramuscular injection, the vaccine particles fuse to the body's cells, releasing the mRNA. The cells' molecules read the mRNA sequence and build spike proteins, which then protrude from the surface of the cells, triggering the body's immune response. The vaccine induces both neutralizing antibody and cellular immune responses (T-cell and B-cell) to the spike (S) antigen of the virus. The mRNA does not enter the nucleus of the cell or interact with the cell's genome, it does not replicate, and is eventually destroyed by the cell, leaving no permanent trace.¹</p>
Additional dose for immunocompromised	<p>NACI has recommended that an additional dose of an authorized mRNA COVID-19 vaccine be provided as part of the <i>primary series</i> to moderately or severely immunocompromised individuals. It is important to distinguish between a 3-dose primary series for immunocompromised individuals and booster doses for the general population. A primary vaccine series is considered to be the number of vaccine doses needed to develop a complete and robust immune response. 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</p> <p>Nunavut is adopting this NACI recommendation for its COVID-19 immunization programs. For eligible immunocompromised individuals who received a 2-dose schedule of the Moderna SPIKEVAX® or Pfizer COMIRNATY® mRNA COVID-19 vaccines, this authorization provides a third dose to complete the primary series.</p> <p>As of September 2021, the Department of Health will start providing an additional dose of one of our available vaccines to individuals who meet all three of the following conditions:</p> <ol style="list-style-type: none"> 1. Meet the age eligibility for either the Moderna SPIKEVAX® or Pfizer-BioNTech COMIRNATY® COVID-19 vaccines currently available in Nunavut. This interim authorization applies to individuals who are 12 years of age and older. 2. 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). Verification of these conditions should be made by clinicians authorized to diagnose and manage medical conditions. <ol style="list-style-type: none"> a. Active treatment for solid tumour or hematologic malignancies; b. Receipt of solid-organ transplant and taking immunosuppressive therapy; c. Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (with 2 years of transplantation or taking immunosuppression therapy); d. Moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome);

	<ul style="list-style-type: none"> e. Stage 3 or advanced untreated HIV infection and those with acquired immunodeficiency syndrome; f. Active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20, and CD22), high-dose systemic corticosteroids (refer to the Canadian Immunization Guide for suggested definition of high-dose steroids), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive. <p>3. Meeting the minimal dosing interval requirement (at least 28 days) after receiving a 1 or 2-dose complete primary series.</p>
<p>Booster dose for long-term care residents and seniors living in other congregate settings</p>	<p>Waning immunity over time and efficacy of vaccines against variants of interest and variants of concerns are two factors that are being examined in the context of booster doses. At present time, NACI is not suggesting the need for booster doses of COVID-19 vaccines for the general population after the vaccine series is complete.</p> <p>For all long-term care residents and seniors living in other congregate settings who have received a primary COVID-19 vaccine series (with a homologous or heterologous schedule using mRNA or viral vector vaccines), NACI recommends that a booster dose of an authorized mRNA COVID-19 vaccine (Pfizer-BioNTech COMIRNATY[®] or Moderna SPIKEVAX[®]) should be offered. This dose should be offered at a recommended interval of at least six months after the primary series has been completed. Informed consent for a booster dose should include discussion about what is known and unknown about the risks and benefits, including the off-label status of NACI’s recommendation.⁴ Please reach out to your RCDC if you have any questions about this guidance.</p> <p><u>In Nunavut, this applies to individuals who meet both of the following criteria:</u></p> <ul style="list-style-type: none"> - Age 60 or greater; - Living in a long-term care facility or other congregate facility.
<p>Vaccine interchangeability</p>	<p>NACI recommends that, 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, 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. The previous dose(s) should be counted, and the series need not be restarted.²</p> <p>For mixed COVID-19 vaccine schedules, the minimum interval between doses should be based on the minimum interval of the product used for the first dose (e.g., Pfizer-BioNTech COVID-19 vaccine should be offered a minimum of 28 days after AstraZeneca COVID-19 vaccine).²</p>
<p>Contraindications</p>	<p>Until further study is completed, the Moderna SPIKEVAX[®] COVID-19 vaccine is only authorized for use in people age 12 years and older.</p> <p>Moderna COVID-19 vaccine is contraindicated in persons with proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its packaging.²</p>

Rare anaphylactic reactions have been reported following immunization with mRNA COVID-19 vaccines. Two vaccine components have been identified as potentially resulting in a rare allergic reaction: polyethylene glycol (PEG) and tromethamine.²

An authorized COVID-19 vaccine should **not** be offered routinely to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after previous administration of a COVID-19 vaccine.²

If the patient has a history of myocarditis or pericarditis secondary to receipt of a COVID-19 vaccine, please consult the Office of the Chief Public Health Officer (CPHO) for guidance before administering any COVID-19 vaccine.

Precautions and additional notes

Anaphylaxis: As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of this vaccine. Vaccine recipients should be kept under observation for at least 15 minutes after immunization.

Individuals with proven anaphylaxis to **injectable therapy** not related to a component of authorized COVID-19 vaccines (e.g. intramuscular, intravenous, or subcutaneous vaccines or therapies) may be routinely vaccinated – an extended period of observation post-vaccination of 30 minutes should be provided.²

Individuals with suspected but unproven allergy to a vaccine component (e.g., PEG) may be routinely vaccinated and do not need a specific assessment regarding this suspected allergy - an extended period of observation post-vaccination of 30 minutes should be provided.²

Individuals with a history of allergy not related to a component of authorized COVID-19 vaccines or other injectable therapy (e.g., foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions. Individuals should be observed for a minimum of 15 minutes following vaccination.²

Myocarditis and pericarditis: Very rare cases of myocarditis and pericarditis following vaccination with Moderna SPIKEVAX[®] COVID-19 vaccine have been reported during post-authorization use. These cases occurred more commonly after the second dose and in adolescents and young adults. Typically, the onset of symptoms has been within a few days following receipt of Moderna SPIKEVAX[®] COVID-19 vaccine. Available short-term follow-up data suggest that the symptoms resolve in most individuals, but information on long-term sequelae is lacking. The decision to administer the Moderna SPIKEVAX[®] COVID-19 vaccine to an individual with a history of myocarditis or pericarditis should consider the individual's clinical circumstances and the decision on further COVID-19 vaccines should be at the discretion of the Office of the CPHO. Cardiology consultation for management and follow-up should also be considered.¹

Health care professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with a COVID-19 vaccine. This could allow for early diagnosis and treatment.

Acute illness: Consideration should be given to postponing immunization in persons with severe febrile illness or severe acute infection. Persons with moderate or severe acute illness should be vaccinated as soon as the acute illness has improved.

Vaccination of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. However, vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms, in order to avoid attributing any complications resulting from SARS-CoV-2 infection to vaccine-related AEFI and to minimize the risk of COVID-19 transmission at an immunization clinic/venue.²

Hematologic-Bleeding: As with other intramuscular injections, the Moderna SPIKEVAX® COVID-19 Vaccine should be given with caution in individuals with bleeding disorders, such as haemophilia, or individuals currently on anticoagulant therapy, to avoid the risk of haematoma following the injection, and when the potential benefit clearly outweighs the risk of administration.

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.²

Immune: Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. They should still wear a mask as advised and practice a higher level of precautions until a significant proportion of their community has been immunized. Refer to guidance contained in *Additional dose for immunocompromised* section of protocol.

Syncope: Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions.¹

Administration of other drugs, or biological products

COVID-19 vaccines may be given at the same time as, or any time before or after, other vaccines, including live, non-live, adjuvanted or unadjuvanted vaccines.

Vaccines administered during the same visit should be administered at different injection sites. As with other vaccines, when possible, administration on the same day is preferred to vaccines being given within a few days of each other. Studies looking at the simultaneous administration of COVID-19 vaccines with other vaccines are underway

and ongoing. NACI will continue to monitor the evolving evidence and will update recommendations as needed.²

There is a theoretical risk that the Moderna SPIKEVAX® COVID-19 vaccine may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If tuberculin skin testing or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks afterwards. Vaccination may take place at any time after all steps of tuberculin skin testing have been completed.²

However, 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.** In this situation, re-testing, at least 4 weeks post immunization, of individuals with negative results for whom there is high suspicion of TB infection may be prudent to avoid missing cases due to potentially false-negative results.²

Please refer to additional guidance provided by the Nunavut Tuberculosis Program in Appendix F.

COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma – expert opinion should be sought on a case-by-case basis.²

Special Populations

Individuals previously infected with SARS-CoV-2: People with SARS-CoV-2 infection can be vaccinated once they are no longer infectious and no longer have acute symptoms of COVID-19. NACI recommends previously infected individuals may receive a complete series of a COVID-19 vaccine. The optimal timing of vaccination after infection is not certain. Although it is known that re-infection is not common in the first 6 months after infection, the circulations of variants of concern may increase the risk of re-infection.²

Individuals who have an autoimmune condition: People who are immunocompromised and people with autoimmune disease should be vaccinated with COVID-19 vaccines (unless otherwise contraindicated). As for all individuals, mRNA vaccines are the preferred option because of their higher efficacy and because they do not carry a risk of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). Ideally, the COVID-19 vaccine series should be completed 2 weeks before starting immunosuppressive therapy or when immunosuppressive therapy is the lowest but can be given when needed. This ensures that COVID-19 protection is provided sooner. The immune response may be lower in those who are immunosuppressed. These individuals should continue to follow public health recommendations on preventing infection with SARS-CoV-2 (such as wearing a mask, physical distancing, and hand hygiene) even if they have been vaccinated. Vaccination of their close contacts will also help protect them.²

Individuals who are pregnant or breastfeeding: People who are pregnant and breastfeeding should be vaccinated with COVID-19 vaccines (unless otherwise contraindicated). As for all individuals, mRNA vaccines are the preferred option because

	<p>of their higher efficacy and because they do not carry a risk of VITT. Emerging evidence suggests that COVID-19 mRNA vaccination during pregnancy is also immunogenic and results in comparable antibody titres to those generated in non-pregnant women. Maternal IgG humoral response to mRNA COVID-19 vaccines transfers across the placenta to the fetus, leading to a significant and potentially protective, antibody titre in the neonatal bloodstream one week after the second dose. Observational studies consistently show that both anti-spike IgG and IgA are present in breastmilk for at least 6 weeks after maternal vaccination with mRNA vaccines.²</p>
Post-vaccination counselling	<p>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</p> <p>The After Care Sheet (Appendix I) should be given to clients following vaccination.</p>
Vaccine supply and distribution	<p>Review section on vaccine ordering in the Policy and Procedure section of the Nunavut Drug Formulary.</p> <p>Follow vaccine vial inventory, tracking, and reporting processes. Wastage is to be documented for punctured and unpunctured vials separately.</p> <p>Questions or concerns re: vaccine supply and distribution should be forwarded to the Regional Pharmacies.</p>
Storage of frozen vials prior to use	<p>The vaccine should be stored at temperatures of -25°C to -15°C and protected from light. Do not store on dry ice or below -40°C.¹</p>
Thawing	<p>Thaw each vial before use:</p> <ul style="list-style-type: none"> • Thaw in refrigerated conditions between +2 °C to +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 25 °C for 1 hour. • After refrigerating (which will thaw vaccine), do not re-freeze.¹
Thawed, unpunctured vials	<p>If not punctured, the SPIKEVAX® COVID-19 vaccine can be thawed and refrigerated at +2°C to +8°C for up to 30 days, or kept at room temperature (+8°C to +25°C) for up to 24 hours. <u>The total time at room temperature for the Moderna SPIKEVAX® COVID-19 vaccine should not exceed 24 hours. For instance, if a vial is punctured after 23 hours of being at room temperature, it is only stable for another 1 hour (cumulative total of 24 hours). The time of puncture does not reset the time. **</u></p>
Thawed, punctured vials	<p>Once the vial has been entered, it should be discarded after 24 hours. Do not refreeze. Thawed vials and filled syringes can be handled in room light conditions. The date and time brought into room temperature or the refrigerator should be marked so that the product is not used beyond the appropriate time.</p>
Consent	<p>Consent forms must be reviewed and signed prior to vaccination. Clients with capacity to consent (i.e. 18+ and mature minors) will review and sign consent forms at time of vaccination. Clients without capacity to consent (i.e. developmental delay, under 12 years of age) will require a parent or legal guardian to provide consent. (For more</p>

	information, please refer to Appendix C <i>Orientation to Obtaining Consent for Administration of the Moderna SPIKEVAX® COVID-19 Vaccine</i>).
Anaphylaxis	Review the principles of the emergency management of anaphylaxis in the Nunavut Immunization Manual Section 3 (3.7) including checking contents of the two anaphylaxis kits. Further information can be found in: Anaphylaxis: Initial Management in Non-Hospital Settings , in the Canadian Immunization Guide.
Side Effects	<p><i>Injection site reactions:</i> pain at injection site, tenderness and swelling of the lymph nodes (underarm) in the same arm of the injection, swelling (hardness), and redness.</p> <p><i>Systemic side effects:</i> fatigue, headache, muscle aches, joint pain, chills, nausea and vomiting, and fever.</p> <p>In general, side effects are more common after second dose and among younger age groups (18-64). Side effects had a median duration of 1 to 3 days.¹</p> <p>The most frequently reported adverse reactions after any dose were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%) and chills (45.4%).¹</p> <p>Safety data in adolescents (12 to 17 years of age) reflect that the most frequently reported adverse reactions in adolescent subjects were pain at the injection site (97.2%), headache (78.4%), fatigue (75.2%), myalgia (54.3%) and chills (49.1%).¹</p> <p>There is a remote chance that the Moderna SPIKEVAX® COVID-19 Vaccine could cause a severe allergic reaction. It is important to have each person wait for 15-30 minutes after receiving their immunization and know how to contact clinic staff if they feel unwell.²</p>
Reportable Adverse Events/Side Effects/Administration Errors	<p>Report all serious adverse events requiring medical attention, unusual/unexpected events, or medication errors to the RCDC. Review section 3.5 Management and Reporting of Adverse Events in the Nunavut Immunization Manual. Appendix D <i>Reporting an Adverse Event Following Immunization</i> provides additional information.</p> <p><i>Rare reactions:</i> Rare reactions that have been reported and confirmed after taking an mRNA vaccine are:</p> <ul style="list-style-type: none"> • Myocarditis and pericarditis • Bell’s palsy (facial paralysis) • Guillain- Barré syndrome • Anaphylaxis <p>The AEFI form is available here: https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization.html</p> <p>Section 3.5 of the Immunization Manual is available here: https://www.gov.nu.ca/health/information/manuals-guidelines</p> <p>If an inadvertent vaccine error is found, health care providers in Nunavut should:</p> <ol style="list-style-type: none"> 1. Inform the client of the vaccine administration error as soon as possible. <ul style="list-style-type: none"> • Explain the possibility for local or systemic reactions.

	<ol style="list-style-type: none"> 2. Complete an incident report on Meditech and notify the RCDC. Some examples of inadvertent administration errors include incorrect route, higher-than-authorized dose volume administered, lower-than-authorized dose volume administered, dose administered past the expiration date, etc. 3. Complete an AEFI form and submit it to the RCDC only if the inadvertent vaccine administration error results in an AEFI.
Vaccine Coverage and Reporting	Vial tracking forms must be filled out for each vial of Moderna SPIKEVAX [®] and submitted by e-mail to the RCDC and CDCLabs@gov.nu.ca . Please see Appendix E.
Documentation	<p>Health care providers are required to document vaccine administration in Meditech and ensure the consent form is completed and stored according to health centre processes.</p> <p>Update the recipient’s Personal Immunization Record and/or COVID-19 Vaccine wallet card as requested and provide date of next dose of vaccine.</p> <p>Follow operational team guidance on processes to track and call back clients for second dose.</p>
Vaccinations in the context of COVID-19	<p>In the context of a pandemic, staff must abide by the infection prevention and control requirements for the immunization clinics, including wearing the appropriate personal protective equipment as currently recommended in health centres, performing hand hygiene and remaining 2 metres apart from others where feasible and except as required to offer immunizations.² For additional information on infection prevention and control please consult:</p> <p>https://www.gov.nu.ca/sites/default/files/infection_prevention_and_control_resource_s.pdf.</p> <p>A point of care risk assessment is the usual practice for decisions about personal protective equipment. Immunizers should wear a mask and eye shield. In communities with an ongoing outbreak of COVID-19, additional precautions may be considered in line with current guidance and approach of health centre.</p>
Materials and resources	<p>Nunavut Immunization Manual https://gov.nu.ca/health/information/manuals-guidelines</p> <p>COVID-19 Vaccine Information Sheet, Consent Form, After Care Sheet, Nunavut Communicable Disease Manual: COVID-19 Public Health Protocol https://gov.nu.ca/health/information/manuals-guidelines</p> <p>All protocols and materials are available on the Department of Health website (www.gov.nu.ca/health)</p>
Appendices	<p>Appendix 1 Condition-specific criteria and prescribed actions (attached in this protocol)</p> <p>Appendix B Guidance for Vaccination with COVID-19 Vaccines During a Home Visit</p> <p>Appendix C Orientation to Obtaining Consent for Administration of COVID-19 Vaccines</p> <p>Appendix D Reporting an Adverse Event Following Immunization</p> <p>Appendix E COVID-19 Vaccine Transport Protocol</p> <p>Appendix F Nunavut Guidance on TSTs and COVID-19 Vaccines</p> <p>Appendix G Vaccine Clinic Screening Questions (with translations)</p>

Appendix H Vaccine Clinic Booking Script (with translations)
Appendix I Vaccine Aftercare Sheet (with translations)
Appendix J Vaccine Consent Form (with translations)
Appendix K Vaccine Information Sheet (with translations)

References

1. Moderna (2021). *SPIKEVAX® (elasomeran mRNA vaccine)*. Moderna: 2021. Available: [covid-19-vaccine-moderna-pm-en.pdf \(canada.ca\)](#) (accessed September 20, 2021).
2. National Advisory Committee on Immunization (2021). *An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI): Recommendations on the use of COVID-19 Vaccines*. Public Health Agency of Canada: 2021. Available: <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html> (accessed October 02, 2021).
3. National Advisory Committee on Immunization (2021). *National Advisory Committee on Immunization (NACI) rapid response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series September 10, 2021*. Public Health Agency of Canada: 2021. Available: [National Advisory Committee on Immunization \(NACI\) rapid response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series - Canada.ca](#) (accessed September 20, 2021).
4. National Advisory Committee on Immunization (2021). *National Advisory Committee on Immunization (NACI) rapid response: Booster dose of COVID-19 vaccine in long-term care residents and seniors living in other congregate settings September 28, 2021*. Public Health Agency of Canada: 2021. Available: [NACI rapid response: Booster dose in long-term care residents and seniors living in other congregate settings - Canada.ca](#) (accessed October 01, 2021).

Approved by the Chief Public Health Officer on October 04, 2021.

Department of Health, Government of Nunavut

Appendix 1. Condition-specific criteria and prescribed actions.

The criteria listed below include indications, contraindications, and precautions for implementing the vaccine protocol. However, the criteria must be reviewed and further delineated according to the licensed prescriber's parameters. Additional criteria and prescribed actions may be necessary. A licensed prescriber must review the criteria and actions and determine the appropriate action to be prescribed.

	Criteria	Prescribed Action
Indications	Client is aged ≥ 18 years	Proceed to vaccinate if meets remaining criteria.
	Client is aged 12-17 years (defined as a minor in Nunavut).	Proceed to vaccinate if meets remaining criteria and consent obtained from individual as mature minor or from parent/guardian as required.
	Client is less than 12 years of age.	Do not vaccinate.
Contraindications	Client had a systemic allergic reaction, anaphylaxis, to first dose of COVID-19 vaccine	Do not vaccinate and consult the Office of the CPHO for further guidance.
	Client was diagnosed with myocarditis or pericarditis following a previous COVID-19 vaccine.	Do not vaccinate and consult the Office of the CPHO for further guidance.
	Client has an allergy to polyethylene glycol (PEG), tromethamine or has had a severe allergic reaction to another component of the vaccine.	Do not vaccinate and consult the Office of the CPHO for further guidance.
	Client has received another vaccine in the past 14 days (not COVID-19)?	Proceed to vaccinate if meets remaining criteria.
Special Populations	Client is currently or may be pregnant.	Proceed to vaccinate if meets remaining criteria.
	Client is breastfeeding.	Proceed to vaccinate if meets remaining criteria.
	Patient has problems with immune system from disease such as cancer or treatment/medications such as chemotherapy or corticosteroids.	Proceed to vaccinate if meets remaining criteria and refer to section in the protocol on Additional Dose for Immunocompromised.
	Patient has an auto-immune disorder.	Proceed to vaccinate if meets remaining criteria and refer to section in the protocol on Additional Dose for Immunocompromised.